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Tuesday
September 7, 1982

Selected Subjects

Air Pollution Control
Environmental Protection Agency

Antibiotics
Food and Drug Administration

Aviation Safety
Federal Aviation Administration

Cable Television
Federal Communications Commission

Civil Rights
Farmers Home Administration

Credit
Federal Reserve System

Endangered and Threatened Wildlife
Fish and Wildlife Service

Fisheries
National Oceanic and Atmospheric Administration

Flood Insurance
Federal Emergency Management Agency

Food Ingredients
Food and Drug Administration

Freedom of Information
Federal Deposit Insurance Corporation

Labeling
Food and Drug Administration

Marine Resources
National Oceanic and Atmospheric Administration

CONTINUED INSIDE

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Questions and requests for specific information may be directed to the telephone numbers listed under INFORMATION AND ASSISTANCE in the READER AIDS section of this issue.

Selected Subjects

Military Personnel
Navy Department

Occupational Safety and Health
Occupational Safety and Health Administration

Organization and Functions (Government Agencies)
Information Resources Management Office, Agriculture Department

Over-the-Counter Drugs
Food and Drug Administration

Radio Broadcasting
Federal Communications Commission

Railroad Safety
Federal Railroad Administration

Search Warrants
Justice Department

Contents

Federal Register
Vol. 47, No. 173
Tuesday, September 7, 1982

Agency for International Development
NOTICES
Authority delegations:
39262 Deputy Administrator et al.; order of succession as Acting Administrator

Agriculture Department
See also Farmers Home Administration; Forest Service; Information Resources Management Office, Agriculture Department.
NOTICES
Import quotas and fees:
39223 Sugar import quota system; review

Commerce Department
See International Trade Administration; National Oceanic and Atmospheric Administration.

Comptroller of Currency
NOTICES
Senior Executive Service:
39269 Performance Review Board; membership

Consumer Product Safety Commission
NOTICES
39271 Meetings; Sunshine Act (2 documents)
39227 Privacy Act; systems of records

Defense Department
See also Engineers Corps; Navy Department.
NOTICES
Meetings:
39229 Electron Devices Advisory Group (2 documents)

Energy Department
See Federal Energy Regulatory Commission.

Engineers Corps
NOTICES
Environmental statements; availability, etc.
39228 Mississippi River, Baton Rouge to the Gulf, GDM Supplement No. 2, La., project; maintenance of pass and river navigability

Environmental Protection Agency
RULES
Air pollutants, hazardous; national emission standards:
39168 Vinyl chloride; test methods and quality assurance procedures
Air quality implementation plans; approval and promulgation; various States, etc.:
39167 Indiana
PROPOSED RULES
Air pollution; standards of performance for new stationary sources:
39204 Gas analysis for carbon dioxide, oxygen, excess air, and dry molecular weight
39205 Stack gas moisture content, and particulate emissions; quality assurance procedures
Air quality implementation plans; approval and promulgation; various States:
39203 Tennessee
39202 West Virginia
NOTICES
Toxic and hazardous substances control:
39241 Premanufacture notices receipts

Farmers Home Administration
RULES
Loan and grant programs:
39127 Civil rights compliance review requirements

Federal Aviation Administration
RULES
Airworthiness directives:
39135 EMBRAER
39136 Garrett
39133 General Dynamics
39135 Piper
39137–39141 Control zones (5 documents)
39142–39145 Restricted areas (4 documents)
39145 Standard instrument approach procedures
39140 Transition areas
39141 VOR Federal airways
PROPOSED RULES
Airworthiness directives:
39189 Boeing
39190 Transition areas
NOTICES
Meetings:
39269 Future Navigation Systems Planning—Economic Considerations Conference

Federal Communications Commission
RULES
Radio stations; table of assignments:
39185 Alaska
PROPOSED RULES
Radio stations; table of assignments:
39207 Alaska; extension of time
Television broadcasting:
39207 Cable television operators; community antenna television systems; diversification of control
39212 Cable television systems and national television networks; elimination of prohibition on common ownership
NOTICES
39246 Agency forms submitted to OMB for review
Frequency allocations and radio treaty matters:
39246 Spectrum utilization policy for fixed and mobile services use of bands; inquiry; extension of time

Federal Deposit Insurance Corporation
RULES
39130 Freedom of Information Act; implementation

Federal Emergency Management Agency
RULES
Flood insurance; special hazard areas:
39179 Illinois et al.

Federal Energy Regulatory Commission
NOTICES
Hearings, etc.:
39229 Bangor Hydro-Electric Co.
39230 Bluepond Associates
39230 Colorado Interstate Gas Co.
39231 Consumers Power Co.
39231 Electro Ecology, Inc.
39232, 39233 Energenics Systems, Inc. (3 documents)
39234 Forte Brothers, Inc.
39235 General Energy Development, Inc.
39236 Homestake Consulting & Investments, Inc.
39236 Hydro Development, Inc.
39236 Inter-City Minnesota Pipelines Ltd.
39236 Mega Hydro, Inc.
39237 Michigan Wisconsin Pipe Line Co.
39237 North American Hydro, Inc.
39238 Oasis Pipe Line Co.
39239 Standard Pacific Gas Line Inc.
39239 Tennessee Gas Pipeline Co.
39239 Uncompahgre Valley Water Users Association & Montrose Partners
39240 Wawa, Inc.
39271 Meetings; Sunshine Act
Small power production and cogeneration facilities; qualifying status; certification applications, etc.:
39234 Faber-Castell Corp.
39238 Resource Authority in Sumner County
39241 Whitney, Justin W.

Federal Home Loan Bank Board
NOTICES
39271 Meetings; Sunshine Act

Federal Mine Safety and Health Review Commission
NOTICES
39271 Meetings; Sunshine Act (2 documents)

Federal Railroad Administration
RULES
39398 Truck safety standards

Federal Reserve System
RULES
Credit extension by Federal Reserve Banks (Regulation A):
39129 Discount rate changes
NOTICES
Applications, etc.:
39248 Liberty Bancorp of Owasso, Inc., et al.
39247 Manufacturers Bancorp, Inc.
39246 MB Sub, Inc.
Bank holding companies; proposed de novo nonbank activities:
39247 Citicorp et al.

Federal Trade Commission
NOTICES
Premerger notification waiting periods; early terminations:
39248 Hudson Bay Mining & Smelting Co., Ltd.
39248 Impresit-Girola-Lodigiani-Impregilo S.p.A.
39249 Regie Nationale des Usines Renault

Fish and Wildlife Service
PROPOSED RULES
Endangered Species Convention:
39219 Appendixes; amendments
NOTICES
39253 Agency forms submitted to OMB for review
39253 Endangered and threatened species permit applications

Food and Drug Administration
RULES
39155 Antibiotic drugs and antibiotic susceptibility medical devices; exemption from certification
Drug labeling:
39147 Prescription drug products; patient package insert requirements; revocation
PROPOSED RULES
GRAS or prior-sanctioned ingredients:
39199 "Current good manufacturing practice" definition, detailed conditions of use requirement elimination, etc.
Human drugs:
39464 Antifungal drug products, topical (OTC); monograph establishment; advance notice and reopening of administrative record
39412 External analgesic drug products (OTC); monograph establishment; advance notice and reopening of administrative record
39470 Pregnant or nursing women; over-the-counter (OTC) drugs generally recognized as safe and effective and not misbranded warning
39436 Skin protectant drug products (OTC); monograph establishment; advance notice and reopening of administrative record
39406 Topical antimicrobial drug products (OTC); monograph establishment; advance notice and reopening of administrative record
NOTICES
Drug labeling:
39249 Prescription drugs; patient package inserts; final guideline revoked and draft guideline withdrawn

Forest Service
NOTICES
39454 National wild and scenic rivers system; eligibility, classification, and management guidelines

General Services Administration
NOTICES
39249 Agency forms submitted to OMB for review

Health and Human Services Department
See Food and Drug Administration; Social Security Administration.

Housing and Urban Development Department
NOTICES
39252 Agency forms submitted to OMB for review
39251 Privacy Act; systems of records

Information Resources Management Office, Agriculture Department
RULES
39128 Organization and Functions, and Freedom of Information Act implementation

Interior Department
See also Fish and Wildlife Service; Land Management Bureau; National Park Service; Surface Mining Reclamation and Enforcement Office.
NOTICES
Committees; establishment, renewals, terminations, etc.:
39256 Federal-State Task Force on Hawaiian Homes Commission Act
Meetings:
39256 Federal-State Task Force on Hawaiian Home Commission Act

International Development Cooperation Agency
See Agency for International Development.

International Trade Administration
NOTICES
Countervailing duties:
39394 Carbon steel plate from Brazil
39384 Carbon steel structural shapes, hot-rolled carbon steel plate and bar, and cold-formed carbon steel bar from United Kingdom
39364 Carbon steel structural shapes from Luxembourg
39225 Railcars from Canada; postponement
39304, 39331 Steel products from Belgium (2 documents)
39332 Steel products from France
39356, 39364 Steel products from Italy (2 documents)
39372 Steel products from Netherlands
39379 Steel products from South Africa
39345 Steel products from West Germany
Scientific articles; duty free entry:
39224 Brookhaven National Laboratory
39224 Duke University
39224 Georgetown University Medical Center
39225 St. Vincent Medical Center
39225 Stanford University
39226 University of Utah Medical Center

Interstate Commerce Commission
RULES
Motor carriers:
39185 Lease and interchange of vehicles; extension of compliance date
NOTICES
39272 Meetings; Sunshine Act
Motor carriers:
39256, 39259 Permanent authority applications (2 documents)
39262 Permanent authority applications; correction
39260 Permanent authority applications; restriction removals
Railroad operation, acquisition, construction, etc.:
39262 Carolina & Northwestern Railway Co.

Justice Department
RULES
Organization, functions, and authority delegations:
39161 Agriculture Department, Inspector General, et al.; issuance of search warrants

Labor Department
See Occupational Safety and Health Administration.

Land Management Bureau
NOTICES
Opening of public lands:
39253 Washington

National Aeronautics and Space Administration
NOTICES
Meetings:
39263 Space Systems and Technology Advisory Committee; postponement

National Oceanic and Atmospheric Administration
RULES
Fishery conservation and management:
39186 Gulf of Alaska and Bering Sea and Aleutian Islands groundfish; foreign and domestic fishing
PROPOSED RULES
Fishery conservation and management:
39221 Stone crab, Gulf of Mexico; hearing
Marine sanctuaries:
39191 Potential marine sanctuary candidates; identifying and selecting procedures

National Park Service
NOTICES
Environmental statements; availability, etc.:
39254 Canyon de Chelly National Monument, Ariz.; floodplain management and wetland protection, development concept plan
Historic Places National Register; pending nominations:
39254 Connecticut et al.
Meetings:
39254 National Capital Region; 1982 Christmas Pageant of Peace
39454 National wild and scenic rivers system; eligibility, classification, and management guidelines

Navy Department
RULES
39166 Naval Discharge Review Board; standards amended

Nuclear Regulatory Commission
NOTICES
Applications, etc.:
39265 Commonwealth Edison Co.; Dresden Nuclear Power Station, Units 2 and 3, Ill.
39266 Consolidated Edison Co. of New York, Inc.
39268 Florida Power & Light Co. et al.
39266 Nebraska Public Power District
39267 Pacific Gas & Electric Co.
39267 South Carolina Electric & Gas Co. et al.; Virgil C. Summer Nuclear Station
39264, 39267 Texas Utilities Generating Co. et al. (3 documents)
Environmental statements; availability, etc.:
39264 Cleveland Electric Illuminating Co. et al.; Perry Nuclear Power Plant, Units 1 and 2, Ohio
Meetings:
39263 Reactor Safeguards Advisory Committee
39272 Meetings; Sunshine Act
39265 Regulatory guides; issuance, availability, and withdrawal

Occupational Safety and Health Administration
RULES
Health and safety standards:
39161 Private service station attendants, and ban on use of latch-open devices on gasoline delivery nozzels; removal of standards
State plans; development, enforcement, etc.:
39164 Puerto Rico
NOTICES
Meetings:
39262 Occupational Safety and Health National Advisory Committee

Small Business Administration
NOTICES
Applications, etc.:
39268 BPC Washington Partners
39269 PNC Capital Corp.
Disaster loan areas:
39269 Tennessee

Social Security Administration
NOTICES
Organization, functions, and authority delegations:
39250 Hearings and Appeals Office

Social Security Reform, Naitonal Commission
NOTICES
39263 Meetings

Surface Mining Reclamation and Enforcement Office
PROPOSED RULES
39201 Permanent regulatory program; reopening of public comment periods

Textile Agreements Implementation Committee
NOTICES
Cotton, wool, or man-made textiles:
39226 Indosesia
39227 Singapore

Transportation Department
See Federal Aviation Administration; Federal Railroad Administration.

Treasury Department
See also Comptroller of Currency.
NOTICES
Notes, Treasury:
39270 G–1987 series

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.

7 CFR
1901 39127
2700 39128
2710 39128

12 CFR
201 39129
309 39130

14 CFR
39 (4 documents) 39133–39136
71 (7 documents) 39137–39141
73 (4 documents) 39142–39145
97 39145

Proposed Rules:
39 39189
71 39190

15 CFR

Proposed Rules:
922 39191

21 CFR
203 39147
314 39155
433 39155
510 39155
809 39155

Proposed Rules:
184 39199
186 39199
330 39170
333 (2 documents) 39406, 39464
347 39436
348 39412

28 CFR
60 39161

29 CFR
1910 39161
1952 39164

30 CFR

Proposed Rules:
700 39201
701 39201
715 39201
717 39201
736 39201
760 39201
762 39201
769 39201
770 39201
771 39201
772 39201
773 39201
775 39201
776 39201
778 39201
779 39201
780 39201
782 39201
783 39201
784 39201
785 39201
786 39201
787 39201
788 39201
815 39201
816 39201
817 39201
818 39201
819 39201
822 39201
823 39201
824 39201
826 39201
827 39201
843 39201
850 39201

32 CFR
724 39166

40 CFR
52 39167
61 39168

Proposed Rules:
52 (2 documents) 39202, 39203
60 (2 documents) 39204, 39205

44 CFR
65 39179

47 CFR
73 39185

Proposed Rules:
73 39207
76 (2 documents) 39207, 39212

49 CFR
213 39398
1057 39385

50 CFR
611 39186

Proposed Rules:
23 39219
654 39221

Rules and Regulations

Federal Register
Vol. 47, No. 173
Tuesday, September 7, 1982

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 month.

DEPARTMENT OF AGRICULTURE

Farmers Home Administration

7 CFR Part 1901

Civil Rights Compliance Review Requirements

AGENCY: Farmers Home Administration, USDA.

ACTION: Final rule.

SUMMARY: The Farmers Home Administration (FmHA) amends administrative provisions in its regulation regarding civil rights compliance requirements. This action is being undertaken to change the summary report of civil rights compliance reviews conducted for Title VI loan and grant programs. This action is needed to attain compliance with certain requirements of the Department of Justice.

EFFECTIVE DATE: September 7, 1982.

FOR FURTHER INFORMATION CONTACT: Violeta Baluyut, Equal Opportunity Staff, USDA, FmHA, 14th Street and Independence Avenue, SW, Room 5429–S, Washington, DC 20250, Telephone (202) 382–9702.

SUPPLEMENTARY INFORMATION: This final action has been reviewed under USDA procedures established in Secretary's Memorandum 1512–1 to implement Executive Order 12291, and has been determined to be exempt from those requirements because it involves only internal Agency management affecting internal information gathering and subsequent reporting of such information to another governmental agency. It is the policy of this Department that rules relating to public property, loans, grants, benefits, or contracts shall be published for comment notwithstanding the exemption in 5 U.S.C. 553 with respect to such rules. This action, however, is not published for proposed rulemaking since the purpose of this change involves only internal Agency management and publication for comment is unnecessary.

The FmHA programs and projects which are affected by this regulation are subject to State and local clearinghouse review in the manner delineated in Subpart H of Part 1901 of this Chapter.

The Catalog of Federal Domestic Assistance numbers and titles for this regulation are:

Number and Program Title

10.405 Farm Labor Housing Loans and Grants
10.408 Grazing Association Loans
10.409 Irrigation, Drainage, and Other Soil and Water Conservation Loans
10.411 Rural Housing Site Loans (Section 523 and 524 Site Loans)
10.413 Recreation Facility Loans
10.414 Resource Conservation and Development Loans
10.415 Rural Rental Housing Loans
10.418 Water and Waste Disposal Systems for Rural Communities
10.419 Watershed Protection and Flood Prevention Loans
10.420 Rural Self-Help Technical Assistance (Section 523)
10.422 Business and Industrial Loans (Insured)
10.423 Community Facilities Loans
10.431 Technical and Supervisory Assistance Grants

Environmental Impact Statement

This document has been reviewed in accordance with 7 CFR Part 1901, Subpart G, "Environmental Impact Statements." It is the determination of FmHA that the action does not constitute a major Federal action significantly affecting the quality of the human environment and in accordance with the National Environmental Policy Act of 1969, Pub. L. 91–190, an Environmental Impact Statement is not required.

FmHA State Office summary reports concerning compliance reviews are now to be submitted to the FmHA Administrator no later than July 31 of each year. These reports were previously to be submitted no later than November 30 of each year. Furthermore, these reports are now to indicate whether each review is a pre-award or a post-award one. Implementing these changes will allow FmHA to include the required, civil rights compliance review data in the annual A–11 Budget and Activity Report to the Department of Justice.

List of Subjects in 7 CFR Part 1901

Civil rights, Compliance reviews, Fair housing, Minority groups.

PART 1901—PROGRAM—RELATED INSTRUCTIONS

Accordingly, FmHA amends Subpart E of Part 1901, Chapter XVIII, Title 7, Code of Federal Regulations as follows:

1. Section 1901.204, paragraph (f) is revised to read as follows:

§ 1901.204 Compliance reviews.

* * * * *

(f) State Office summary reports. The State Director will keep a list of all compliance reviews conducted during the reporting year so as to schedule each year's reviews. The State Director will submit a copy of this list to the Administrator, Attention: Equal Opportunity Officer, no later than July 31 of each year. Recipients found in noncompliance will also be listed on the summary report. Exhibit B is a sample report.

2. Exhibit B is revised to read as follows:

Exhibit B.—Summary Report of Civil Rights Compliance Reviews

To: Administrator, FmHA.
Attention: Director, Equal Opportunity Staff.

I. Civil Rights Compliance Reviews have been conducted, and the following recipients were found in compliance with Title VI of the Civil Rights Act of 1964.

	Loan type	Loan number	Type of review	
			Pre-award*	post-award**
1.				
2.				
3.				

*A pre-award review is a compliance review conducted prior to loan or grant approval.
**A post-award review is a compliance review conducted after loan closing.

II. The following recipients were found in non-compliance:

Name of borrower	Loan type	Loan number	Type of review		Date report of noncompliance sent to nat. ofc.
			Pre-award	post-award	
1.					
2.					
3.					

State Director.

(7 U.S.C. 1989; 42 U.S.C. 1480; 7 CFR 2.23; 7 CFR 2.70)

Dated: August 5, 1982.

Charles W. Shuman,

Administrator, Farmers Home Administration.

[FR Doc. 82-24486 Filed 9-3-82; 8:45 am]

BILLING CODE 3410-07-M

Office of Information Resources Management

7 CFR Parts 2700 and 2710

Organization, Functions and Availability of Information to the Public

AGENCY: Office of Information Resources Management, USDA.

ACTION: Final rule.

SUMMARY: This rule explains the organization and functions of the Office of Information Resources Management and how to request records from it under the Freedom of Information Act. It supplements the Department's regulations in 7 CFR 1.1–1.16 and Appendix A.

EFFECTIVE DATE: October 1, 1982.

ADDRESSES: Send comments to Francis Seng, Information Access and Disclosure Officer, Office of Information Resources Management, U.S. Department of Agriculture, Room 407–W, Washington, D.C. 20250.

FOR FURTHER INFORMATION CONTACT: Francis Seng (Access/Disclosure), Office of Information Resources Management, U.S. Department of Agriculture, Washington, D.C. 20250 (202–447–8641).

SUPPLEMENTARY INFORMATION: This rule is an interpretative rule. Therefore, prior notice for comments is not required. See 5 U.S.C. 553(b). However, the Department will consider comments to change this rule. This rule has been reviewed under Secretary's Memorandum 1512–1 and Executive Order 12291 and has been designated a non-major rule.

List of Subjects

7 CFR Part 2700

Organization and functions (Government agencies).

7 CFR Part 2710

Availability of information to the public.

7 CFR is amended by adding a new Chapter XXVII and Parts 2700 and 2710 reading as follows:

CHAPTER XXVII—OFFICE OF INFORMATION RESOURCES MANAGEMENT, DEPARTMENT OF AGRICULTURE

PART 2700—ORGANIZATION AND FUNCTIONS

Sec.

2700.1 General statement.
2700.2 Organization.
2700.3 Functions.

Authority: 5 U.S.C. 301, 552; 7 CFR 2.81.

§ 2700.1 General statement.

This part is issued in accordance with 5 U.S.C. 552(a) to provide guidance for the general public as to the organization and functions of the Office of Information Resources Management.

§ 2700.2 Organization.

The Office of Information Resources Management (OIRM) was established on January 12, 1982. Delegations of authority to the Director, OIRM appear at 7 CFR 2.81. The organization is comprised of five headquarters divisions, an administrative staff and three computer centers to serve the Department. The organization is headed by the Director or, in the Director's absence, by the Deputy Director or, in the absence of both, by the Director's desginee.

§ 2700.3 Functions.

(a) *Director.* Provides executive direction for OIRM. Develops and recommends Departmental information resources management principles, policies, and objectives; develops and disseminates Departmental information resources management standards, guidelines, rules, and regulations necessary to implement approved principles, policies, and programs; designs, develops, implements, and revises systems, processes, work methods, and techniques to improve the management of information resources and the operational effectiveness of the Department; provides telecommunications and automated data processing services to the Department's agencies and staff offices.

(b) *Deputy Director.* Assists the Director and, in the absence of the Director, serves as the Acting Director.

(c) *Administrative Management Staff.* Provides support for agency management regarding budget, accounting, personnel, and other administrative matters.

(d) *Planning Division.* Defines, develops, guides, and administers the Department's long-range planning process for information resources.

(e) *Information Management Division.* Develops policy, standards and guidelines for collection, protection, access, use and management of information.

(f) *Review and Evaluation Division.* Reviews and evaluates information resources programs and activities of Department agencies and staff offices for conformance with plans, policies, and standards.

(g) *Agency Technical Services Division.* Advises and consults with and assists Department agencies and staff offices on activities related to the development and implementation of automated information systems.

(h) *Operations and Telecommunications Division.* Coordinates the development and implementation of programs for ADP and telecommunications resource planning within Departmental computer centers and the National Finance Center, and for the acquisition and use of Department-wide telecommunications facilities and services.

(i) *Departmental Computer Centers.* The following centers provide ADP facilities and services to agencies and staff offices of the Department.

(1) Washington Computer Center, 14th and Independence Ave., SW., Rm. S–107–South, Washington, D.C. 20250.

(2) Fort Collins Computer Center, 3825 E. Mulberry Street (P.O. Box 1206), Fort Collins, CO. 80524.

(3) Kansas City Computer Center, 8930 Ward Parkway (P.O. Box 205), Kansas City, MO 64141.

PART 2710—AVAILABILITY OF INFORMATION TO THE PUBLIC

Sec.

2710.1 General statement.
2710.2 Public inspection and copying.

Sec.
2710.3 Indexes.
2710.4 Initial request for records.
2710.5 Appeals.
Appendix A—List of Addresses

Authority: 5 U.S.C. 301, 552; 7 CFR 1.1–1.16

§ 2710.1 General statement.

This part is issued in accordance with 7 CFR 1.4 of the U.S. Department of Agriculture regulations governing the availability of records (7 CFR 1.1–1.16 and Appendix A) under the Freedom of Information Act (5 U.S.C. 552). The Department's regulations, as supplemented by the regulations in this part, provide guidance for any person wishing to request records from the Office of Information Resources Management (OIRM).

§ 2710.2 Public inspection and copying.

(a) *Background.* 5 U.S.C. 552(a)(2) required that each agency make certain kinds of records available for public inspection and copying.

(b) *Procedure.* Persons wishing to gain access to OIRM records should contact the Information Access & Disclosure Officer by writing to the address shown in 2710.4(b)(2).

§ 2710.3 Indexes.

(a) *Background.* 5 U.S.C. 552(a)(2) also required that each agency maintain and make available for public inspection and copying current indexes providing identifying information for the public with regard to any records which are made available for public inspection and copying.

(b) *Procedure.* Persons wishing to get an index may contact the division or center that maintains the records. Publication of these indexes as a separate document is unnecessary and impractical.

§ 2710.4 Initial request for records.

(a) *Background.* The Information Access and Disclosure Officer is authorized to:

(1) Grant or deny requests for OIRM records.

(2) Make discretionary releases of OIRM records when it is determined that the public interests in disclosure outweigh the public and/or private ones in withholding.

(3) Reduce or waive fees to be charged where determined to be appropriate.

(b) *Procedure.* Persons wishing to request records from the Office of Information Resources Management may do so as follows:

(1) *How.* Submit each initial request for OIRM records as prescribed in 7 CFR 1.3(a).

(2) *Where.* Submit each initial request to the Information Access and Disclosure Officer, Office of Information Resources Management, USDA, 14th and Independence Ave., SW., Room 407–W, Washington, D.C. 20250.

§ 2710.5 Appeals.

Procedure. Any person whose initial request is denied in whole or in part may appeal that denial, in accordance with 7 CFR 1.3(e) and 1.7, to the Director, Office of Information Resources Management, by sending the appeal to the Information Access and Disclosure Officer, Office of Information Resources Management, USDA, 14th and Independence Ave., SW., Room 407–W, Washington, D.C. 20250. The Director, Office of Information Resources Management, will make the determination on the appeal.

Appendix A—List of Addresses

Section 1. General

This list provides the titles and mailing addresses of officials who have custody of OIRM records. This list also identifies the normal working hours, Monday through Friday, excluding holidays, during which public inspection and copying of certain kinds of records, and indexes to those records, is permitted.

Section 2. List of Addresses

Director, Office of Information Resources Management, 14th and Independence Ave., SW., Rm. 113–W, Washington, D.C. 20250; Hours: 8:30 a.m.–5:00 p.m.

Chief, Planning Division, OIRM, 14th and Independence Ave., SW., Rm. 446–W, Washington, D.C. 20250; Hours: 8:30 a.m.–5:00 p.m.

Chief, Review and Evaluation Division, OIRM, 14th and Independence Ave., SW., Rm. 442–W, Washington, D.C. 20250; Hours: 8:30 a.m.–5:00 p.m.

Chief, Agency Technical Services Division, OIRM, 14th and Independence Ave., SW., Rm. 416–W, Washington, D.C. 20250; Hours: 8:30 a.m.–5:00 p.m.

Chief, Operations and Telecommunications Division, OIRM, 14th and Independence Ave., SW., Rm. 419–W, Washington, D.C. 20250; Hours: 8:30 a.m.–5:00 p.m.

Chief, Information Management Division, OIRM, 14th and Independence Ave., SW., Rm. 404–W, Washington, D.C. 20250; Hours: 8:30 a.m.–5:00 p.m.

Chief, St. Louis Computer Center, OIRM, 1520 Market Street, Rm. 3441, St. Louis, MO 63101; Hours: 8:00 a.m.–4:40 p.m.

Director, Kansas City Computer Center, OIRM, 8930 Ward Parkway, (P.O. Box 205), Kansas City, MO 64141; Hours: 8:00 a.m.–4:45 p.m.

Director, Fort Collins Computer Center, OIRM, 3825 E. Mulberry Street, (P.O. Box 1206), Fort Collins, CO 80521; Hours: 8:00 a.m.–4:30 p.m.

Director, Washington Computer Center, OIRM, 14th and Independence Ave., SW., Rm. S–107–S, Washington, D.C. 20250; Hours: 8:30 a.m.–5:00 p.m.

Information Access and Disclosure Officer, OIRM, 14th and Independence Ave., SW., Rm. 407–W, Washington, D.C. 20250; Hours: 8:30 a.m.–5:00 p.m.

Dated: September 1, 1982.

Glenn Haney,

Director, Office of Information Resources Management.

[FR Doc. 82-24503 Filed 9-3-82; 8:45 am]

BILLING CODE 3410-KR-M

FEDERAL RESERVE SYSTEM

12 CFR Part 201

Extensions of Credit by Federal Reserve Banks; Changes in Discount Rates

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board of Governors has amended its Regulation A, "Extensions of Credit by Federal Reserve Banks," for the purpose of adjusting discount rates with a view to accommodating commerce and business in accordance with other related rates and the general credit situation of the country. The action was taken to bring the discount rate into better alignment with short-term market interest rates.

EFFECTIVE DATE: The changes were effective on the dates specified below.

FOR FURTHER INFORMATION CONTACT: William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 (202/452–3257).

SUPPLEMENTARY INFORMATION: Pursuant to the authority of 5 U.S.C. 553(b)(3)(B) and (d)(3), these amendments are being published without prior general notice of proposed rulemaking, public participation, or deferred effective date. The Board has for good cause found that current economic and financial considerations required that these amendments must be adopted immediately.

List of Subjects in 12 CFR Part 201

Banks, banking, Credit, Credit unions, Foreign banks.

PART 201—EXTENSIONS OF CREDIT BY FEDERAL RESERVE BANKS

Pursuant to sections 10(b) and 14(d) of the Federal Reserve Act (12 U.S.C. 347b and 357) Part 201 is amended as set forth below:

1. Section 201.51 is revised to read as follows:

§ 201.51 Short term adjustment credit for depository institutions.

The rates for short term adjustment credit provided to depository institutions under § 201.3(a) of Regulation A are:

Federal Reserve Bank of—	Rate	Effective
Boston	10	Aug. 27, 1982.
New York	10	Do.
Philadelphia	10	Do.
Cleveland	10	Aug. 30, 1982.
Richmond	10	Aug. 27, 1982.
Atlanta	10	Do.
Chicago	10	Do.
St. Louis	10	Do.
Minneapolis	10	Do.
Kansas City	10	Do.
Dallas	10	Do.
San Francisco	10	Do.

2. Section 201.52 is revised to read as follows:

§ 201.52 Extended credit to depository institutions.

(a) The rates for seasonal credit extended to depository institutions under § 201.3(b)(1) of Regulation A are:

Federal Reserve Bank of—	Rate	Effective
Boston	10	Aug. 27, 1982.
New York	10	Do.
Philadelphia	10	Do.
Cleveland	10	Aug. 30, 1092.
Richmond	10	Aug. 27, 1982.
Atlanta	10	Do.
Chicago	10	Do.
St. Louis	10	Do.
Minneapolis	10	Do.
Kansas City	10	Do.
Dallas	10	Do.
San Francisco	10	Do.

(b) The rates for other extended credit provided to depository institutions under sustained liquidity pressures or where there are exceptional circumstances or practices involving a particular institution under § 201.3(b)(2) of Regulation A are:

Federal Reserve Bank of—	Rate	Effective
Boston	10	Aug. 27, 1982.
New York	10	Do.
Philadelphia	10	Do.
Cleveland	10	Aug. 30, 1982.
Richmond	10	Aug. 27, 1982.
Atlanta	10	Do.
Chicago	10	Do.
St. Louis	10	Do.
Minneapolis	10	Do.
Kansas City	10	Do.
Dallas	10	Do.
San Francisco	10	Do.

Note.—These rates apply for the first 60 days of borrowing. A 1 percent surcharge applies for borrowing during the next 90 days, and a 2 percent surcharge applies for borrowing thereafter.

By order of the Board of Governors of the Federal Reserve System, August 30, 1982.

William W. Wiles,

Secretary of the Board.

[FR Doc. 82-24487 Filed 9-3-82; 8:45 am]

BILLING CODE 6210-01-M

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 309

Disclosure of Information

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Final rule.

SUMMARY: The Federal Deposit Insurance Corporation (FDIC) amends its regulation on the disclosure of information pursuant to the Freedom of Information Act ("FOIA," 5 U.S.C. 552). Substantive changes include a revision of the fee schedule and delegation from the Board of Directors to (1) the General Counsel for determinations of appeals of denials of initial requests and (2) the Executive Secretary for determinations of requests for waiver or reduction of fees.

EFFECTIVE DATE: October 7, 1982.

FOR FURTHER INFORMATION CONTACT: Margaret M. Olsen, Assistant Executive Secretary, Federal Deposit Insurance Corporation, 550–17th Street, N.W., Washington, D.C. 20429, (202) 389–4446.

SUPPLEMENTARY INFORMATION: On May 24, 1982, the FDIC published for 60 days' public comment proposed amendments to its regulations implementing the FOIA. As stated above, the changes would revise the current fee schedule and make delegations to the General Counsel and the Executive Secretary for respective determinations of appeals and fee waivers. No comments were received on these proposed amendments. Thus, the amendments are adopted, with the following changes.

First, § 309.4(e) is amended to provide that select schedules to reports of condition or income may be withheld. The content of these reports is periodically revised and there is a potential that sensitive financial data will be requested as part of the reports. This change provides the FDIC with the flexibility to withhold such information as necessary. Second, § 309.6(c)(9) is amended to clarify that division or office heads may designate subordinates to release otherwise exempt information created by that division. Third, § 309.7 is amended to clarify procedures for service of process on the FDIC. These changes relate to internal agency procedures and practice and do not require further public comment.

In accordance with the Regulatory Flexibility Act, the Board of Directors certifies that the amendments would not have a significant economic impact on a substantial number of small entities as the amendments do not affect any substantive legal right or duty of any small entity and as the majority of requests do not incur charges in excess of $25.00. Also, for the purposes of the Paperwork Reduction Act of 1980, the amendments would not impose any recordkeeping or reporting requirements on any person. Thus, it has been determined under FDIC's statement of policy on drafting of regulations that a cost-benefit analysis, including a small bank impact statement, is not required.

List of Subjects in 12 CFR Part 309

Banks, Banking, Credit, Foreign Banking, Freedom of Information, Privacy.

Accordingly, the Board of Directors amends Part 309 as set forth below.

1. The authority citation for Part 309 reads as follows:

Authority: Sec. 2 (9 "Seventh" and "Tenth"), Pub. L. No. 797, 64 Stat. 881, as amended by title III, sec. 309, Pub. L. No. 95–630, 92 Stat. 3677 (12 U.S.C. 1819 "Seventh" and "Tenth"); 5 U.S.C. 552.

2. Section 309.3 is revised to read as follows:

§ 309.3 Federal Register Publication.

The FDIC publishes the following information in the **Federal Register** for the guidance of the public:

(a) Descriptions of its central and field organization and the established places at which, the officers from whom, and the methods whereby, the public may secure information, make submittals or requests, or obtain decisions;

(b) Statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal and informal procedures available;

(c) Rules of procedure, descriptions of forms available or the places at which forms may be obtained, and instructions as to the scope and contents of all papers, reports or examinations;

(d) Substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the FDIC;

(e) Every amendment, revision or repeal of the foregoing; and

(f) General notices of proposed rulemaking.

3. Section 309.4 is revised to read as follows:

§ 309.4 Publicly available information.

The following information is available upon request or, as noted, available for public inspection during normal business hours, at the listed offices. To the extent permitted by law, the FDIC may delete identifying details when it makes available or publishes a final opinion, final order, statement of policy, interpretation or staff manual or instruction. Fees for furnishing information under this § 309.4 are as set forth in § 309.5(b).

(a) At the Office of Information, Federal Deposit Insurance Corporation, 550–17th Street, NW., Washington, D.C. 20429, (202) 389–4221:

(1) Documents, including press releases, bank letters and proposed and adopted regulations, published by the FDIC and pertaining to its operations and those of insured banks it supervises.

(2) Reports on the competitive factors involved in merger transactions and the bases for approval of merger transactions as required by section 18(c) (4) and (9) of the Federal Deposit Insurance Act (12 U.S.C. 1828(c) (4) and (9)).

(b) At the Office of the Executive Secretary, Federal Deposit Insurance Corporation, 550–17th Street, N.W., Washington, D.C. 20429, which information is available for public inspection:

(1) All final opinions (including concurring and dissenting opinions) and all final orders made in the adjudication of cases.

(2) Statements of policy and interpretations which have been adopted by the FDIC but have not been published in the **Federal Register**.

(3) A current index of matters covered by paragraph (b) (1) and (2) of this section that were issued, adopted or promulgated after July 4, 1967. Copies of the index will be provided at the direct cost of duplication as set forth in § 309.5(b).

(c) At the Division of Bank Supervision, Federal Deposit Insurance Corporation, 550–17th Street, N.W., Washington, D.C. 20429:

(1) Filings and reports required under the provisions of 12 CFR Part 335 and the Securities and Exchange Act of 1934, as amended (15 U.S.C. 78a), by insured nonmember banks the securities of which are registered with the FDIC pursuant to section 12 of that Act (15 U.S.C.78*l*). These filings and reports are available for public inspection as detailed in 12 CFR § 335.702.

(2) At the FDIC's discretion, reports required under section 7(j) of the Federal Deposit Insurance Act (12 U.S.C. 1817(j)) on changes in the control of an insured bank, to the extent that such reports contain (i) the name of the bank in which control has changed; (ii) the names of the sellers and purchasers of the stock; (iii) the number of shares of stock involved in the transaction; and (iv) the number of shares of issued stock of the bank that are outstanding.

(3) Manual of Examination Policies.

(d) At the regional office of the FDIC where the applicant bank is located: In the FDIC's discretion nonconfidential portions of application files as provided in 12 CFR 303.14(c), including applications for deposit insurance, to establish branches, to relocate offices and to merge. A list of FDIC's regional offices is available from the Office of Information, Federal Deposit Insurance Corporation, 550–17th Street, N.W., Washington, D.C. 20429, (202) 389–4221.

(e) At the Data Base Section, Office of Management Systems and Financial Analysis, Federal Deposit Insurance Corporation, 550–17th Street, N.W., Washington, D.C. 20429:

(1) At FDIC's discretion, the Consolidated Reports of Income and Consolidated Reports of Condition filed by insured nonmember banks (and certain nonfederally insured banks in the case of reports of condition), except that select sensitive financial information may be withheld.[1]

(2) At the FDIC's discretion, Summary of Accounts and Deposits filed by insured banks, except that information on the size and number of accounts is not available.[2]

(f) At the Bank Statistics Branch, Office of Management Systems and Financial Analysis, Federal Deposit Insurance Corporation, 550–17th Street, N.W., Washington, D.C. 20429: Annual Reports of Trust Assets for commercial and mutual savings banks.[3]

(g) At the Division of Liquidation, Federal Deposit Insurance Corporation, 550–17th Street, N.W., Washington, D.C., 20429: Instructions to Liquidators.

4. Section 309.5 is revised to read as follows:

§ 309.5 Information made available upon request.

(a) *Initial request.* (1) Except as provided in paragraphs (c), (g) and (h), of this section, the FDIC, upon request for any record in its possession or control, will make the record available to any person who agrees to pay the costs of searching and duplication as set forth in paragraph (b) of this section. The request must be in writing, provide information reasonably sufficient to enable the FDIC to identify the requested records and specify a dollar limit which the requester is willing to pay for the costs of searching and duplication, unless the costs are believed to be less than $25.00. Requests under this paragraph (a) should be addressed to the Office of the Executive Secretary, FDIC, 550–17th Street, N.W., Washington, D.C. 20429.

(2) The FDIC will notify the requester within 10 business days after receipt of the initial request whether it is granted or denied. Denials of requests will be based on the exemptions provided for in paragraph (c) of this section.

(3) Notification of a denial of an initial request will be in writing and will state: (i) If the denial is in part or in whole; (ii) the name and title of each person responsible for the denial (when other than the person signing the notification); (iii) the exemptions relied on for the denial; and (iv) the right of the requester to appeal the denial to the FDIC's General Counsel within 30 business days following receipt of the notification.

(b) *Fees.* (1) Persons requesting records of the FDIC shall be charged for the costs of searching (even though records are not found or released) and duplication unless the total costs are $25.00 or less for any request or series of requests. "Search" includes any method of extracting information from computerized record systems; and, the cost of searching may include direct costs associated with the transfer of records and the indexing and filing of records as necessary to maintain the integrity of FDIC's record systems. Where the FDIC estimates that the costs of searching and duplication will exceed the dollar amount specified in the request, or where no dollar amount is specified, the FDIC will advise the requester of the estimated costs (if greater than $25.00). Whenever it is estimated that the costs will exceed $200.00, the requester must pay in advance an amount equal to 20 percent of the estimated costs. For the purpose of computing the time in which a request must be granted or denied, a request for records will not be deemed to have been received by the FDIC until the requester has agreed in writing to pay the costs of searching and duplication, as estimated by the FDIC, and until the FDIC receives any required advance payment. Upon written request and at fees comparable to those listed in this paragraph (b), the FDIC will undertake to compile requested information in summary, tabular or other form, unless the FDIC determines, in its discretion, that

[1] Reports of income and of condition are described at 12 CFR 304.3 (m)–(p).

[2] Summary of accounts and deposit reports are described at 12 CFR 304.3 (q) and (r).

[3] Annual Report of Trust Assets, FFIEC Form 001.

compliance with the request would be unduly burdensome or time consuming.

(2) Fees for search and duplication are:

Supervisory or professional staff	$14.50/hour.
Clerical staff	7.50/hour.
Duplication	0.10/page.
Computer Generated Documents:	
Computer central processing unit (CPU).	0.021/CPU second.
Core (Main storage)	0.000023/1000 bytes/second.
Magnetic tape drive	0.17/1000 tape input/output operation.
Disk storage device	0.153/1000/disk input/output operation.
Computer paper printout	0.16/1000 lines.
Photocopy printed output	0.76/1000 lines.
Output on computer magnetic tape reel.	75.00.
Address labels	8.00/1000 labels.

(3) Any person may request, as part of the initial request for records, that the FDIC waive or reduce the chargeable fees for searching and duplication. Requests for a waiver or reduction of fees should state how the requested information will primarily benefit the general public. Determinations whether a waiver or reduction of fees is in the public interest because furnishing the information will primarily benefit the general public will be made by the Executive Secretary (or designee). The requester will be notified in writing of the determination whether a waiver or reduction of fees is in the public interest.

(c) *Exempt information.* A request for records may be denied if the requested record contains information which falls into one or more of the following categories.[4] If the requested record contains both exempt and nonexempt information, the nonexempt portions which may reasonably be segregated from the exempt portions will be released to the requester.

(1) Records which are (i) specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and (ii) are in fact properly classified pursuant to such Executive order;

(2) Records related solely to the internal personnel rules and practices of the FDIC;

(3) Records specifically exempted from disclosure by statute (other than the Privacy Act of 1974, 5 U.S.C. 552a), provided that such statute (i) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (ii) establishes particular criteria for withholding or refers to particular types of matters to be withheld;

(4) Trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(5) Interagency or intraagency memoranda or letters which would not be available by law to a private party in litigation with the FDIC;

(6) Personnel and medical files and similar files (including financial files) the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(7) Investigatory records compiled for law enforcement purposes, but only to the extent that disclosure of the records would (i) interfere with enforcement proceedings, (ii) deprive a person of a right to a fair trial or an impartial adjudication, (iii) constitute an unwarranted invasion of personal privacy, (iv) disclose the identity of a confidential source, (v) disclose investigative techniques and procedures, or (vi) endanger the life or physical safety of law enforcement personnel; and

(8) Records contained in or related to examination, operating, or condition reports by or on behalf of, or for the use of, the FDIC or any agency responsible for the regulation or supervision of financial institutions.

(d) *Appeals.* (1) A person whose initial request for records under paragraph (a) of this section has been denied, either in part or in whole, has the right to appeal the denial to FDIC's General Counsel (or designee) within 30 business days after receipt of notification of the denial. Appeals of denials of initial requests must be in writing and include any additional information relevant to consideration of the appeal. Appeals should be addressed to the Office of the Executive Secretary, FDIC, 550—17th Street, N.W., Washington, D.C., 20429.

(2) The FDIC will notify the appellant within 20 business days after receipt of the appeal whether it is granted or denied. Denials of appeals will be based on the exemptions provided for in paragraph (c) of this section.

(3) Notifications of a denial of an appeal will be in writing and will state: (i) whether the denial is in part or in whole; (ii) the name and title of each person responsible for the denial (if other than the person signing the notification); (iii) the exemptions relied upon for the denial; and (iv) the right to judicial review of the denial under the Freedom of Information Act (5 U.S.C. 552).

(e) *Extension of time.* Under unusual circumstances the FDIC may require additional time, up to a maximum of 10 business days, to determine whether to grant or deny an initial request or to respond to an appeal of an initial denial. These circumstances would arise in cases where (1) the records are in facilities, such as field offices or storage centers, that are not part of the FDIC's Washington office, (2) the records requested are voluminous and are not in close proximity to one another, or (3) there is a need to consult with another agency or among two or more components of the FDIC having a substantial interest in the determination. The FDIC will promptly give written notification to the person making the request of the estimated date it will make its determination and the reasons why additional time is required.

(f) *FDIC procedures.* (1) Initial requests for records will be forwarded by the Executive Secretary to the head of the FDIC division or office which has custody of such records. Where it is determined that the requested information may be released, the appropriate division or office head will grant access to the information. A request for records may be denied only by the Executive Secretary (or designee), except that a request for records not responded to within 10 business days following its receipt by the Office of Executive Secretary—by notice to the requester either granting the request, denying the request, or extending the time for making a determination on the request—shall, if the requester chooses to treat such delay in response as a denial, be deemed to have been denied by the head of the division or office to which the request was referred for action.

(2) Appeals from a denial of an initial request will be forwarded by the Executive Secretary to the General Counsel (or designee) for a determination whether the appeal will be granted or denied. The General Counsel (or designee) may on his or her own motion refer an appeal to the Board of Directors for a determination and the Board of Directors on its own motion may consider an appeal.

(g) *Records of another agency.* If a requested record is the property of another Federal agency or department, and that agency or department, either in writing or by regulation, expressly retains ownership of such record, upon receipt of a request for the record the FDIC will promptly inform the requester of this ownership and immediately shall

[4] Classification of a record as exempt from disclosure under the provisions of § 309.5(c) shall not be construed as authority to withhold the record if it is otherwise subject to disclosure under the Privacy Act of 1974 (5 U.S.C. 552a) or other Federal statute, any applicable regulation of FDIC or any other Federal agency having jurisdiction thereof, or any directive or order of any court of competent jurisdiction.

forward the request to the proprietary agency or department either for processing in accordance with the latter's regulations or for guidance with respect to disposition.

(h) *Records of receiver or liquidator of assets.* If a requested record is held by the Corporation in its capacity as the receiver of a closed insured bank or the liquidator of assets acquired from an open or closed insured bank, upon receipt of a request for the record the FDIC will inform the requester of the capacity in which it holds such record and shall forward the request to the FDIC's Division of Liquidation for processing and disposition. Disclosure of such records shall be subject to appropriate Federal or State law applicable to FDIC as receiver or liquidator as well as to the determination of any Federal or State court having jurisdiction over FDIC or over such record. Denials of requests may be appealed to FDIC's General Counsel (or designee) within 30 business days following receipt of notification of the denial.

5. Paragraphs (a) and (c)(9) of § 309.6 are revised to read as follows:

§ 309.6 Disclosure of exempt records by FDIC personnel.

(a) *Exempt records.* The provisions of § 309.6 apply to any records which are exempt from disclosure under § 309.5(c) regardless of the fact that such records may be subject to disclosure under the Privacy Act of 1974 (5 U.S.C. 552a) or other Federal statute, any applicable regulation of the FDIC or any other Federal agency having jurisdiction thereof, or any directive or order of any court of competent jurisdiction.

* * * * *

(c) * * *

(9) *Disclosures by division or office heads.* Except as otherwise provided in paragraphs (c)(1) through (c)(8) of this section, each head (or designee) of a division or office may disclose any exempt record which is in the custody of and was created by or originated in the division or office. Any such disclosure shall be made only: (i) Upon receipt of a written request specifying the record sought and the reason why access to the record is necessary; and (ii) after the division or office head (or designee) determines that disclosure of record is in the public interest and not detrimental to any individual or concern.

* * * * *

6. Section 309.6 is further amended by renumbering existing footnotes 10, 11, 12, 13, 14, 15 as footnotes 5, 6, 7, 8, 9, 10, respectively.

7. Paragraph (a) of § 309.7 is revised to read as follows:

§ 309.7 Service of process.

(a) *Service.* Any subpoena or other legal process to obtain information maintained by the FDIC shall be duly issued and serviced upon either the Executive Secretary, FDIC, 550 17th Street, N.W., Washington, D.C. 20429 or the regional director of the FDIC region where the legal action from which the subpoena or process was issued, is pending. A list of the FDIC's regional offices is available from the Office of Information, FDIC, 550 17th Street, N.W., Washington, D.C. 20429 (telephone 202–389–4221). Any service of process on the FDIC as a party shall be made upon the Executive Secretary, FDIC, 550 17th Street N.W., Washington, D.C. 20429 or upon the agent designated to receive service of process in the States, Territory, or jurisdiction in which any insured bank is located. Identification of the designated agent in the State, Territory, or jurisdiction may be obtained from the Office of the Executive Secretary or from the Office of the General Counsel, FDIC, 550 17th Street N.W., Washington, D.C. 20429.

* * * * *

By Order of the Board of Directors this 30th day of August 1982.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 82-24501 Filed 9-3-82; 8:45 am]

BILLING CODE 6714-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 82-NM-50-AD; Amdt. 39-4458]

Airworthiness Directives: General Dynamics Model 340/440 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes two currently effective airworthiness directives (ADs). Each requires inspection for fatigue cracks and correction, if necessary, in different areas of the same horizontal stabilizer attach fitting on General Dynamics Model 340/440 airplanes. This new amendment combines requirements of the two ADs, incorporates mandatory visual and x-ray inspection procedures, and requires replacement of certain rivets with close tolerance fasteners. This AD is required because fatigue cracks in the horizontal stabilizer attach fittings could propagate to a complete fracture, and possible subsequent loss of the horizontal stabilizer.

DATES: Effective date September 16, 1982. Compliance schedule as prescribed in the body of the AD, unless already accomplished.

ADDRESSES: The applicable service information may be obtained from General Dynamics, Convair Division, P.O. Box 80877, San Diego, California 92138, Attention: Larry Hayes, Manager, Product Support. This information also may be examined at the FAA Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168; or 15000 Aviation Boulevard, Hawthorne, California.

FOR FURTHER INFORMATION CONTACT: William Daley, Aerospace Engineer, ANM-172W, Federal Aviation Administration, Northwest Mountain Region, Western Aircraft Certification Field Office, 15000 Aviation Boulevard, Hawthorne, California, telephone (213) 536-6378.

SUPPLEMENTARY INFORMATION: This amendment supersedes AD 81-16-07, Amendment 39-4180 (46 FR 39431), and AD 80-11-01, Amendment 39-3775 (45 FR 35309), both of which required inspection of different areas of the same horizontal stabilizer attach fitting for fatigue cracking. Two horizontal stabilizer attachment fittings were found completely fractured on General Dynamics (Convair) 340/440 aircraft by one operator while complying with AD 80-11-01 which requires inspection of the attachment fitting lug area of this same part for fatigue cracks.

Since this condition could result in possible loss of the horizontal stabilizer and was likely to exist or develop on other airplanes of the same type design, AD 81-16-07 was issued which required an additional area for visual inspection of the horizontal stabilizer attachment fitting pending development of an improved non-destructive testing procedure. X-ray inspection procedures are now available which will reveal cracks at an earlier stage than is possible through visual means alone.

This superseding airworthiness directive is being issued to combine the ultra-sonic inspection of the fitting lugs in AD 80-11-01 with the visual inspection of the fitting outboard of the lugs in AD 81-16-07, add a visual inspection of the lugs, incorporate x-ray inspections of the upper stabilizer fittings and require replacement of three (3) rivets with interference fit fasteners in each of the upper forward stabilizer

fittings. The service bulletins referenced in each of the superseded ADs have also been superseded.

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

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) is amended by adding the following new Airworthiness Directive:

General Dynamics: Applies to Model 340, 440, and military models eligible or to be made eligible for civil use under Type Certificate 6A6, and all such model airplanes converted to turbopropeller power, certificated in all categories. Compliance required as indicated unless previously accomplished.

To prevent possible loss of a horizontal stabilizer due to failure of the stabilizer attachment fittings (P/Ns 340-8510150 and 340-8510151) caused by fatigue cracks, accomplish the following:

A. Within 250 hours time in service or within 90 days from the effective date of this AD, whichever occurs first, unless previously accomplished within the last 450 hours of time in service, conduct a visual inspection of the upper and lower, forward and aft, horizontal stabilizer attachment fitting lugs in accordance with the applicable provisions of paragraph 2 entitled, "Accomplishment Instructions," General Dynamics Convair Division Service Bulletin 640 (340D) 55-3A, Revision 1, dated June 12, 1981. If cracks are found, replace with a new part before further flight.

B. Within 250 hours time in service or within 90 days from the effective date of this AD, whichever occurs first, unless previously accomplished within the last 1150 hours of time in service, conduct an ultrasonic inspection of the upper and lower, forward and aft, horizontal stabilizer attachment fitting lugs in accordance with the applicable provisions of paragraph 2 entitled, "Accomplishment Instructions" of SB 640 (340D) 55-3A. If cracks are found, replace with a new part before further flight.

C. Repeat the visual inspection required by paragraph A of this AD at intervals not to exceed 700 hours time in service from the last such inspection and repeat the ultrasonic inspection required by paragraph B of this AD at intervals not to exceed 1400 hours time in service from the last such inspection.

D. Within 10,000 hours time in service from the effective date of this AD, unless already accomplished, install bushings in the horizontal stabilizer attachment fitting lug holes in accordance with the applicable provisions of paragraph 2 entitled, "Accomplishment Instructions" of SB 640 (340D) 55-3A. Continue to visually inspect at 700 hour intervals per paragraph A and to inspect by ultrasonic procedures at 1400 hour intervals per paragraph B of this AD.

E. Within 250 hours time in service or within 90 days from the effective date of this AD, whichever occurs first, unless previously accomplished within the last 450 hours time in service, conduct an internal visual inspection for cracks in the horizontal stabilizer attachment fittings, upper, lower, forward and aft, and associated structure outboard of the lugs and butt rib in the area surrounding the fasteners, in accordance with the applicable provisions of paragraph 2 entitled, "Accomplishment Instructions" of General Dynamics Convair Division Service Bulletin 640 (340D) 55-4, Revision 1, dated March 24, 1982. Inspect for evidence of loose rivets or fasteners in the stabilizer attachment fittings with particular attention given to those just outboard of the butt rib which fasten the upper forward fittings to the spar web and rail. If cracks are found in the stabilizer attachment fittings or associated structure, and/or if loose fasteners are detected in the stabilizer attachment fitting: replace fitting with a new part, repair structure, and/or replace the fasteners, in accordance with the applicable provisions of paragraph 2 entitled, "Accomplishment Instructions" of SB 640 (340D) 55-4 before further flight.

F. Within 250 hours time in service or within 90 days from the effective date of this AD, whichever occurs first, unless previously accomplished within the last 1150 hours time in service, conduct an x-ray inspection for cracks in the upper forward and upper aft horizontal stabilizer attachment fittings in the area outboard of the lugs in accordance with the applicable provisions of paragraph 2 entitled, "Accomplishment Instructions" of SB 640 (340D) 55-4. Only the four (4) upper fittings are required to be x-ray inspected as they are the most highly loaded in tension and therefore most susceptible to fatigue cracking. If cracks are found, replace with a new part before further flight.

G. Repeat the visual inspection required by paragraph E of this AD at intervals not to exceed 700 hours time in service from the last such inspection and repeat the x-ray inspection required by paragraph F of this AD at intervals not to exceed 1400 hours time in service from the last such inspection.

H. Within 10,000 hours time in service from the effective date of this AD, unless already accomplished, replace the first three (3) steel rivets outboard of the butt rib through the two (2) forward upper horizontal stabilizer attachment fittings in accordance with the applicable provisions of paragraph 2 entitled, "Accomplishment Instructions" of SB 640 (340D) 55-4. Continue to visually inspect at 700 hour intervals per paragraph E and x-ray inspect at 1400 hour intervals per paragraph F of this AD.

I. Prior to issuance of a Certificate of Airworthiness for military aircraft being converted for civil certification, and prior to further flight for any aircraft that has been out of service for one (1) year or more, the airplane must be inspected in accordance with paragraphs A, B, E and F of this AD.

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

K. Alternative inspections, modifications, or other actions which provide an equivalent level of safety may be used when approved by the Chief, Western Aircraft Certification Field Office, FAA Northwest Mountain Region, Hawthorne, California.

The manufacturer's specifications and procedures identified and described in this directive are incorporated herein and made a part hereof pursuant to 5 U.S.C. 552(a)(1).

All persons affected by this directive who have not already received these documents from the manufacturer may obtain copies upon request to General Dynamics, Convair Division, P.O. Box 80877, San Diego, California 92138. These documents also may be examined at FAA Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168; or Western Aircraft Certification Field Office, 15000 Aviation Boulevard, Hawthorne, California.

This supersedes AD 81-16-07, Amendment 39-4180 (46 FR 39431), issued July 24, 1981, and AD 80-11-01, Amendment 39-3775 (45 FR 35309), issued May 13, 1980.

This Amendment becomes effective September 16, 1982.

(Secs. 313(a), 601, and 603 of the Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421, and 1423); Section 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)); and 14 CFR 11.89)

Note.—The FAA has determined that this regulation is an emergency regulation that is not major under Section 8 of Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been further determined that this document involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant/major regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation or analysis is not required). A copy of it, when filed, may be obtained by contacting the person identified under the caption "**FOR FURTHER INFORMATION CONTACT.**"

Issued in Seattle, Wash., on August 27, 1982.

Charles R. Foster,

Director, Northwest Mountain Region.

[FR Doc. 82-24182 Filed 9-3-82; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 82-CE-7-AD; Amdt. 39-4455]

Airworthiness Directives; Embraer Models EMB-110P1 and EMB-110P2 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment revises existing Airworthiness Directive (AD) 82-05-01 Amendment 39-4325 (47 FR 8155, 8156) applicable to EMBRAER Model 110 Series airplanes. It increases the repetitive inspection interval of the wing flap actuators from 250 hours to 500 hours time-in-service. The action is being taken because the FAA has determined from service experience that the flap actuators inspections interval can be extended without compromising safety in the operation of the affected airplanes. The revision relieves the operators of the burden of accomplishing inspections which the FAA has determined are unnecessary.

EFFECTIVE DATE: August 24, 1982.

Compliance: As prescribed in body of AD.

ADDRESSES: EMBRAER Service Bulletin No. 110-27-043, dated March 20, 1981, applicable to this AD, may be obtained from Empresa Brasileira de Aeronautica S/A (EMBRAER), P.O. Box 343-CEP 12.200, Sao Jose dos Campos—S.P., Brasil. A copy of the service bulletin is also contained in the Rules Docket, Office of the Regional Counsel, Room 1558, 601 East 12th Street, Kansas City, Missouri 64106.

FOR FURTHER INFORMATION CONTACT: George Carver, Systems Branch, ACE-130A, Atlanta Aircraft Certification Office, FAA, P.O. Box 20636, Atlanta, Georgia 30320, Telephone (404) 763-7781.

SUPPLEMENTARY INFORMATION: The FAA issued AD 82-05-01 Amendment 39-4325 (47 FR 8155, 8156) which required installation of improved design wing flap actuators on or before September 30, 1982, and imposed continuing special inspection and adjustment procedures on both the improved and replaced actuators. Subsequent to the issuance of this AD, the operators of the affected airplanes have accumulated and submitted data to the FAA which substantiates that the 250 hour time-in-service interval for the inspections imposed by this AD can be increased to 500 hours time-in-service without compromising safety on the improved P/N D2246-5 and D2246-6 or D2246-31 or D2246-41 actuators required to be installed on or before September 30, 1982, by paragraph B) of this AD. Further, the FAA has been informed that the operators of the affected airplanes are accomplishing conversion to the improved actuators ahead of the schedule established in this AD and that modification of all affected airplanes is imminent. Therefore, the FAA is revising AD 82-05-01 by increasing the 250 hours time-in-service interval specified in paragraph A) for the repetitive inspection to 500 hours time-in-service.

Since this amendment is relieving in nature and imposes no additional burden on any person, notice and public procedure hereon are unnecessary and good cause exists for making the amendment effective in less than 30 days.

List of Subjects in 14 CFR Part 39

Aircraft, Aviation safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, AD 82-05-01, Amendment 39-4325 (47 FR 8155, 8156), § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) is amended as follows:

Restate paragraph A) to read as follows:

"(A) Within the next 50 hours time-in-service after March 1, 1982, and thereafter at intervals not to exceed 500 hours time-in-service:"

This amendment becomes effective on August 24, 1982.

(Secs. 313(a), 601, and 603 of the Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421, and 1423); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); § 11.89 of the Federal Aviation Regulations (14 CFR 11.89))

Note.—The FAA has determined that this regulation is relieving in nature and is not considered to be major under Executive Order 12291 or significant under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979), and certifies that the rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act since it involves an inspection procedure affecting only a few if any aircraft owned by small entities. If this action is subsequently determined to involve a significant regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket; otherwise, an evaluation is not required. A copy of it, when filed, may be obtained by contacting the Rules Docket at the location identified under the caption "ADDRESSES." This rule is a final order of the Administrator under the Federal Aviation Act of 1958, as amended. As such, it is subject to review only by the various Courts of Appeals of the United States, or the United States Court of Appeals for the District of Columbia.

Issued in Kansas City, Missouri, on August 24, 1982.

John E. Shaw,

Acting Director, Central Region.

[FR Doc. 82-24171 Filed 9-3-82; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 82-CE-11-AD; Amdt. 39-4456]

Airworthiness Directives; Piper PA-31 Series Airplanes

AGENCY: Federal Aviation Administration.

ACTION: Final rule, revision and correction of existing Airworthiness Directive (AD).

SUMMARY: This action revises and corrects AD 82-08-06, Amendment 39-4368 (47 FR 16615, 16616) by extending the compliance date for the modification required by paragraph a)4. from August 1, 1982, to November 1, 1982. It also corrects the part number of the Autopilot/Flap Operation Placard cited in paragraph c)3. to read P/N 81009-02. The extension in compliance date is necessary because the manufacturer is unable to provide the Flap Travel Restrictions and Placard Kit P/N 764-396 to all operators on or before August 1, 1982. The extension in compliance time will avoid unnecessary grounding of airplanes which can be safety operated when accomplishing the other requirements of the AD.

EFFECTIVE DATE: August 25, 1982.

FOR FURTHER INFORMATION CONTACT: W. H. Trammell, ACE-130A, Atlanta Aircraft Certification Office, FAA, P.O. Box 20636, Atlanta, Georgia 30320; Telephone (404) 763-7781.

SUPPLEMENTARY INFORMATION: Subsequent to issuance of AD-82-08-06, Amendment 39-4368 (47 FR 16615, 16616), the FAA has become aware through operator requests for relief that the Piper Flap Travel Restrictions and Placard Kit P/N 764 396 was unavailable. The manufacturer has verified that insufficient kits have been produced to modify all airplanes to which paragraph a)4. is applicable. The FAA found, prior to issuance of AD 82-08-06, that pending installation of the kit, compliance with other restrictions and maintenance required in paragraph a) of the AD would provide an acceptable level of safety in the operation of the affected airplanes. Accordingly, the August 1, 1982, date specified in paragraph a)4 for installation of the kits was predicated on the manufacturer's schedule for kit

manufacturer and distribution. Therefore, extension of the compliance time to allow the manufacturer to supply kits to all operators of affected airplanes will have no significant effect on safety and will prevent unnecessary grounding of some airplanes. In addition, the FAA has learned that the part number in paragraph c)3. of this AD for the permanent Autopilot/Flap Operation Placard is erroneously cited as Piper P/N 81109–02 instead of the correct Piper P/N 81009–02.

Therefore, the FAA is revising AD 82–08–06, Amendment 39–4368 (47 FR 16615, 16616), by increasing the compliance time on paragraph a)4. from August 1, 1982, to November 1, 1982, and correcting the part number listed in paragraph c)3. for the Autopilot Flap Operation Placard to read "Piper P/N 81009–02." Since this amendment is both relieving and clarifying in nature and imposes no additional burden on any person, notice and public procedure hereon are unnecessary and good cause exists for making the amendment effective in less than 30 days.

List of Subjects in 14 CFR Part 39

Aircraft, Aviation safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, AD 82–08–06, Amendment 39–4368 (47 FR 16615, 16616) § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) is amended as follows:

(1) Restate paragraph a)4. to read: "On or before November 1, 1982, install Piper Flap Travel Restrictions and Placard Kit, P/N 764 396 in Model PA–31, PA–31–300, PA–31–325, and PA–31–350 airplanes and P/N 764 397 in Model PA–31P airplanes."

(2) In paragraph c)3. correct the part number cited for the Autopilot/Flap Operation Placard to read "Piper P/N 81009–02."

This amendment becomes effective on August 25, 1982.

(Secs. 313(a), 601, and 603 of the Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421 and 1423); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); § 11.89 of the Federal Aviation Regulations (14 CFR 11.89))

Note.—The FAA has determined that this action is relieving in nature and revises a regulation that is not considered to be major under Executive Order 12291 or significant under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket; otherwise, an evaluation is not required. A copy of it, when filed, may be obtained by contacting the Rules Docket at the location identified under the caption "ADDRESSES."

This rule is a final order of the Administrator under the Federal Aviation Act of 1958, as amended. As such, it is subject to review by only the various Courts of Appeals of the United States or the United States Court of Appeals of the District of Columbia.

Issued in Kansas City, Missouri, on August 25, 1982.

John E. Shaw,

Acting Director, Central Region.

[FR Doc. 82-24172 Filed 9-3-82; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 39

[Docket No. 82-ANE-10; Amdt. 39-4457]

Airworthiness Directives; Garrett Turbine Engine Company Engine Models TSE331-3 and TPE331-1, -2, -3, -5, and -6 Series Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comment.

SUMMARY: This action amends a currently effective airworthiness directive (AD) which revised turbine wheel life limits. The previous AD was issued to reduce the possibility of rapid destruction of the engine turbine resulting from separation of a portion of the turbine wheel rim. This amendment clarifies the AD to preclude wheels failing a required inspection from being returned to service, to establish that normal cyclic life limits are listed in a Garrett service bulletin (SB), to identify and limit by specific part number (P/N) affected third stage turbine wheels, and to make less restrictive the turbine wheel replacement option.

DATES: Effective September 9, 1982. Comments must be received or before October 9, 1982. Compliance schedule—As prescribed in the body of the AD.

ADDRESSES: The applicable service information may be obtained from Garrett Turbine Engine Company, P.O. Box 5217, Phoenix, Arizona 85010; telephone (602) 267–3011.

A copy of the service information is contained in the FAA Rules Docket, Federal Aviation Administration, New England Region, Office of the Regional Counsel, Attn: Docket No. 82–ANE–10, 12 New England Executive Park, Burlington, Massachusetts 01803.

FOR FURTHER INFORMATION CONTACT: Bill Moring, Aerospace Engineer, ANM–174W, Western Aircraft Certification Field Office, Northwest Mountain Region, P.O. Box 92007, World Way Postal Center, Los Angeles, California 90009; telephone: (213) 536–6381.

SUPPLEMENTARY INFORMATION: AD No. 82–10–05, Amendment 39–4382, (47 FR 20562) made effective on May 13, 1982, reduced the cyclic life limit of TSE331–3 and TPE 331–1, –2, –3, –5, and –6 series engine third stage turbine wheels. This action was required because failures occurred at less than the published cyclic life limits. Since issuance of AD 82–10–05, service experience has shown the need for clarification of the requirements of the AD. Accordingly, AD 82–10–05, Amendment 39–4382, is being amended to clarify Paragraph (c) to preclude wheels failing the inspection from being returned to service; to administratively establish, in Paragraph (d), that FAA-approved rotating component normal cyclic life limits are not controlled by the AD but rather by FAA-approved Garrett SB; to clarify existing instructions of Paragraph (f) by identifying the specific P/Ns of the two series of third stage turbine wheels which are affected; and to make less restrictive the option of replacement third stage turbine wheels in Subparagraph (f)(2). The remaining compliance requirements of AD 82–10–05, Amendment 39–4382, remain unchanged.

Since this amendment provides clarification and relaxation, and imposes no additional burden on any person, notice and public procedure is impracticable, and good cause exists for making this amendment effective in less than 30 days.

Request for Comments on the Rule

Although this action is in the form of a final rule which was not preceded by notice and public procedure, comments are invited on the rule. When the comment period ends, the FAA will use the comments submitted, together with other available information, to review the regulation. After the review, if the FAA finds that changes are appropriate, it will initiate rulemaking proceedings to amend the regulation. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in evaluating the effects of the AD and determining whether additional rulemaking is needed. Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule.

List of Subjects in 14 CFR Part 39

Engines, Air transportation, Aircraft, Aviation safety, and Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13), Amendment 39-4382, AD No. 82-10-05, is amended as follows:

1. Paragraph (c). Add the following new sentence to the end of Paragraph (c): "Third stage wheels which do not meet the inspection limits of this service bulletin may not be returned to service."

2. Revise Paragraph (d) to read as follows:

(d) As of May 13, 1982, turbine wheels specified below may not be operated in service in excess of these service life limits except as provided in Paragraphs (a) or (b) of this AD, as applicable:

Wheel stage	Part number	Cycle life
Third	895539-1, -2, -3, and -4	2400
Third	868630-1, -2, -3, -4, and -7	3600

Note.—Normal cyclic life limits are listed in Garrett SB No. TSE/TPE 331-72-0019, Revision 9, dated June 25, 1982, or FAA-approved equivalent.

Note.—For purposes of this AD, an operating cycle is defined as any operating sequence involving an engine start, aircraft takeoff and landing, followed by engine shutdown, and one cycle shall be counted for each operational sequence.

3. Revise Paragraph (f) to read as follows:

(f) Prior to accumulating an additional 1,800 operating hours after February 11, 1982, on all affected engines containing P/Ns 868630-1, -2, -3, or -4 or P/Ns 895539-1, -2, -3, or -4 third stage turbine wheels, or upon next removal of the third stage turbine wheel, after the effective date of this AD, whichever occurs earlier, either:

(1) Remove curvic coupling gasket, P/N 868892-2, located forward of third stage turbine wheel, and replace it with a serviceable P/N 868892-9 curvic coupling gasket as prescribed in Paragraph 2 of Garrett Service Bulletin TPE331-72-0300, dated September 9, 1981, or FAA approved equivalent, or;

(2) Replace the third stage turbine wheel with a P/N 868630-7, P/N 868630-8, or FAA-approved equivalent third stage turbine wheel.

Note.—The P/Ns 868630-1, -2, -3, or -4 turbine wheel may be modified to the P/N 868630-7 third stage turbine wheel design by compliance with instructions provided in Garrett Service Bulletins TPE 331-72-0327, dated December 14, 1981, or FAA approved equivalent. This amends AD 82-10-05, Amendment 39-4382, 47 FR 20562.

This amendment becomes effective September 9, 1982.

(Secs. 313(a), 601, and 603, Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421, and 1423); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c); 14 CFR 11.89).)

Note.—Since this regulation provides clarification of, and makes less restrictive, an existing AD, the FAA has determined that it: (1) Is not a major rule under Executive Order 12291; (2) is not a significant rule under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal.

Issued in Burlington, Massachusetts on August 25, 1982.

Robert E. Whittington,

Director, New England Region.

[FR Doc. 82-24173 Filed 9-3-82; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 71

[Airspace Docket No. 82-ASO-40]

Designation of Federal Airways, Area Low Routes, Controlled Airspace, and Reporting Points; Alteration of Certain Control Zones in North Carolina and Tennessee

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment alters certain Control Zones in North Carolina and Tennessee by including in the descriptions a provision that will permit use of the FAA's Notice to Airmen (NOTAM) system and the Airport/Facility Directory (A/FD) to publicize the hours during which the Control Zones are effective. No change in airspace is intended by this action which is directed towards standardizing the descriptions of Control Zones within the FAA's Southern Region.

DATES: Effective date: 0901 G.m.t., October 28, 1982. Comments must be received on or before September 28, 1982.

ADDRESSES: Send comments on the rule in triplicate to: Federal Aviation Administration, Manager, Airspace and Procedures Branch, ASO-530, Air Traffic Division, P.O. Box 20636, Atlanta, Georgia 30320.

The official docket may be examined in the Office of the Regional Counsel, Room 652, 3400 Norman Berry Drive, East Point, Georgia 30344, telephone: (404) 763-7646.

FOR FURTHER INFORMATION CONTACT: Donald Ross, Airspace and Procedures Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone: (404) 763-7646.

SUPPLEMENTARY INFORMATION:

Request for Comments on the Rule

Although this action is in the form of a final rule, which involves adding a provision to two Control Zones which will permit use of the FAA's NOTAM system to publicize the hours during which the Control Zones are effective, and, thus, was not preceded by notice and public procedure, comments are invited on the rule. When the comment period ends, the FAA will use the comments submitted, together with other available information, to review the regulation. After the review, if the FAA finds that changes are appropriate, it will initiate rulemaking proceedings to amend the regulation. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in evaluating the effects of the rule and determining whether additional rulemaking is needed. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy aspects of the rule that might suggest the need to modify the rule.

The Rule

The purpose of this amendment to § 71.171 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is to add a provision to the descriptions of two Control Zones which will permit future notification of changes in effective hours through use of the NOTAM system. After issuance of appropriate NOTAM's, the effective hours of each Control Zone would thereafter be listed in the A/FD, thus providing a single source reference for pertinent data relating to a specific airport. If future aeronautical activities should indicate a change in effective hours is necessary, such changes could be publicized in a rapid and effective manner to airspace users. Section 71.171 of Part 71 of the Federal Aviation Regulations was republished in Advisory Circular AC 70-3 dated January 29, 1982. Under the circumstances presented, the FAA concludes that there is a need for a regulation to provide a means to publicize changes to hours during which certain Control Zones are effective. Therefore, I find that notice or public procedure under 5 U.S.C. 553(b) is unnecessary and that good cause exists for making this amendment effective in less than 60 days after its publication in the **Federal Register.**

List of Subjects in 14 CFR Part 71

Aviation safety, Airspace, Control zone.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, § 71.171 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) (as amended) is further amended, effective 0901 G.m.t., October 28, 1982, as follows:

Elizabeth City, NC—Revised

By deleting the words, "* * * This Control Zone is effective from 0700 to 2200 hours, local time, daily * * *" and substituting for them the words, "* * * This Control Zone is effective during the specific days and times established in advance by a Notice to Airmen. The effective days and times will thereafter be continuously published in the Airport/Facility Director * * *"

Dyersburg, TN—Revised

By deleting the words, "* * * to the VORTAC, effective from 0600 to 2200 hours local time daily * * *" and substituting for them the words, "* * * to the VORTAC. This Control Zone is effective during the specific days and times established in advance by a Notice to Airmen. The effective days and times will thereafter be continuously published in the Airport/Facility Directory * * *"

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); and 14 CFR 11.69.)

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

Issued in East Point, Georgia, on August 24, 1982.

George R. LaCaille,

Acting Director, Southern Region.

[FR Doc. 82-24174 Filed 9-3-82: 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 71

[Airspace Docket No. 82-ASO-39]

Designation of Federal Airways, Area Low Routes, Controlled Airspace, and Reporting Points; Alteration of Control Zone, Miami, Fla. (Opa Locka Airport)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment alters the description of the Miami, Florida (Opa Locka Airport), Control Zone by deleting reference to the Miami International Airport Control Zone. This action will more clearly establish a demarcation line between the two Control Zones and reduce the size of the Opa Locka Control Zone by approximately four square miles.

DATES: Effective date: 0901 G.m.t., October 28, 1982. Comments must be received on or before September 28, 1982.

ADDRESSES: Send comments on the rule in triplicate to: Federal Aviation Administration, Manager, Airspace and Procedures Branch, ASO-530, Air Traffic Division, P.O. Box 20636, Atlanta, Georgia 30320.

The official docket may be examined in the Office of the Regional Counsel, Room 652, 3400 Norman Berry Drive, East Point, Georgia 30344, telephone: (404) 763-7646.

FOR FURTHER INFORMATION CONTACT: Donald Ross, Airspace and Procedures Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone: (404) 763-7646.

SUPPLEMENTARY INFORMATION:

Request for Comments on the Rule

Although this action is in the form of a final rule, which involves an editorial change in the description of the Miami, Florida (Opa Locka Airport), Control Zone and, thus, was not preceded by notice and public procedure, comments are invited on the rule. When the comment period ends, the FAA will use the comments submitted, together with other available information, to review the regulation. After the review, if the FAA finds that changes are appropriate, it will initiate rulemaking proceedings to amend the regulation. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in evaluating the effects of the rule and determining whether additional rulemaking is needed. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy aspects of the rule that might suggest the need to modify the rule.

The Rule

The purpose of this amendment to § 71.171 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is to more clearly define the dimensions of the Control Zone which is centered on Opa Locka Airport by deleting reference to Miami International Airport. A latitude ordinate will be used in the description to define the southern boundary of the Control Zone. Section 71.171 of Part 71 of the Federal Aviation Regulations was republished in Advisory Circular AC 70-3 dated January 29, 1982. Under the circumstances presented, the FAA concludes that there is a need for an editorial change to the regulation to clearly define a line of demarcation between the two Control Zones which are centered on Opa Locka and Miami International Airports. Therefore, I find that notice or public procedure under 5 U.S.C. 553(b) is unnecessary and that good cause exists for making this amendment effective in less than 60 days after its publication in the **Federal Register.**

List of Subjects in 14 CFR Part 71

Aviation safety, Airspace, Control zone.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, § 71.171 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) (as amended) is further amended, effective 0901 G.m.t., October 28, 1982, as follows:

Miami, FL (Opa Locka Airport) [Revised]

By deleting the words "* * * excluding the portion which coincides with the Miami (International Airport) Control Zone * * *." and substituting for them the words "* * * excluding that airspace south of latitude 25°52'02"N * * *."

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); and 14 CFR 11.69)

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

that this rule will not have a signficiant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Issued in East Point, Ga., on August 20, 1982.

George R. LaCaille,

Acting Director, Southern Region.

[FR Doc. 82-24176 Filed 9-3-82; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 71

[Airspace Docket No. 82-ASO-24]

Alteration of Certain Control Zones in Alabama, Florida, Georgia, Kentucky, Mississippi, and Tennessee

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment alters certain Control Zones in Alabama, Florida, Georgia, Kentucky, Mississippi, and Tennessee by including in the descriptions a provision that will permit use of the FAA's Notice to Airmen (NOTAM) system and the Airport/Facility Directory (A/FD) to publicize the hours during which the Control Zones are effective. No change in airspace is intended by this action which is directed towards standardizing the descriptions of Control Zones within the FAA's Southern Region.

EFFECTIVE DATE: 0901 g.m.t., October 28, 1982.

FOR FURTHER INFORMATION CONTACT: Donald Ross, Airspace and Procedures Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone: (404) 763-7646.

SUPPLEMENTARY INFORMATION:

History

On Thursday, June 17, 1982, the FAA proposed to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) by adding a provision to the descriptions of certain Control Zones which will permit future notification of changes in effective hours through use of the Notice to Airmen (NOTAM) system. After issuance of appropriate NOTAM's, the effective hours of each Control Zone would thereafter be listed in the Airport/Facility Directory (A/FD), thus providing a single source reference for all pertinent data relating to specific airports. If future aeronautical activities should indicate a change in effective hours is necessary, such changes could be publicized in a rapid and effective manner to airspace users (47 FR 26157).

After publication of the Notice of Proposed Rulemaking, it was determined that the communications and weather reporting requirements for Control Zones, as outlined in FAA publications, are satisfied at Roosevelt Roads, Puerto Rico. The Department of the Navy has a requirement for a full-time Control Zone at Roosevelt Roads so that the Navel Station can fulfill its operational role in support of fleet exercises and aircraft carrier training. Therefore, Roosevelt Roads Control Zone has been deleted from this rule.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. In response to the proposal, comments were received from the Paducah, Kentucky, Airport Manager who felt that the proposal would not enhance aviation safety and there did not appear to be any logical reason to "part-time" the Paducah Control Zone. The Airport Manager correctly noted that, when FAA facilities are not available to provide weather reporting service, such service can be provided by contract weather observers. If we should elect to reduce the hours of operation of our Paducah facilities, such action will be fully coordinated with the aviation community and, if federally certificated weather observer service is provided, the hours of the Control Zone would not be reduced.

Another commenter suggested that the hours of part-time Control Zones be shown on aeronautical charts as a convenience of transient pilots. Aeronutical charts presently depict part-time Control Zones in one of two methods: if the Control Zone is subject to seasonal changes, the charts are annotated to refer the user to the Airport/Facility Directory (A/FD) for effective hours; if the Control Zone is not subject to change, the effective hours of the Control Zone are depicted. As aeronautical charts are issued every six months, it would be impossible to keep such charts current with a depiction of Control Zone hours that are subject to seasonal change. To delay a change in Control Zone hours to correspond with a charting date would ofter result in an inefficient utilization of airspace.

Except for the deletion of Roosevelt Roads, Puerto Rico, this amendment is the same as that proposed in the notice. Section 71.171 of Part 71 of the Federal Aviation Regulations was republished in Advisory Circular AC 70-3 dated January 29, 1982.

The Rule

This amendment to Part 71 of the Federal Aviation Regulations will add a provision to the descriptions of the Control Zones listed below which will permit future notification of changes in effective hours through use of the Notice to Airmen (NOTAM) system.

List of Subjects in 14 CFR Part 71

Aviation safety, Airspace, Control zone.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, § 71.171 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) (as amended) is further amended, effective 0901 GMT, October 28, 1982, by adding the following words at the end of the text of each of the Control Zones listed below:

"* * * This Control Zone is effective during the specific days and times established in advance by a Notice to Airmen. The effective days and times will thereafter be continuously published in the Airport/Facility Directory * * *"

Albany, Georgia
Anniston, Alabama
Bowling Green, Kentucky
Dothan, Alabama
Gainesville, Florida
Greenwood, Mississippi
Macon, Georgia
Paducah, Kentucky
Tri-City, Tennessee

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); and 14 CFR 11.69)

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

Issued in East Point, Georgia, on August 25, 1982.

George R. LaCaille,

Acting Director, Southern Region.

[FR Doc. 82-24177 Filed 9-3-82; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 71

[Airspace Docket No. 82-ACE-08]

Designation of Federal Airways, Area Low Point Routes, Controlled Airspace and Reporting Points; Alteration of Transition Area—Webster City, Iowa

AGENCY: Federal Aviation Administration (FAA), DOT
ACTION: Final rule.

SUMMARY: The nature of this federal action is to alter the 700-foot transition area at Webster City, Iowa, by adding an extension to the transition area northwest of the Webster City Municipal Airport. This alteration will provide additional controlled airspace for aircraft executing a new instrument approach procedure to the Webster City Municipal Airport, utilizing the fort Dodge, Iowa, VOR as a navigational aid. The intended effect of this action is to ensure segregation of aircraft using the new approach procedure under Instrument Flight Rules (IFR) and other aircraft operating under Visual Flight Rules (VFR).

EFFECTIVE DATE: October 28, 1982.
FOR FURTHER INFORMATION CONTACT: Dwaine E. Hiland, Airspace Specialist, Airspace and Procedures Section, Operations and Airspace Branch, Air Traffic Division, ACE-532, FAA, Central Region, 601 East 12th Street, Kansas City, Missouri 64106, Telephone (816) 374-3408.

SUPPLEMENTARY INFORMATION: To enhance airport usage, an additional instrument approach procedure to the Webster City, Iowa, Municipal Airport, is being established utilizing the Fort Dodge, Iowa, VOR as a navigational aid. The establishment of an instrument approach procedure based on this approach aid entails alteration of a transition area at Webster City, Iowa, at and above 700 feet above the ground (AGL) within which aircraft are provided air traffic control service. The intended effect of this action is to ensure segregation of aircraft using the new approach procedure under Instrument Flight Rules (IFR) and other aircraft operating under Visual Flight Rules (VFR).

Discussion of Comments

On pages 29256 and 29257 of the Federal Register dated July 6, 1982, the Federal Aviation Administration published a Supplemental Notice of Proposed Rulemaking which would amend § 71.181 of Part 71 of the Federal Aviation Regulations so as to alter the transition area at Webster City, Iowa. Interested persons were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No objections were received as a result of the Supplemental Notice of Proposed Rulemaking.

List of Subjects in 14 CFR Part 71

Aviation safety, Transition areas.

Accordingly, pursuant to the authority delegated to me, § 71.171 and/or § 71.181 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is amended, effective 0901 g.m.t., October 28, 1982, by altering the following transition area:

Webster City, Iowa

That airspace extending upward from 700 feet above the surface within a 6-mile radius of the Webster City Municipal Airport (Latitude 42°26'15" N, Longitude 93°52'10" W) and 4½ miles each side of the FOD 112°R extending from the 6-mile radius area to 7 miles northwest of the airport.

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); and Sec. 11.69 of the Federal Aviation Regulations (14 CFR 11.69))

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

Issued in Kansas City, Mo., on August 25, 1982.

John E. Shaw,
Acting Director, Central Region.

[FR Doc. 82-24181 Filed 9-3-82; 8:45 am]
BILLING CODE 4910-13-M

14 CFR Part 71

[Airspace Docket No. 82-ASO-32]

Designation of Federal Airways, Area Low Routes, Controlled Airspace, and Reporting Points; Alteration of Control Zone, Miami, Fla.

AGENCY: Federal Aviation Administration (FAA), DOT.
ACTION: Final rule.

SUMMARY: This amendment alters the Miami, Florida (International Airport), Control Zone by (1) revoking three arrival extensions, (2) deleting reference to a navigational aid which is being relocated, (3) increasing the size of the basic control zone and (4) deleting reference to the airport name in the title of the control zone.

EFFECTIVE DATE: 0901 g.m.t., October 28, 1982.

FOR FURTHER INFORMATION CONTACT: Donald Ross, Airspace and Procedures Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone: (404) 763-7646.

SUPPLEMENTARY INFORMATION:

History

On Monday, July 19, 1982, the FAA proposed to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) by altering the description of the Miami, Florida, Control Zone. The control zone is presently described as a five-mile radius of Miami International Airport and includes three arrival extensions. The arrival extensions are predicated in part on a navigational aid, which is being relocated, and various radials of the Miami VORTAC and two localizer courses. The currently designated airspace is required for containment of instrument flight rules (IFR) operations to and from the airport (47 FR 31289). Increasing the size of the control zone from five to a six-mile radius of the airport will provide the necessary controlled airspace for IFR operations in the vicinity of the airport and will permit simplication of the description by deleting reference to VORTAC radials and localizer courses. Elimination of the words "International Airport" from the title of this control zone will have no effect on the description. Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No objections to the proposal were received in response to publication. Except for editorial changes, this amendment is the same as that proposed in the notice. Section 71.171 of Part 71 of the Federal Aviation Regulations was republished in Advisory Circular AC 70-3 dated January 29, 1982.

The Rule

This amendment to Part 71 of the Federal Aviation Regulations alters the description of the Miami, Florida, Control Zone, by revoking three arrival extensions and enlarges the radius of the control zone from five to six miles.

List of Subjects in 14 CFR Part 71

Aviation safety, Airspace, Control zone.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, § 71.171 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) (as amended) is further amended, effective 0901 GMT, October 28, 1982 as follows:

Miami, FL [Revised]

Within a six-mile radius of Miami International Airport (Lat. 25°47'34"N., Long. 80°17'10"W.); excluding that airspace north of Latitude 25°52'02"N., and east of the west shoreline of Biscayne Bay.

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); and 14 CFR 11.69)

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

Issued in East Point, Ga., on August 27, 1982.

George R. LaCaille,

Acting Director, Southern Region.

[FR Doc. 82-24180 Filed 9-3-82; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 71

[Airspace Docket No. 82-ASW-59]

Designation of Federal Airways, Area Low Routes, Controlled Airspace, and Reporting Points; Alteration of Control Zones; Houston, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment alters the control zones at Houston, TX (Ellington AFB and William P. Hobby). This amendment will return to public use airspace no longer required for the protection of aircraft arriving/departing Ellington AFB and the William P. Hobby Airports. The amendment is necessary since a review of the controlled airspace and the description revealed that the airspace designated was excessive of that required and clerical errors were in the current description of the two control zones.

DATES: Effective date—December 23, 1982. Comments on the rule must be received before December 1, 1982.

ADDRESSES: Send comments on the action in triplicate to: Manager, Airspace and Procedures Branch, Air Traffic Division, Southwest Region, Docket No. 82-ASW-59, Federal Aviation Administration, P.O. Box 1689, Fort Worth, TX 76101.

FOR FURTHER INFORMATION CONTACT: Kenneth L. Stephenson, Airspace and Procedures Branch (ASW-535), Air Traffic Division, Southwest Region, Federal Aviation Administration, P.O. Box 1689, Fort Worth, TX 76101, telephone (817) 624-4911, extension 302.

SUPPLEMENTARY INFORMATION:

History

Federal Aviation Regulation Part 71, Subpart F § 71.171 as republished in Advisory Circular AC 70-3 dated January 29, 1982, contains the description of control zones designated to provide controlled airspace for the benefit of aircraft conducting instrument flight rules (IFR) activity. Alteration of the control zones at Houston, TX (Ellington AFB and William P. Hobby), will necessitate an amendment to this subpart. A review of the necessary controlled airspace has revealed that a reduction in the dimensions can be made and adequate protection for aircraft can be provided.

The Rule

This amendment to Part 71 of the Federal Aviation Regulations (14 CFR 71) amends the dimensions of the Houston, TX (Ellington AFB and William P. Hobby) control zones. Because this action reduces a burden on the public by releasing controlled airspace, I find that notice and public procedure and publication 30 days before the effective date are unnecessary; however, comments are invited on the rule. When the comment period ends, the FAA will use the comments and any other available information to review the regulation.

List of Subjects in 14 CFR Part 71

Control zones, Transition areas.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Section 71.171 of Part 71 of the Federal Aviation Regulations (14 CFR 71) as republished in Advisory Circular AC 70-3 dated January 29, 1982, is amended, effective 0901 G.M.T., December 23, 1982, as follows:

Houston, TX (Ellington AFB) [Revised]

That airspace within a 5-mile radius of Ellington AFB (latitude 29°36'22" N., longitude 95°09'35" W.) and within a 3-mile radius of Clear Lake Metroport STOL (latitude 29°33'33" N., longitude 95°08'21" W.) excluding that airspace north of a line from latitude 29°32'00" N., longitude 95°15'00" W., to latitude 29°45'00" N., longitude 95°10'00" W.

Houston, TX (William P. Hobby) [Revised]

That airspace within a 5-mile radius of William P. Hobby Airport (latitude 29°38'44" N., longitude 95°16'42" W.) and within 2 miles each side of Hobby VOR 142° radial extending to 7 miles southeast of the VOR, excluding that airspace south of a line from latitide 29°32'00" N., longitude 95°15'00" W., to latitude 29°45'00" N., longitude 95°10'00" W.

(Sec. 307(a), Federal Aviation Act of 1958, as amended (49 U.S.C. 1348(a)); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); and 14 CFR 11.61(c))

Note.—The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) Is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 1103; February 26, 1979);and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. It is certified that the rule will not have a significant economic impact on a substantial number of small entities as the anticipated impact is minimal.

Issued in Fort Worth, TX, on August 26, 1982.

F. E. Whitfield,

Acting Director, Southwest Region.

[FR Doc. 82-24179 Filed 9-3-82; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 71

[Airspace Docket No. 82-AGL-19]

Designation of Federal Airways, Area Low Routes, Controlled Airspace, and Reporting Points; Alteration of VOR Federal Airway V-177

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: This action amends the description of VOR Federal Airway V-177 by deleting the exclusion of airspace on V-177 between Duluth, MN, and Ely, MN, at 10,000 feet MSL and above when the Snoopy Military Operations Area (MOA) is in use. This action increases availability of airspace for civil aviation use.

DATES: Effective date—October 28, 1982. Comments must be received on or before October 7, 1982.

ADDRESSES: Send comments on the rule in triplicate to: Director, FAA Great Lakes Region, Attention: Manager, Air Traffic Division, Docket No. 82-AGL-19, Federal Aviation Administration, 2300 East Devon, Des Plaines, IL 60018.

The official docket may be examined in the Rules Docket, weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m. The FAA Rules Docket is located in the Office of the Chief Counsel, Room 916, 800 Independence Avenue, SW., Washington, D.C.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division.

FOR FURTHER INFORMATION CONTACT: Bill Hill, Airspace Regulations and Obstructions Branch (AAT-230), Airspace and Air Traffic Rules Division, Air Traffic Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591, telephone: (202) 426-8783.

SUPPLEMENTARY INFORMATION:

Request for Comments on the Rule

Although this action is in the form of a final rule, which deletes the exclusion of airspace at 10,000 feet MSL and above on V-177 within the Snoopy MOA between Duluth, MN, and Ely, MN, increasing the availability of airspace for civil aviation use and, thus, was not preceded by notice and public procedure, comments are invited on the rule. When the comment period ends, the FAA will use the comments submitted, together with other available information, to review the regulation. After the review, if the FAA finds that changes are appropriate, it will initiate rulemaking proceedings to amend the regulation. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in evaluating the effects of the rule and determining whether additional rulemaking is needed. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy aspects of the rule that might suggest the need to modify the rule.

The Rule

The purpose of this amendment to § 71.123 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is to make available for civil aviation use airspace on V-177 at and above 10,000 feet MSL within the Snoopy MOA between Duluth, MN, and Ely, MN, during periods when the Snoopy MOA is activated. Since this action presents no additional burden on the public and increases the release of airspace for public use, notice and public procedure thereon are unnecessary. Section 71.123 of Part 71 of the Federal Aviation Regulations was republished in Advisory Circular AC 70-3 dated January 29, 1982.

List of Subjects in 14 CFR Part 71

Federal airways.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, § 71.123 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is amended as follows:

V-177 [Amended]

Delete "The airspace 10,000 feet MSL and above between Duluth and Ely is excluded during the times Snoopy MOA is activated by NOTAM."

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); and 14 CFR 11.69)

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

Issued in Washington, D.C., on August 27, 1982.

B. Keith Potts,

Manager, Airspace and Air Traffic Rules Division.

[FR Doc. 82-24188 Filed 9-3-82; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 73

[Airspace Docket No. 82-ASW-15]

Special Use Airspace; Subdivision of Restricted Area R-5107C, White Sands Missile Range, NM

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: This action amends Part 73 of the Federal Aviation Regulations (14 CFR Part 73) by subdividing the White Sands Missile Range, NM, Restricted Area R-5107C. This redesignation of R-5107C into three areas, R-5107C, R-5107H, and R-5107J, provides the same overall airspace to the using agency and increases the ability to release airspace for civil aviation use.

DATES: Effective date—October 28, 1982. Comments must be received on or before October 7, 1982.

ADDRESSES:

Send comments on the rule in triplicate to: Director, FAA Southwest Region, Attention: Manager, Air Traffic Division, Docket No. 82-ASW-15, Federal Aviation Administration, P.O. Box 1689, Fort Worth, TX 76101.

The official docket may be examined in the Rules Docket, weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m. The FAA Rules Docket is located in the Office of the Chief Counsel, Room 916, 800 Independence Avenue, SW., Washington, D.C.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division.

FOR FURTHER INFORMATION CONTACT: Bill Hill, airspace Regulations and Obstructions Branch (AAT-230), Airspace and Air Traffic Rules Division, Air Traffic Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591, telephone: (202) 426-8783.

SUPPLEMENTARY INFORMATION:

Request for Comments on the Rule

Although this action is in the form of a final rule, which involves the subdividing of a restricted area proving beneficial to general aviation by increasing available airspace and, thus, was not preceded by notice and public procedure, comments are invited on the rule. When the comment period ends, the FAA will use the comments submitted, together with other available information, to review the regulation. After the review, if the FAA finds that changes are appropriate, it will initiate rulemaking proceedings to amend the regulation. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in evaluating the effects of the rule and determining whether additional rulemaking is needed. Comments are specifically invited on the overall regulatory, aeronautical, economic, and energy aspects of the rule that might suggest the need to modify the rule. Send comments on environmental and land use aspects to: Deputy for Air Force, White Sands Missile Range, NM 88002.

The Rule

The purpose of this amendment to § 73.51 of Part 73 of the Federal Aviation Regulations (14 CFR Part 73) is to subdivide the White Sands Missile Range, NM, Restricted Area R–5107C into three different areas as follows:

R–5107C White Sands Missile Range, NM, is redefined with a new base of 9,000 feet MSL. The boundary remains unchanged.
R–5107H is established in Part 73.
R–5107J is established in Part 73.

Since this action involves no addition of airspace to the present restricted area, presents no additional burden on the public, and increases the release of airspace for public use, notice and public procedure thereon are unnecessary. Section 73.51 of Part 73 of the Federal Aviation Regulations was republished in Advisory Circular AC 70–3 dated January 29, 1982.

List of Subjects in 14 CFR Part 73

Restricted areas.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, § 73.51 of Part 73 of the Federal Aviation Regulations (14 CFR Part 73) is amended as follows:

R–5107C White Sands Missile Range, NM [Amended]

Change designated altitude to read "9,000 feet MSL to unlimited."

R–5107H White Sands Missile Range, NM [New]

Boundaries. Beginning at lat. 34°17'00" N. long. 106°04'00" W.; to lat. 33°52'30" N., long. 106°04'00" W.; to lat. 33°52'30" N., long. 106°25'10" W.; to lat. 33°49'45" N., long. 106°25'10" W.; to lat. 33°49'45" N., long. 106°45'20" W.; to lat. 34°15'45" N., long. 106°40'30" W.; to lat. 34°17'00" N., long. 106°12'00" W.; to point of beginning.
Designated altitudes. Surface to and including 9,000 feet MSL.
Controlling Agency. Federal Aviation Administration, Albuquerque ARTCC.
Using Agency. Deputy for Air Force, White Sands Missile Range, NM 88002.
Time of use. As published in NOTAM's at least 12 hours in advance.

R–5107J White Sands Missile Range, NM [New]

Boundaries. Beginning at lat. 33°52'30" N., long. 106°04'00" W.; to lat. 33°44'45" N., long. 106°04'00" W.; thence along the south side of U.S. Highway 380; to lat. 33°49'30" N., long. 106°16'30" W.; to lat. 33°49'45" N., long. 106°25'10" W.; to lat. 33°52'30" N., long. 106°25'10" W.; to point of beginning.
Designated altitudes. Surface to and including 9,000 feet MSL.
Controlling Agency. Federal Aviation Administration, Albuquerque ARTCC.
Using Agency. Deputy for Air Force, White Sands Missile Range, NM 88002.
Time of use. Continuous Monday through Friday. Other times as activated by NOTAM.

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); and 14 CFR 11.69)

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

Issued in Washington, D.C., on August 27, 1982.

John W. Baier,

Manager, Airspace and Air Traffic Rules Division.

[FR Doc. 82-24187 Filed 9-3-82; 8:45 am]
BILLING CODE 4910-13-M

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14 CFR Part 73

[Airspace Docket No. 82-ANM-6]

Special Use Airspace; Alteration of Restricted Area, Fort Carson, CO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment combines Restricted Areas R–2601 and R–2602 and redesignates both Restricted Areas R–2601. The only change to this restricted area is the elimination of the boundary line between R–2601 and R–2602. This action eliminates the confusion experienced by pilots and controllers as to which area is activated.

DATES: Effective date—October 28, 1982. Comments must be received on or before October 7, 1982.

ADDRESSES: Send comments on the rule in triplicate to: Director, FAA Northwest Mountain Region, Attention: Chief, Air Traffic Division, Docket No. 82–ANM–6, Federal Aviation Administration, FAA Building, Boeing Field, Seattle, WA 98108.

The official docket may be examined in the Rules Docket, weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m. The FAA Rules Docket is located in the Office of the Chief Counsel, Room 916, 800 Independence Avenue, SW., Washington, D.C.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division.

FOR FURTHER INFORMATION CONTACT:

Lewis W. Still, Airspace Regulations and Obstructions Branch (AAT–230), Airspace and Air Traffic Rules Division, Air Traffic Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591, telephone: (202) 426–8783.

SUPPLEMENTARY INFORMATION:

Request for Comments on the Rule

Although this action is in the form of a final rule, which involves the combining of Restricted Areas R–2601 and R–2602 and thus, was not preceded by notice and public procedure, comments are invited on the rule. When the comment period ends, the FAA will use the comments submitted, together with other available information, to review the regulation. After the review, if the FAA finds that changes are appropriate, it will initiate rulemaking proceedings to amend the regulation. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in evaluating the effects of the rule and determining whether additional rulemaking is needed. Comments are specifically invited on the overall regulatory, aeronautical, economic, and energy aspects of the rule that might suggest the need to modify the rule.

The purpose of this amendment to § 73.26 of Part 73 of the Federal Aviation Regulations (14 CFR Part 73) is to consolidate Restricted Areas R–2601 and R–2602 as one single restricted area identified as R–2601. This action will simplify charting, aid navigation, improve flight planning, and end confusion to both pilots and controllers. Section 73.26 of Part 73 of the Federal Aviation Regulations was republished in Advisory Circular AC 70–3 dated January 29, 1982.

Since this amendment is minor in nature and does not change the current overall boundaries of these restricted areas and does not inflict additional burden on the public, I find that notice or public procedure under 5 U.S.C. 553(b) is contrary to the public interest and that good cause exists for making this amendment effective upon publication in the **Federal Register.**

List of Subjects in 14 CFR Part 73

VOR Federal airways.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, § 73.26 of Part 73 of the Federal Aviation Regulations (14 CFR

Part 73) is amended, effective 0901 GMT, October 28, 1982, as follows:

R-2601 Fort Carson, CO [Amended]

By deleting the text of "Boundaries." only and substitute the following:

"Boundaries. Beginning at lat. 38°38'19" N., long. 104°52'00" W.; to lat. 38°42'40" N., long. 104°49'04" W.; to lat. 38°41'20" N., long. 104°47'00" W.; to lat. 38°40'15" N., long. 104°46'20" W.; to lat. 38°40'00" N., long. 104°45'40" W.; to lat. 38°32'06" N., long. 104°45'00" W.; to lat. 38°25'35" N., long. 104°45'00" W.; to lat. 38°25'35" N., long. 104°49'00" W.; to lat. 38°26'10" N., long. 104°49'00" W.; to lat. 38°26'08" N., long. 104°57'30" W.; to lat. 38°29'35" N., long. 104°57'30" W.; thence to point of beginning."

R-2602 Fort Carson, CO [Revoked]

Title and text are revoked.

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); and 14 CFR 11.69)

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

Issued in Washington, D.C., on August 30, 1982.

B. Keith Potts,

Chief, Airspace and Air Traffic Rules Division.

[FR Doc. 82-24186 Filed 9-3-82; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 73

[Airspace Docket No. 82-AWP-12]

Special Use Airspace; Alteration of Restricted Area R-2311, Army Proving Grounds, Yuma, AZ

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment extends the time of designation of temporary Restricted Area R-2311, Army Proving Grounds, Yuma, AZ, from October 31, 1982, to July 31, 1983. Production delays beyond the control of the testing agency have prevented the completion of the scheduled test program during the allotted period. This action will allow completion of the test program and thus avoid possible cost overruns which could occur if the program is further delayed or terminated.

DATES: Effective date: October 31, 1982. Comments must be received on or before October 7, 1982.

ADDRESSES: Send comments on the rule in triplicate to: Director, FAA Western-Pacific Region, Attention: Manager, Air Traffic Division, Docket No. 82-AWP-12, Federal Aviation Administration, 15000 Aviation Boulevard, P.O. Box 92007, Worldway Postal Center, Los Angeles CA 90009.

The official docket may be examined in the Rules Docket, weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m. The FAA Rules Docket is located in the Office of the Chief Counsel, Room 916, 800 Independence Avenue, SW., Washington, D.C.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division.

FOR FURTHER INFORMATION CONTACT: Robert Maxey, Airspace Regulations and Obstructions Branch (AAT-230), Airspace and Air Traffic Rules Division, Air Traffic Service, Federal Aviation Administration, 800 Independence Avenue SW., Washington, D.C. 20591, telephone: (202) 426-8783.

SUPPLEMENTARY INFORMATION:

Request for Comments on the Rule

Although this action is in the form of a final rule, which involves the extension of the time of designation of Restricted Area R-2311, Yuma, AZ, from October 31, 1982, until July 31, 1983, and, thus, was not preceded by notice and public procedure, comments are invited on the rule. When the comment period ends, the FAA will use the comments submitted, together with other available information, to review the regulation. After the review, if the FAA finds that changes are appropriate, it will initiate rulemaking proceedings to amend the regulation. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in evaluating the effects of the rule and determining whether additional rulemaking is needed. Comments are specifically invited on the overall regulatory, aeronautical, economic and energy aspects of the rule that might suggest the need to modify the rule.

Send comments on environmental and land use aspects to: Mr. Willard C. Robinson, Chief, Facility Engineering Directorate, U.S. Army Proving Grounds, Yuma, AZ 85364, Telephone: (602) 328-2167.

The Rule

The purpose of this amendment to § 73.23 of Part 73 of the Federal Aviation Regulations (14 CFR Part 73) is to extend the time of designation of temporary Restricted Area R-2311, Army Proving Grounds, Yuma, AZ, to allow sufficient time for completion of the test program and thus avoid possible cost overruns which could occur if the program is further delayed or terminated. This action would add the period of October 31, 1982, through July 31, 1983, to the present time of designation. The restricted area is activated by NOTAM only when required for testing and, when not in use for test purposes, is available for civil use. Section 73.23 of Part 73 of the Federal Aviation Regulations was republished in Advisory Circular AC 70-3 dated January 29, 1982.

Under the circumstances presented, the FAA concludes that there is an immediate need for a regulation to extend the time of designation of temporary Restricted Area R-2311, Yuma, AZ. Therefore, I find that notice or public procedure under 5 U.S.C. 553(b) is contrary to the public interest.

List of Subjects in 14 CFR Part 73

Restricted areas.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, § 73.23 of Part 73 of the Federal Aviation Regulations (14 CFR Part 73) as amended, (47 FR 12789) (47 FR 16252) is further amended effective 0901 g.m.t., October 28, 1982, as follows:

R-2311 Army Proving Grounds, Yuma, AZ [Amended]

Under time of designation by deleting the words "October 1, 1980, through October 31, 1982" and substituting for them the words "October 1, 1980, through July 31, 1983."

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); and 14 CFR 11.69)

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

Issued in Washington, D.C., on August 30, 1982.

B. Keith Potts,

Manager, Airspace and Air Traffic Rules Division.

[FR Doc. 82-24185 Filed 9-3-82; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 73

[Airspace Docket No. 82-ANM-3]

Special Use Airspace; Designation of Restricted Area—Saylor Creek, ID

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment designates Restricted Area R-3202D, Saylor Creek, ID, located approximately 50 miles south of Boise, ID. R-3202D provides a safe environment for launching Pershing II missiles.

EFFECTIVE DATE: October 28, 1982.

FOR FURTHER INFORMATION CONTACT: Lewis W. Still, Airspace Regulations and Obstructions Branch (AAT-230), Airspace and Air Traffic Rules Division, Air Traffic Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591; telephone: (202) 426-8783.

SUPPLEMENTARY INFORMATION:

History

On May 13, 1982, the FAA proposed to amend Part 73 of the Federal Aviation Regulations (14 CFR Part 73) to designate new Restricted Area R-3202D, Saylor Creek, ID, for launching Pershing II missiles (47 FR 20620). This new launch location will be used to complete test requirements and test objectives. R-3202D will be activated only when a Pershing II missile is to be fired. Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No objections to the proposal were received. Except for editorial changes, this amendment is the same as that proposed in the notice. Section 73.32 of Part 73 of the Federal Aviation Regulations was republished in Advisory Circular AC 70-3 dated January 29, 1982.

The Rule

This amendment to Part 73 of the Federal Aviation Regulations designates Restricted Area R-3202D, Saylor Creek, ID. The restricted area provides a safe environment for test launching of Pershing II missiles.

List of Subjects in 14 CFR Part 73

Restricted area.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, § 73.32 of Part 73 of the Federal Aviation Regulations (14 CFR Part 73) is amended, effective 0901 GMT, October 28, 1982, as follows:

R-3202D Saylor Creek, ID [New]

Boundaries. Beginning at lat. 42°56'00" N., long. 116°13'20" W.; lat. 42°12'00" N., long. 115°10'40" W.; lat. 42°00'00" N., long. 115°30'30" W.; lat. 42°51'00" N., long. 116°21'00" W.; to point of beginning.

Designated Altitudes. Surface to unlimited.

Times of Designation. Intermittent, 24 hours in advance by NOTAM.

Controlling Agency. Federal Aviation Administration, Salt Lake City, ARTC Center.

Using Agency. Deputy for Air Force Armament Division, White Sands Missile Range, NM.

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); and 14 CFR 11.69)

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

Issued in Washington, D.C., on August 30, 1982.

B. Keith Potts,

Manager, Airspace and Air Traffic Rules Division.

[FR Doc. 82-24184 Filed 9-3-82; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 97

[Docket No. 23277; Amdt. No. 1224]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: An effective date for each SIAP is specified in the amendatory provisions.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, D.C. 20591;
2. The FAA Regional Office of the region in which the affected airport is located; or
3. The Flight Inspection Field Office which originated the SIAP.

For Purchase

Individual SIAP copies may be obtained from:

1. FAA Public Information Center (APA-430), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, D.C. 20591; or
2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription

Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendant of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

FOR FURTHER INFORMATION CONTACT: Donald K. Funai, Flight Procedures and Airspace Branch (AFO-730), Aircraft Programs Division, Office of Flight Operations, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591; telephone (202) 426-8277.

SUPPLEMENTARY INFORMATION: This amendment to Part 97 of the Federal Aviation Regulations (14 CFR Part 97) prescribes new, amended, suspended, or revoked Standard Instrument Approach Procedures (SIAPs). The complete regulatory description of each SIAP is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR Part 51, and § 97.20 of the Federal Aviation Regulations (FARs). The applicable FAA Forms are

identified as FAA Forms 8260–3, 8260–4 and 8260–5. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form document is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

This amendment to Part 97 is effective on the date of publication and contains separate SIAPs which have compliance dates stated as effective dates based on related changes in the National Airspace System or the application of new or revised criteria. Some SIAP amendments may have been previously issued by the FAA in a National Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP amendments may require making them effective in less than 30 days. For the remaining SIAPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Approach Procedures (TERPs). In developing these SIAPs, the TERPs criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs is unnecessary, impracticable, or contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

List of Subjects in 14 CFR Part 97

Approaches, Standard instrument.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, Part 97 of the Federal Aviation Regulations (14 CFR Part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 g.m.t. on the dates specified, as follows:

1. By amending Part 97.23 VOR-VOR/DME SIAPs identified as follows:

** * * Effective October 28, 1982*

Greensburg, IN—Greensburg-Decatur County, VOR-A, Original
Marion, IN—Marion Muni, VOR Rwy 4, Amdt. 9
Marion, IN—Marion Muni, VOR Rwy 15, Amdt. 6
Marion, IN—Marion Muni, VOR Rwy 22, Amdt. 12
Ruston, LA—Ruston Muni, VOR/DME Rwy 16, Orig.
Ruston, LA—Ruston Muni, VOR Rwy 34, Amdt. 2
Beverly, MA—Beverly Muni, VOR Rwy 16, Original
Beverly, MA—Beverly Muni, VOR Rwy 16, Amdt. 2, cancelled
Green Bay, WI—Austin Straubel Field, VOR Rwy 12, Amdt. 16
Green Bay, WI—Austin Straubel Field, VOR/DME or TACAN Rwy 36, Amdt. 2

** * * Effective October 14, 1982*

Fullerton, CA—Fullerton Muni, VOR-A, Amdt. 4
Santa Maria, CA—Santa Maria Public, VOR/DME-B, Amdt. 10, cancelled
Pompano Beach, FL—Pompano Beach Airpark, VOR Rwy 14, Amdt. 7
Danville, IL—Vermilion County, VOR Rwy 21, Amdt. 10
Danville, IL—Vermilion County, VOR/DME Rwy 3, Amdt. 8
Richmond, KY—Madison, VOR/DME Rwy 18, Amdt. 1
Westminster, MD—Carroll County, VOR Rwy 34, Amdt. 2
Bay City, MI—James Clements Muni, VOR-A, Amdt. 7
Cross Keys, NJ—Cross Keys, VOR Rwy 9, Amdt.1
Sebring, OH—Tri-City, VOR Rwy 17, Amdt. 2
Norman, OK—Max Westheimer, VOL/DME Rwy 3, Original
Westerly, RI—Westerly State, VOR-A, Amdt. 8
Borger, TX—Hutchinson County, VOR Rwy 17, Amdt. 5
Dallas, TX—Redbird, VOR Rwy 13, Amdt. 7
El Campo, TX—El Campo Metro Airport, Inc., VOR/DME Rwy 17, Amdt. 1
El Campo, TX—El Campo Metro Airport, Inc., VOR/DME Rwy 35, Amdt. 2
Palacios, TX—Palacios Muni, VOR Rwy 13, Amdt. 8

** * * Effective September 30, 1982*

Waterloo, IA—Waterloo Muni, VOR Rwy 6, Amdt. 1
Waterloo, IA—Waterloo Muni, VOR Rwy 12, Amdt. 8
Waterloo, IA—Waterloo Muni, VOR Rwy 18, Amdt. 6
Waterloo, IA—Waterloo Muni, VOR Rwy 24, Amdt. 14
Waterloo, IA—Waterloo Muni, VOR Rwy/DME 30, Amdt. 13
Waterloo, IA—Waterloo Muni, VOR Rwy 36, Amdt. 15
Flint, MI—Bishop, VOR Rwy 9, Amdt. 21
Flint, MI—Bishop, VOR Rwy 18, Amdt. 14
Flint, MI—Bishop, VOR Rwy 27, Amdt. 17
Flint, MI—Bishop, VOR Rwy 36, Amdt. 11
Bismarck, ND—Bismarck Muni, VOR-A, Amdt. 18
Moses Lake, WA—Grant County, VOR Rwy 32R, Amdt. 17

** * * Effective August 25, 1982*

Burbank, CA—Burbank-Glendale-Pasadena, VOR Rwy 7, Amdt. 5

** * * Effective August 12, 1982*

Mountain Home, AR—Baxter County Regional, VOR-A, Amdt. 5

2. By amending Part 97.25 SDF-LOC-LDA -SIAPs identified as follows:

** * * Effective October 28, 1982*

Green Bay, WI—Austin Straubel Field, LOC BC Rwy 24L, Amdt. 13
Milwaukee, WI—General Mitchel Field, LOC Rwy 25L, Original
Milwaukee, WI—General Mitchel Field, LOC Rwy, Amdt. 6, cancelled

** * * Effective October 14, 1982*

Winder, GA—Winder, LOC Rwy 31, Amdt. 4
Cleveland, OH—Burke Lakefront, LOC Rwy 24R, Amdt. 6
Westerly, RI—Westerly State, LOC Rwy 7, Amdt. 1

** * * Effective September 30, 1982*

Waterloo, IA—Winder, LOC BC Rwy 30, Amdt. 7
Bismarch, ND—Bismarck Muni, LOC/DME BC Rwy 13, Amdt. 6, cancelled
Dayton, OH—Dayton General Arpt South, LOC/DME Rwy 20, Original

3. By amending Part 97.27 NDB/ADF SIAPs identified as follows:

** * * Effective October 28, 1982*

Drummond Island, MI—Drummond Island, NDB-A, Original
Green Bay, WI—Austin Straubel Field, NDB Rwy 6R, Amdt. 14

** * * Effective October 14, 1982*

Winder, GA—Winder, NDB Rwy 31, Amdt. 4
Campbellsville, KY—Taylor County, NDB Rwy 23, Amdt. 1
Cleveland, OH—Burke Lakefront, NDB Rwy 24R, Amdt. 5
El Campo, TX—El Campo Metro Airport Inc., NDB Rwy 35, Amdt. 1
Farmville, VA—Farmville Muni, NDB Rwy 3, Amdt. 3
Phillips, WI—Price County, NDB-A, Amdt. 1
Rice Lake, WI—Rice Lake Muni, NDB Rwy 36, Amdt. 2

** * * Effective September 30, 1982*

Waterloo, IA—Waterloo Muni, NDB Rwy 12, Amdt. 7
Flint, MI— Bishop, NDB Rwy 9, Amdt. 21
Bismark, ND—Bismarck Muni, NDB Rwy 31, Amdt. 29
Moses Lake, WA—Grant County, NDB Rwy 32R, Amdt. 14

* * * *Effective August 26, 1982*

Nashville, TN—Nashville Metropolitan, NDB Rwy 2L, Amdt. 3
Nashville, TN—Nashville Metropolitan, NDB Rwy 2R, Amdt. 3

* * * *Effective August 20, 1982*

Marysville, KS—Marysville Muni, NDB Rwy 33, Amdt. 1

4. By amending Part 97.29 ILS–MLS SIAPs identified as follows:

* * * *Effective October 28, 1982*

Marion, IN—Marion Muni, ILS Rwy 4, Amdt. 3
Green Bay, WI—Austin Straubel Field, ILS Rwy 6R, Amdt. 15
Green Bay, WI—Austin Straubel Field, ILS Rwy 36, Amdt. 2

* * * *Effective October 14, 1982*

Danville, IL—Vermilion County, ILS Rwy 21, Amdt. 2
Waco, TX—TSTI-Waco, ILS Rwy 17L, Amdt. 9

* * * *Effective September 30, 1982*

Waterloo, IA—Waterloo Muni, ILS Rwy 12, Amdt. 5
Flint, MI—Bishop, ILS Rwy 9, Amdt. 15
Flint, MI—Bishop, ILS Rwy 27, Amdt. 1
Bismarck, ND—Bismarck Muni, ILS Rwy 13, Original
Bismarck, ND—Bismarck Muni, ILS Rwy 31, Amdt. 30
Moses Lake, WA—Grant County, ILS Rwy 32R, Amdt 16

* * * *Effective August 26, 1982*

Nashville, TN—Nashville Metropolitan, ILS Rwy 2L, Amdt. 3

* * * *Effective August 25, 1982*

Burbank, CA—Burbank-Glendale-Pasadena, ILS Rwy 7, Amdt. 31

* * * *Effective August 16, 1982*

Lincoln, NE—Lincoln Muni, ILS Rwy 17R, Amdt. 1

5. By amending Part 97.31 RADAR SIAPs identified as follows:

* * * *Effective October 14, 1982*

Chicago, IL—Chicago-Midway, RADAR-1, Amdt. 23, cancelled
Mansfield, OH—Mansfield Lahm Muni, RADAR-1, Original

6. By amending Part 97.33 RNAV SIAPs identified as follows:

* * * *Effective October 28, 1982*

Grand Ledge, MI—Abrams Muni, RNAV Rwy 27, Original

* * * *Effective October 14, 1982*

Danville, IL—Vermilion County, RNAV Rwy 34, Amdt. 1
Richmond, KY—Madison, RNAV Rwy 36, Amdt. 1
Pottstown, PA—Pottstown Limerick, RNAV Rwy 28, Original

* * * *Effective September 30, 1982*

Waterloo, IA—Waterloo Muni, RNAV Rwy 6, Amdt. 4

(Secs. 307, 313(a), 601, and 1110, Federal Aviation Act of 1958 (49 U.S.C. 1348, 1354(a), 1421, and 1510); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); and 14 CFR 11.49(b)(3))

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

Issued in Washington, D.C. on August 27, 1982.

John M. Howard,

Acting Manager, Aircraft Programs Division.

Note.—The incorporation by reference in the preceding document was approved by the Director of the Federal Register on December 31, 1982.

[FR Doc. 82-24178 Filed 9-3-82; 8:45 am]
BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 203

[Docket Nos. 79N-0186 and 80N-0370]

Prescription Drug Products; Revocation of Patient Package Insert Requirements

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revoking its final rule establishing requirements for the preparation and distribution of patient package inserts (PPI's) for prescription drug products for human use. This action is taken because the agency has determined that a mandatory pilot PPI program is unjustifiable, and that it is now preferable to encourage alternative patient information efforts. The agency believes that cooperation with health professionals and others in both the public and private sectors and reliance upon expanding privately sponsored initiatives in patient education should serve to provide patients with needed information about prescription drugs.

EFFECTIVE DATE: September 7, 1982.

FOR FURTHER INFORMATION CONTACT: Eileen R. Hodkinson, National Center for Drugs and Biologics (HFD-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6490.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 17, 1982 (47 FR 7200) and reprinted February 19, 1982 (47 FR 7458), FDA proposed to revoke its final rule issued September 12, 1980 (45 FR 60754) establishing requirements for the preparation and distribution of PPI's for prescription drug products for human use. The regulation would have required leaflets to be given to patients when prescription drugs were dispensed. Manufacturers would have been obligated to prepare the leaflets and provide them to dispensers, who then would have been obligated to provide them to patients with each new prescription dispensed. The final rule established a pilot program that would have applied to 10 classes of drug products for 3 years. This pilot program was intended to provide more definitive data about the costs and benefits of PPI's.

In the proposal to revoke the final rule, the agency explained that the Commissioner of Food and Drugs had carefully reviewed the entire administrative record of the patient package insert program, the results of a 3-year study conducted under contract for the agency by the Rand Corp. on the effects of prototype PPI's, and information presented at public meetings FDA held on September 30 and October 1, 1981, to solicit views on PPI's.

Based on this review, the proposal noted, the agency believed it could no longer justify the PPI pilot program. First, the agency had been persuaded that the program would not likely have achieved a principal objective, that of enabling FDA to determine whether a mandatory, pharmacy-oriented, drug leaflet program was the most practical way of increasing patient knowledge about prescription drugs. Secondly, the agency pointed out that, since the promulgation of the pilot program, the private sector had provided new initiatives in patient information and was currently developing others. The various private sector initiatives, if effectively implemented, were considered likely to provide consumers with the same type of information about prescription drugs as would have been provided by the agency's pilot program. Moreover, as these initiatives would not be limited to 10 drugs or drug classes, or to pharmacy-distributed leaflets, it was believed possible that they would be capable of providing more information than the agency's pilot program. Also, the agency stressed that cooperation with the private sector would encourage

experimentation with diverse systems for delivering patient information, thereby promoting innovation in delivery systems.

The proposal discussed other aspects of the mandatory program that contributed to the Commissioner's decision. It cited the limited value of providing patient information only at the time of dispensing, the cost of the mandatory program, the strong disagreement about the design and value of the program on the part of the health professionals who would have to implement it, and the need for Federal regulations to be both necessary and cost effective. Based on these factors, the agency tentatively decided to withdraw its mandatory pilot PPI regulation following public comment.

The agency received 602 comments on the proposal. FDA received these comments from trade associations, individual firms involved in the manufacture and distribution of prescription drug products, organizations of health care professionals, individual physicians, pharmacists, and other health care professionals, organized consumer groups, individual consumers, and others. On the basis of the information in the proposal, a review of the comments, and other information received by the agency through its Committee on Patient Education (COPE), the agency believes that encouraging diverse private sector efforts for providing consumers with adequate prescription drug information is now preferable to implementing a single, mandated Federal program.

Most of the comments came from individuals who expressed support for or opposition to the concept of patient labeling. These comments did not, however, address the agency's rationale as set forth in the proposal to revoke the regulation. Most comments from physicians, pharmacists, and other health professionals supported revocation of the regulation, although most comments from consumers were opposed to the revocation. Many comments merely reiterated opinions and views about the value of providing patients with health information, little of which the agency disputes. Because the agency analyzed these issues at length in the preambles to both the proposal and the final rule establishing these PPI requirements (44 FR 40022-40025, July 6, 1979 and 45 FR 60754–60784, September 12, 1980), they will be discussed only briefly here. Comments received on the agency's rationale for proposing to revoke the regulation will be discussed at greater length later in this preamble.

General Comments

1. Most individual consumers and consumer organizations expressed opposition to the proposal to revoke the PPI regulation based on their belief that patients have a right to know about the prescription drugs they are taking, and that health professionals currently fail to provide this information. Further, they expressed the view that patients can use prescription drug products safely and effectively only if they are informed of their benefits, risks, and proper uses. They contended that increasing patient awareness of the importance of taking a drug properly will, in fact, maximize the efficacy of prescribed treatment. They referred to studies assessing PPI's to show that such leaflets lead to significant improvement in patient knowledge. Most individual consumers cited personal adverse experiences from being uninformed about using drugs.

Several consumer organizations referred to surveys that confirmed their belief that patients are receiving little or no information from their physicians or pharmacists about prescription drugs. The claimed that patients are not getting adequate information because physicians do not have time to explain important details about drugs, are not themselves knowledgeable about all the side effects of the drugs, or do not believe patients need to be informed about prescription drugs. These comments further noted that the agency, in the preamble to the final regulations establishing the PPI pilot program, recognized that health professionals were not providing sufficient information to patients about the drugs they prescribe and relied on this fact to justify the PPI program. These comments argued that the agency failed to present any basis for concluding that professionals were now providing adequate information or that, if they are not, it is no longer necessary to correct the deficiency by means of mandatory PPI's.

The agency has repeatedly affirmed that patients have both a right and a need to know about the drugs they use. Further, the agency acknowledges that consumers have not traditionally had available to them adequate information about prescription drug use. The agency believes, however, that private sector efforts to provide consumers with drug educational materials have increased and, therefore, that the mandatory Federal program is not now needed and may have a restrictive effect on private sector efforts. Thus, in the agency's view, the planned Federal program, if now implemented, would likely produce results contrary to, rather than consistent with, those sought by the comments and by the agency. (Some of these private sector initiatives are described in more detail later in this preamble.)

2. Most consumers believed that written information in the form of a PPI is the most effective method to reinforce information transfer because patients can refer to it later. Many comments pointed out that written information is especially important for elderly patients, who frequently do not pick up their prescriptions in person and would not, therefore, benefit by the various voluntary systems that might be located in the pharmacy. Several comments contended that it is unreasonable to expect consumers to purchase books containing prescription drug information because they are too costly and labeling information for individual drugs is likely to change over time, thus requiring the patient to purchase a revised book periodically. Further, comments stressed that only written information adequately informs patients, because patients who are ill and consulting with their physicians generally are reluctant to engage in a discussion about the side effects of the drugs being prescribed. The comment suggested that only later can the patient study the information to learn how best to make effective use of the drug.

The agency agrees with the comments that written information, which the patient can retain and refer to later, is very useful to most patients. It stresses, however, that most current and planned private sector programs will provide this type of written information, to be available either at the pharmacy in the form of pamphlets, tear-off sheets, etc., or directly from the prescribing physician. With respect to special problems of the elderly, private sector efforts appear capable of offering information systems at least as effective as that which the mandatory program might have provided. A mail-order pharmacy service operated by a national organization of retired persons has developed leaflets that are similar to the originally mandated PPI's and that will be mailed with the drugs to patients. Unlike the mandated program, however, this program is able not only to emphasize drugs used mostly by the elderly, but to tailor the information provided in the leaflets to the particular needs of the elderly. These results were not achievable by the 10-drug pilot program, where drugs chosen included many not frequently used by the elderly, and where information had to be directed at a wider audience. It should be noted that FDA actively participated

in the preparation of the leaflets to be used in this private program, reflecting an agency commitment to work with the private sector to provide voluntary programs with high likelihood of success.

Also, as the proposal states, FDA is aware of a planned effort by the American Medical Association to supply physicians with written drug information that can be given to the patient at the time of prescribing. FDA views this initiative, which would likely not have been undertaken if the mandatory program had remained in effect, as embodying all of the advantages of the mandatory program plus the additional advantage that the information will be provided by the physician. Moreover, it will be provided at the time of prescribing, where the patient can, if he or she wishes, discuss the information more fully with the physician. In some instances, this may be the optimal time for patients to receive such information.

The agency is aware of approximately 25 commercially available books that provide readily understandable information about numerous prescription drugs. FDA disagrees with the comments that claimed these books are too costly for consumers. Virtually all of these publications are available in paperback at a reasonable price. Moreover, such books have the recognizable benefit of providing drug information on many drugs in a single retainable volume, which the patient can conveniently refer to with each refill of a prescription. Under the agency's mandatory program, information would have been limited to 10 drugs and would have been given to the patient only when the prescription was initially filled.

Finally, the agency views as exaggerated the criticism that such volumes may have to be repurchased because of recurring changes in information. Although significant new information about individual drugs is developed from time to time, the overwhelming body of drug use information remains constant for most drugs over long periods of time. Such significant new information will continue to be brought to the attention of health professionals under traditional methods such as professional labeling changes. On rare occasions, the agency may require patient labeling such as that now in effect for estrogens and related products. Available sources of patient information will include forms less costly than books, such as leaflets, so that patients will be able to obtain significant new information at minimal cost.

3. Several comments misunderstood the proposal and commented as though the agency was about to establish a program to provide drug information to consumers and was asking for general comments on this concept. Therefore, the agency received many comments that did not discuss the pilot program but instead suggested various ways to educate consumers. Although most of these suggestions were already heard at public meetings held before the agency proposed to establish the PPI regulations and were analyzed in the preamble to the proposed rule (44) FR 40022; July 6, 1979), a few comments presented some new ideas.

a. One comment suggested that FDA should require manufacturers to prepare and distribute a limited number of leaflets and that a notice of availability of the leaflet should be printed on each prescription label so consumers who want information would have adequate instructions about how to obtain it from the pharmacist.

The agency believes that requiring manufacturers to print leaflets whose availability would be indicated on all prescription drug labels differs little from the obligations imposed on the manufacturers, distributors, and dispensers of prescription drugs by the mandatory PPI pilot program. Moreover, fewer patients would acutally receive patient information under the plan proposed by the comment, as it would require patients to ask for information before it was provided to them. The agency notes that under many of the major patient information programs that have been implemented, or that will be implemented soon, patients will receive written information without requesting it.

b. Another comment stated that, instead of a Federally mandated PPI program, individual States should require physicians to advise patients not only about the use of drugs but about their side effects. Under this plan, pharmacists would be required to verify with purchasers that a physician had explained the drug's reactions and its uses to the patient. The comments stated that this plan could be enforced by a State-controlled committee or board and physicians not complying could be penalized. The agency has no authority to require States to take action to impose such requirements on physicians and pharmacists.

c. Another comment suggested requiring pharmacists to dispense the "most lethal" drugs in red vials for instant warning.

The agency believes that identifying certain drugs by placing them in red or other special vials cannot serve as a substitute for patient information. The purpose of patient information is to increase patient knowledge about prescription drugs, and thereby promote their optimal use, not simply to pinpoint possible hazards, the function that would be served by special vials. The suggestion for special vials for the "most lethal" drugs, moreover, implies in an overly broad manner that some drugs are more hazardous than others. Such an assumption ignores that as part of the approval process to which virtually all prescription drugs are subject, risks are weighed against potential benefits, and not considered as absolutes. Patient information that is heavily "warning" oriented, therefore, might undermine the more balanced approach to informing patients about drug therapy to which both FDA's pilot program and the various private sector efforts have been directed.

4. Some comments from individual consumers did not understand the content of the final PPI regulation, and thus were not pertinent. Some of these comments mistakenly interpreted the proposal to mean that by revoking this regulation, the agency would no longer be requiring labeling for OTC drug products; some comments expressed concern that physician labeling would no longer be available to patients upon request; and some expressed the belief that private-sector patient education systems now in use in many pharmacies were mandatory and would no longer be available. Still other comments questioned whether the revocation of the general PPI regulations would affect the requirements for PPI's to be distributed with oral contraceptives, certain intrauterine devices, estrogens, and progestational drug products. A few comments stated erroneously that drug manufacturers currently provide PPI's for all drugs but pharmacists routinely throw them out. They argued that the pharmacist should be required to leave the insert that the manufacturer now supplies for each drug in the package with each drug when it is dispensed instead of forcing patients to request it.

The agency emphasizes that the revocation of this regulation will not affect the labeling of over-the-counter drug products or any existing requirements for professional labeling. Further, since the patient education systems already in use by many pharmacies are voluntary private sector programs, they also will not be affected by the revocation of the agency's mandatory program. Similarly,

revocation of the general PPI regulation will not affect the agency's authority to require individual PPI's through notice and comment rulemaking and will not revoke the existing requirements for PPI's to be distributed with the drugs mentioned by the comment.

In response to the argument that the pharmacists should leave the PPI now supplied by the manufacturer in the package with each drug, the agency points out that these comments are referring to the official professional labeling, not to PPI's. Professional labeling is the only information now supplied with prescription drugs (except for drugs subject to particular PPI requirements) and is written in technical language that is directed to health care professionals. This information is not intended for the ultimate consumers of the drug products. In fact, only one copy of this labeling usually accompanies the shelf package from which many prescriptions are filled. Nonetheless, consumers may request copies of this labeling from pharmacists, and FDA has traditionally encouraged pharmacists and other health care professionals to make it available.

Rationale for Agency Decision

5. Several comments from consumer organizations questioned the statement in the proposal that the pilot program would "likely not show whether the program's ultimate goal—improving patient knowledge about prescription drugs—could be achieved by other initiatives, including those sponsored by the private sector, or whether other methods might produce even better results." One comment contended that because the pilot program was only testing one method of disseminating drug information, obviously it could not be expected to produce sufficient data on all other methods to determine whether they "might produce even better results." A few comments also criticized the statement attributed to those who opposed the program that it lacked "well-documented evidence of a positive impact on health care" as being illogical since the program had not even been implemented. Most of these comments expressed the view that only by going forward with the pilot program and comparing it with the private sector programs, could the agency gather sufficient data to identify those programs that have a positive impact on health care and that produce the best results.

Although the pilot program did provide for the use and evaluation of alternative patient education systems, FDA believes its orientation toward pharmacy-distributed leaflets became inherently self-limiting in terms of alternatives that might have been tested. In the limited period between issuance of the rule and the entrance of the interim stay of its effectiveness on April 28, 1981, only pharmacy-oriented alternatives had been suggested to FDA, none offering greater information exposure to patients than the mandatory program.

Even with these alternatives, however, the mandatory program would have been substantially limited in the type of information it might have produced. First, it was limited to no more than 10 drugs for a 3-year period. Second, potential noncompliance also presented a significant problem.

The most limiting aspect of the program, however, appears to stem from its mandatory nature. Its existence seems to have been responsible for the lack of some private sector initiatives, initiatives which have grown measurably since the agency indicated that withdrawal of the rule was contemplated. Several groups have initiated programs of varying types, only some of which resemble the PPI model. They are described in greater detail below. Even those that do resemble the PPI model, however, will provide information on more than the 10 drugs covered by the FDA program.

The scope and diversity of the private sector efforts have highlighted the limited potential of the 10-drug mandatory pilot program as a test of the utility of PPI's. The pilot program might have measured the technical viability of the PPI program, but it could not have measured the extent to which PPI's would provide patient awareness greater than that provided by other methods. That is, the pilot program would not have provided comparisons with those systems not yet attempted because of the preemptive effect of the Federally mandated program. In addition, given the similarity between at least one voluntary effort and the agency's PPI program, that of the American Association of Retired Persons (though the latter will include more drugs than the 10 subject to the Federal program), and the continued existence of mandatory PPI requirements for estrogens and related drugs, there will still be an opportunity for comparative evaluations to be made.

The argument raised by health professionals that a PPI program required well-documented evidence of a positive impact on health care prior to enactment was rejected by the agency in implementing the pilot program, and is not relied on here as justification for revocation of the progam. Rather, it simply reiterates one of the reasons health professionals failed to support the program, a factor on which the agency does rely.

6. Several comments criticized the agency for proposing to revoke the PPI program based on the "new initiatives in patient information programs that have been undertaken by the private sector," without even describing them specifically. Most of these comments further stated they were not aware of any new private sector patient information programs and were especially critical of the statement in the proposal that private sector initiatives, if effectively implemented, could provide consumers with more information than may have been possible under the agency's pilot program. They contended that these voluntary efforts have been tried and have been proven to be inadequate. A few such comments referred to recent studies on both mandatory and voluntary PPI's currently in use and they argued that the results of these studies confirm that even extensively promoted, industry sponsored voluntary PPI's for Darvon have reached only 5 to 7 percent of their targeted population, whereas mandatory PPI's for oral contraceptives have reached over 93 percent of people using them.

The proposal did describe at least one significant private sector initiative—a plan (sponsored by the American Medical Association (AMA)) to supply physicians with drug information which would be given to patients at the time of prescribing. The agency is also aware of several other new programs in patient drug education and has no reason to doubt the private sector's public commitment to continue developing and implementing these programs.

FDA does not agree that these efforts will necessarily suffer the same low compliance rates as current "voluntary" programs. What is significantly different is that these new programs have been devised and will be implemented by the party responsible for providing the patient information (in the case of AMA, by an organization of which the provider is a member). Earlier voluntary PPI's, such as the one for Darvon, were initiatives only of manufacturers, not providers. The agency believes it may reasonably assume that compliance will be higher in programs that have been created and implemented by the party who will actually provide the patient with information.

The comparison drawn by the comment to compliance rates with oral contraceptives is invalid. These products, unlike virtually all others

subject to PPI requirements, are packaged in "unit-of-use" containers, virtually assuring that each patient receives a patient brochure with the drug. Other drugs subject to mandatory PPI requirements, those packaged in bulk for pharmacy dispensing which required the pharmacist to dispense independently a PPI with each prescription, have been found, on the basis of FDA's data, to produce much lower compliance rates, calling into question the conclusion that a mandatory program will necessarily achieve the results suggested by the comment.

As information becomes available to the agency on various private sector initiatives, it is placed on file with FDA's Dockets Management Branch, in the file on The Committee on Patient Education. Some of the private sector initiatives that are in effect, or being planned, to provide patients with information about prescription drugs include:

a. The American Medical Association has long been involved in programs aimed at educating patients about the drugs they use. Beginning in late 1982, AMA will launch a major new program in that area, Patient Medication Instructions (PMI's)—drug information leaflets to be handed out by physicians at the time of prescribing. These leaflets will be supplied to physicians by AMA, and by 1984 will cover approximately 200 commonly prescribed drugs.

b. The American Society of Hospital Pharmacists (ASHP) has designed several publications to help both hospital and retail pharmacists provide medication information for hospitalized patients, and has developed audio-visual presentations to provide patients with information about specific drugs. This year, ASHP has published the "Consumer Drug Digest," a book for consumers about prescription drugs which is available at book stores and offered by four national book clubs.

c. The United States Pharmacopeial Convention, Inc. (USP) produces its "USP Dispensing Information," containing information for physicians on prescription drugs. Using the same information, USP has now begun offering for sale to consumers several publications, including "The Physicians' and Pharmacists' Guide to Your Medicines," "About Your Medicines," "About Your High Blood Pressure Medicines," and others. Spanish translations are available for many of these publications. The USP had also developed other products aimed at providing patients and health care professionals with post-prescription information, such as newsletters, brochures, and posters, and currently is pursuing the possibility of providing patient information through cable television programs.

d. The Retired Persons Services, Inc., a pharmacy service of the American Association of Retired Persons, has been selling books about medications to its mail-order pharmacy service customers. The newest of its efforts, package inserts provided directly with new prescriptions filled by its mail-order pharmacy service, has already begun for 5 drugs, and will eventually encompass 75 to 90 drugs or drug classes. FDA participated in the preparation of the inserts used in this program.

e. Biomedical Information, Inc., a New York-based medical publisher, provides physicians with free copies of its "Compendium of Drug Therapy," a compilation of medical information about prescription drugs. This year Doubleday, Inc. has begun selling a layman's version of this compilation directly to consumers. Also, in the final stages of development is a new companion piece to the "Compendium of Drug Therapy," a "Compendium of Patient Information" that will contain tear-out sheets about specific diseases for physicians to give to patients and will provide sufficient space for physicians to write information about drugs being prescribed.

f. Many of the nation's retail pharmacies now provide their customers with free patient information, in the form of pamphlets, posters, and books. One supplier of such material alone provides over 3,000 pharmacies with its "Patient Guide to Prescription Product Information," a loose-leaf book containing patient information on drugs that is intended to be attached to the pharmacy counter.

7. One consumer group argued that trying to provide large-scale patient information through a variety of voluntary efforts would only result in chaos. The comment contended that only a uniform, mandatory program could assure that the majority of people using prescription drugs would get accurate and complete drug information. The comment suggested that under a voluntary system the pharmacist would have difficulty choosing from a myriad of patient information available in a variety of formats and would be overwhelmed by letters, catalogs, and brochures describing the latest patient education systems. Also, the comment pointed out that the voluntary educational materials sent to pharmacists by drug manufacturers would probably be in a variety of formats. One manufacturer might send a binder, another might send tear-off sheets, and yet another might send a brochure or a folded insert. The comment claimed that the pharmacy shelf space would be so rapidly consumed with such a variety of offerings that even a pharmacist who intends to educate the consumer would be confused.

The agency disagrees strongly that a variety of systems will be chaotic for pharmacists or patients. As noted in the response to the previous comment, drug manufacturers, organizations of health care professionals, and consumer groups have begun experimenting with a variety of methods for conveying drug information to consumers, including leaflets and newsletters mailed to individual members, commercially available books, films, telephone systems, and physician-distributed information. Rather than causing chaos, the agency views this competition as beneficial to both pharmacists and patients because it should produce more information on more drugs for a greater number of audiences, and allow health care professionals to use systems suitable for their patients' needs. Further, the agency believes such competition reflects a genuine interest on the part of participating groups to provide worthwhile and useful patient information to consumers, a view substantiated by the quality of patient information now being developed. FDA believes that pharmacists, highly trained and skilled professionals, will have no difficulty dealing with more than one patient information system and the comment provides no reason to believe otherwise.

8. Several comments expressed the belief that under a voluntary system there would be inconsistencies in the amount of information presented to the patient and that only a random audience would receive it. For example, one comment pointed out that under a physician-distributed patient information program, only physicians who have the time and inclination to educate patients about the drugs they prescribe will do so, while others will not bother. Also, the comment argued that if a physician is using written materials, proposed and prepared by the manufacturer in a voluntary system, the materials would lack completeness and balance. The comment stated that a manufacturer who wants to maximize sales and profits could not be expected to highlight the negative side effects associated with the use of a product.

The agency acknowledges that there may be differences in the content of information presented to patients under the various systems, but does not view

these differences as necessarily disadvantageous. Patients will not have to rely solely on a single sheet of paper for all the information about the proper use of each drug prescribed because they will have access to this type of information from numerous sources. Further, information can be targeted to particular populations who might not benefit from general-purpose materials, e.g., the elderly (as contemplated by one private initiative), children (or their parents), the blind, and non-English-speaking groups. The agency believes, therefore, that the competitive nature of the marketplace will encourage the development of many systems able to meet varying consumer needs.

Given the recent growth of private sector efforts, the agency believes it too speculative now to conclude that health care professionals will not bother to distribute materials and that, therefore, only a random audience will receive information. During the past year, in contrast to earlier years, the agency has seen enthusiastic support for patient education on the part of the entire health care community. Moreover, while particular pharmacists or physicians might be reluctant to give patients drug information, the availability of numerous systems provides patients with more opportunity to obtain this information on their own. The comments overlook the fact that under the agency's mandated pilot program only a small part of the prescription drug-using population would have been reached because PPI's were required to be dispensed with only 10 classes of drugs, and then only when the prescription was initially filled.

Regarding the comment that physician-distributed information will be prepared by drug manufacturers and be promotional in nature, manufacturers have traditionally borne responsibility for preparing professional drug labeling which, of necessity, includes both positive and negative aspects of drug use. Moreover, insofar as patient labeling is prepared by drug manufacturers, FDA can exercise regulatory supervision to assure balance in content. With respect to the one program intended for physician distribution, that sponsored by AMA, the material has not been prepared by manufacturers, but is based on AMA's own guidelines together with material from the USP.

9. Several comments stated that most voluntary drug information programs have arisen only as a direct result of FDA pressure and argued that if the agency revokes the PPI program, the promise of voluntary alternative programs will fade and the programs will never materialize. They claimed that for years physicians, pharmacists, and manufacturers have been encouraged to educate patients about prescription drugs but they have chosen not to do so.

The agency disagrees that patient information systems will never be implemented if this regulation is revoked. To the contrary, FDA believes that revocation of the final PPI regulation will encourage cooperative and private sector experimentation with new forms of patient education. Recently, more drug manufacturers, health care associations, chain drug stores, and trade associations have become aware of the needs of patients taking prescription drugs and have generally agreed that more and better prescription drug information should be available to patients. Many professional organizations have encouraged their members to provide information to patients, and numerous providers of health care have publicly pledged their commitment to work with FDA's Committee on Patient Education.

In March 1982, representatives of AMA met with FDA's Committee on Patient Education and announced a timetable for instituting the AMA-PMI program in patient education and also announced that AMA is preparing a public relations campaign to generate public awareness of the PMI's and to encourage the public to seek and use them.

A consortium of major health professional, trade, and consumer groups are forming a National Council on Patient Information and Education. The Council will encourage health professionals to provide more information to patients about prescription drugs, and will sponsor a national advertising campaign that will encourage patients to seek more information about drug use. A Steering Committee, formed to organize the Council, has met twice and has appointed several specific committees to consider activities such as program development and Council membership. The full Council's first meeting will be held before the end of 1982; membership is open to all interested organizations that are involved in disseminating information to patients about prescription drugs, including professional societies, drug manufacturers and their associations, and consumer groups. The Ciba-Geigy Corp. has offered $1 million toward funding and staffing the Council.

Given the resources that have been invested in these and other programs by the private sector in developing alternatives to mandatory PPI's the agency sees no reason to believe that they will fade following revocation of the rule. Although FDA cannot guarantee that all of these programs will ultimately be successful, it is reasonable for the agency to conclude, on the basis of their current development and the statements as to future plans by their sponsors, that these privately sponsored voluntary initiatives represent viable, promising alternatives.

10. A few comments suggested that if the agency revokes the PPI pilot program, it should have a plan to evaluate the mass of alternative efforts. They stressed that this plan should be discussed in the final rule and the agency should also state what action it will take if efforts diminish.

FDA is conducting surveys of consumers and health care professionals to evaluate the availability of adequate patient information on a nationwide basis. The agency will assess this information over the next several years while encouraging the sponsors of these programs to conduct evaluations of their efforts. These evaluations should help to promote the best designs and most effective programs. The agency is interested in collecting and sharing the results of these evaluations of individual programs, but does not plan to conduct a Federally sponsored evaluation of all patient information efforts. Consumers and health professionals using the various programs will probably render the most important evaluation of the programs by their acceptance and demand for the preferred approaches.

The agency believes it would be counterproductive to the development of private initiatives for it to develop and publicly announce a course of action it might take should these private initiatives not materialize. Nonetheless, FDA fully intends to play an active role in encouraging private sector initiatives in patient education through its Committee on Patient Education and its association with the National Council on Patient Information and Education, and by cooperating with sponsors of various private sector initiatives in developing individual patient education efforts.

11. Several comments contended that the agency has no basis for determining that the regulation would not have been cost effective and argued that the pilot program would have provided information on the cost and effectiveness of mandatory PPI's. Most consumers argued that the costs associated with the program are small compared to the cost in dollars and human suffering associated with

uninformed drug use, inappropriate prescribing, adverse reactions, and failure of health professionals to instruct patients on how to take drugs to maximize their benefits. Consumer organizations stated that surveys on patient package inserts suggest that consumer benefits from PPI's justify any increased costs and that consumers have consistently demonstrated a willingness to pay for this information.

The agency believes that the cooperative activities and efforts of the private sector described above would benefit consumers by providing needed information about prescription drugs. In the proposal, the agency did not state conclusively that the PPI program was not cost effective, but rather that the program, given its substantial cost, should produce a better information delivery system than the one originally envisioned. The agency believes that cooperative efforts, because of their greater flexibility and inherent diversity, will ultimately prove to be more effective than a single mandatory approach. Because the mandatory approach would have been limited to a single distribution system, the agency contends it would have stifled innovation in patient information delivery systems. Experimentation with diverse solutions, however, should stimulate competition and thus produce the most effective systems.

12. Many consumers expressed disapproval of FDA's statement that one ground for its revocation was the fact that "medical professionals and the drug industry * * * did not support the program." They believed that this statement shows that the agency is disregarding the concerns of consumers. One comment stated that the proposal does not equally discuss the well-documented broad-based consumer support for the program. Several comments accused the agency of abandoning its responsibility to protect the health of American citizens.

These comments show a misunderstanding of FDA's concern about the lack of support for the PPI program expressed by professions and the drug industry. For the agency's mandatory PPI program to have benefitted the consumer, the support of the health professions was essential. Lack of pharmacist support, for example, is related to compliance rates of less than 40 percent for existing mandatory programs. Lack of enthusiasm on the part of other health professions, similarly, given the great respect consumers traditionally have for them, cannot but diminish the importance and value of the government program in the minds of consumers. The agency believes, therefore, it was entirely justified in citing this lack of support as an important reason for deciding to encourage the efforts of the private sector instead of implementing a mandatory government program. Although the agency realizes that consumer groups generally supported the PPI pilot program, it believes that as the voluntary systems emerge, consumers will receive not only an adequate supply of prescription drug information from a variety of sources, but should receive more information about more drugs than would have resulted from a mandatory system. FDA also believes that the current regulatory environment demands that these various private sector efforts be given the opportunity to demonstrate that they can meet consumers' needs as well, if not better than, a government program.

13. One comment stated that the complaint by pharmacists that they are "singled out as having most of the program's burden placed on their shoulders" is unfounded. The comment contended that for years by their publications and advertising, pharmacists have encouraged the public to see the pharmacist as the one best suited to warn them about complications arising from combinations of drugs. The comment stated that pharmacists have now assumed this highly responsible role in the health field and should accept the responsibilities inherent in such a role.

The agency disagrees that the complaints of pharmacists are unfounded. As stated in the proposal, pharmacists were required to play the major role in actually dispensing PPI's to patients and, accordingly, were subject to most of the regulatory burdens imposed by the regulations. Although many groups of health care professionals, including pharmacists, agree there is a need for better patient education about prescription drugs, most thought the responsibility should be shared by the various health professions. The agency acknowledges that these comments played a role in its decision to encourage current programs in patient education, rather than to enforce a program that may not be the best means of providing patient information and that places a disproportionate burden on any single profession.

14. One consumer group objected to FDA's negating a major premise of its mandatory drug information program as stated in the July 6, 1979 proposed rule that "A drug product's labeling is misleading if it fails to reveal facts that are material in light of representations made in the labeling or material with respect to consequences that may result from the use of the product under the conditions of use prescribed in its labeling or under customary or usual conditions of use."

As the agency stated in the proposal, the regulation requiring PPI's for prescription drugs is a discretionary one, issued under sections 201(n), 502(a), 505, and 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(n), 352(a), 355, and 371(a)). The legal authority is discussed at length at 45 FR 60758–60759 (September 12, 1980). This authority justified, but did not mandate, the requirement for PPI's for prescription drugs. Because the regulation is a discretionary one, FDA believes it is authorized to revoke it under the same discretionary authority that permitted its issuance.

The standard by which such authority is applied is that a regulation must take into account all relevant considerations, be reasonable in effect, and accord with the law. This regulation revoking the mandatory PPI program meets that standard. The considerations relevant to the revocation are explained above: the mandatory program is likely to be less useful to patients than alternative programs in development or planned; the program would likely not yield benefits commensurate with its costs; the program would almost certainly deter the development of alternative means of patient education that might be equally or more effective; proper implementation of the program would be uncertain.

Revocation of the program will have a reasonable effect. Patients will have access to a variety of programs of drug education and information. Pharmacists will not bear an undue share of the managerial and cost burdens associated with patient information services. At least one alternative program under development—the AMA's—will provide patient information at the time a drug is prescribed. This means of patient education, which is recognized as superior to providing patient labeling at the time of dispensing, would likely not be used if PPI's were Federally mandated.

Revocation of the PPI program is consistent with the law. The argument that absence of PPI's misbrands prescription drugs is based on a misunderstanding of the manner in which FDA utilizes its broad statutory authority in support of specific regulations. A regulation, such as the PPI program, is issued under FDA's authority to promulgate regulations for

the efficient enforcement of the Federal Food, Drug, and Cosmetic Act (Sec. 701(a) (21 U.S.C. 371(a))). Such a regulation must also be justified by other, more specific, authority in the act, in this case the prohibition against misbranding. After a regulation is promulgated, failure to adhere to the regulation causes a violation of the specific statutory authority on which the regulation is based. In the absence of the regulation, however, violation of that specific authority does not necessarily occur by conduct that the regulation would have covered. To suggest that it does is tantamount to saying that all regulations issued under section 701(a) of the act are merely interpretive, for substantive regulations would be redundant of the legal requirements inherent in other provisions of the act. This view is plainly wrong. FDA has issued numerous substantive regulations under section 701(a) of the act. Most of these regulations created new legal requirements of general applicability and did not simply explain existing requirements.

The PPI regulation was discretionary and therefore there is no statutory barrier to its revocation. Aside from the discretionary nature of the regulation, circumstances have changed since the regulation was proposed. The agency has conducted a thorough reevaluation of the need for the PPI program that included consideration of existing and new information. FDA is entitled to reevaluate the basis for a regulatory program and to arrive at a different conclusion from the one originally reached even if no new information has come to light. See *Bell* v. *Goddard,* 366 F.2d 177, 181 (7th Cir. 1966). With respect to the need for Federally mandated patient labeling, new information was available that demonstrated to the agency's satisfaction that the PPI program is not necessary.

15. One consumer group claimed that the majority of industrial countries and many third world nations already require PPI's and believed that the American consumers are entitled to the same vital information about the benefits, risks, and proper uses of the drugs they take.

The agency has reviewed drug dispensing practices in other countries and has not found programs to exist that provide information comparable either to that which the PPI pilot program would have provided, or which will be provided by most voluntary programs. American consumers are not, therefore, being shortchanged in this area as compared to consumers in other countries. What is provided abroad is either less comprehensive or less useful than that which domestic programs have sought to provide. For example, drugs that may require a prescription for dispensing in the United States may be offered for sale as over-the-counter (OTC) drugs in some other countries, thus requiring some form of consumer labeling. Such OTC labeling, however, is rarely as comprehensive as the consumer labeling for prescription drugs which domestic programs have attempted to provide. Second, many countries dispense prescription drugs to patients in unit-of-use packaging, and frequently include professional labeling in the package. Drugs are not routinely dispensed in unit-of-use packaging in the United States, however. Even if they were, professional labeling cannot be considered an effective form of patient information; it is highly technical in content and not understandable to the average layperson. Professional labeling is available to the American consumer as well, usually upon request from health professionals or through the Physicians' Desk Reference, which is now commonly sold in bookstores. Thus, the implication that American consumers are unreasonably disadvantaged because other countries already make patient information of the type mandated by the PPI program available to consumers cannot be substantiated.

Committee on Patient Education

Comments from both supporters and opponents of the proposed revocation commended the agency for establishing the Committee on Patient Education. Although a few comments argued that the Committee is not needed because consumers are currently receiving sufficient information about prescription drugs, most comments from individual consumers, health care professionals, and trade associations agreed with the agency's belief that patients need to be better informed about the prescription drugs they take and expressed a willingness to assist the Committee. Specific comments about the functions of the Committee are summarized and discussed below.

16. A few comments stated that the proposal should have discussed the ways the Committee would alert consumers to prescription drug information and questioned whether consumers would be represented on the Committee.

FDA's Committee on Patient Education is an internal FDA Committee, formed to develop and implement a comprehensive plan to encourage voluntary patient information on drugs. The Committee has made coordination with consumer groups a high priority because it believes that active consumer participation is critical to the success of patient information programs. The Associate Commissioner for Consumer Affairs is a member of the Committee and will be representing consumers' interests. The agency will continue to advise consumers of COPE activities and meetings with outside groups through publications and a variety of educational campaigns and efforts. Minutes of all COPE meetings and communications between COPE and the public have been and will continue to be placed on file with FDA's Dockets Management Branch.

In March 1982, the Commissioner of Food and Drugs wrote to the major interested consumer groups, asking for their support and advice, and soliciting information on the activities they had initiated. The information gathered as a result of these letters is being cataloged in FDA's newly established Patient Education Resource Center for dissemination to others and shared with the National Council on Patient Information and Education.

On May 4, 1982, the Committee met with representatives from Retired Persons Service, Inc., a pharmacy service of American Association of Retired Persons (AARP). The Committee learned of, and encouraged, AARP's efforts to provide package inserts with prescriptions filled through its mail-order pharmacy service. The Committee plans to meet with other consumer groups as its work progresses. Already planned for the summer is a meeting with a coalition of consumer groups, at which time consumer support can be further encouraged, consumer views can be solicited, and consumer representatives can learn more about the Committee and its work.

The agency notes that the National Council on Patient Information and Education has several consumer groups as members and has announced plans to sponsor communication programs to the public and keep its member organizations aware of efforts in patient information.

17. Several comments argued that because the results of the Committee's efforts would not be visible for some time, the pilot program regulation already in place should be implemented. They claimed that other organizations are still in the planning stages of their programs, whereas FDA has completed those initial steps and developed a definite plan.

FDA's Committee on Patient Education is already actively working

with outside organizations and providing advice and guidance to groups involved in supplying patient information materials. Also, as discussed earlier in this preamble, many programs to educate consumers about prescription drugs are already in place, more will begin shortly, and others are being planned. Although the agency acknowledges that the basic structure of the pilot program is in place, it could not have been implemented for some time because manufacturers, distributors, and dispensers would have to have been given adequate time to comply. Therefore, the agency cannot justify going forward merely because the regulation establishing the basic structure for the program is already in place.

Because this action removes 21 CFR Part 203, the stays of the effective dates for this regulation and the guidelines issued on April 28, 1981 (45 FR 23739) are now moot. Elsewhere in this issue of the **Federal Register**, the agency is revoking the 5 final guideline patient package inserts (45 FR 78516; November 25, 1980 and 46 FR 160; January 2, 1981) and withdrawing the 5 proposed guideline patient package inserts for the 10 drugs or drug classes to which FDA had intended to apply the regulation during the pilot program (45 FR 60785; September 12, 1980 and 45 FR 80740; December 5, 1980).

The agency has determined pursuant to 21 CFR 25.24(b)(12) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore neither an environmental assessment nor an environmental impact statement is required.

In accordance with the Regulatory Flexibility Act (Pub. L. 96–354; 94 Stat. 1164–1170) and Executive Order 12291, the agency has determined that because the patient package insert final regulation was never implemented, its revocation has no economic impact.

List of Subjects in 21 CFR Part 203

Labeling, Packaging and containers, Prescription drugs.

PART 203 [REMOVED]

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 503, 505, 506, 507, 701, 52 Stat. 1041 as amended, 1050–1053 as amended, 1055–1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended (21 U.S.C. 321, 352, 353, 355, 356, 357, 371)) and the Public Health Service Act (sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262)) and under 21 CFR 5.11 as revised (see 47 FR 16010; April 14, 1982), Title 21 of the Code of Federal Regulations is amended by removing Part 203.

Effective date September 7, 1982.

(Secs. 201, 502, 503, 505, 506, 507, 701, 52 Stat. 1041 as amended, 1050–1053 as amended, 1055–1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended (21 U.S.C. 321, 352, 353, 355, 356, 357, 371))

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Dated: August 16, 1982.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82-24453 Filed 9-3-82; 8:45 am]

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21 CFR Parts 314, 433, 510, and 809

[Docket No. 82N-0033]

Exemption of Antibiotic Drugs and Antibiotic Susceptibility Medical Devices From Certification

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the antibiotic drug and new animal drug regulations to exempt all classes of antibiotic drugs from batch certification requirements. FDA also is amending the medical device regulations to exempt antibiotic susceptibility devices from batch certification. Because of the high level of manufacturer compliance with existing standards, FDA has determined that batch-by-batch testing by FDA is not necessary to ensure the safety and efficacy of antibiotic drugs and antibiotic susceptibility devices. Under the exemption, manufacturers would not be required to obtain, before marketing, certification of each batch of antibiotic drug or antibiotic susceptibility device.

DATES: Effective October 1, 1982; notice of participation and request for hearing by October 7, 1982; data, information, and analyses to justify a hearing by November 8, 1982.

ADDRESS: Dockets Management Branch (HFA–305), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

For human drugs: Robert J. Meyer, National Center for Drugs and Biologics (HFD–30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5220.

For animal drugs: Frank G. Pugliese, Bureau of Veterinary Medicine (HFV–103), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4313.

For medical devices: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 7, 1982 (47 FR 19954), FDA proposed to amend the antibiotic drug and new animal drug regulations to exempt all classes of antibiotic drugs from batch certification requirements. FDA also proposed to exempt antibiotic susceptibility devices from batch certification. Because of the high level of manufacturer compliance with existing standards, FDA tentatively determined that batch-by-batch certification by FDA is not necessary to ensure the safety and efficacy of antibiotic drugs and antibiotic susceptibility devices. Under the exemption, manufacturers would not be required to obtain, before marketing, certification of each batch of antibiotic drug. Interested persons were given to June 7, 1982 to submit comments on the proposal and to May 17, 1982 to submit requests for an informal conference.

In the **Federal Register** of May 11, 1982 (47 FR 20186), FDA announced an interim policy under which manufacturers' tests of batches of antibiotic drugs and antibiotic susceptibility devices would not be routinely replicated by FDA. The purpose of the interim policy was to avoid interruption of supplies of antibiotic drug products pending the agency's final decision on the proposed rule to exempt these products from certification. Interested persons were given to June 10, 1982 to submit comments regarding this interim policy.

Seven comments were received regarding the interim policy of discretionary replication. All comments supported this policy.

Fourteen comments and one request for an informal conference, which was later withdrawn, were received on the proposed rule. The comments came from antibiotic manufacturers, industry trade associations, the United States Pharmacopeial Convention (USPC), and an individual. All the comments generally supported the proposal, but a few objected to or questioned certain specific provisions. A summary of the substantive questions or objections and the agency's responses follows:

1. One manufacturer, while concurring with the proposal to exempt from certification antibiotics manufactured by domestic firms, objected to exempting the products of foreign manufacturers. The basis for the objection is the contention that foreign manufacturers are not subject to

unannounced FDA inspections, as are domestic manufacturers, and are able to prepare for the inspection. Therefore compliance with current good manufacturing practice (CGMP) regulations is suspect. The comment further contended that foreign manufacturers are not subject to the CGMP regulations concerning penicillin contamination.

FDA disagrees with this comment. Drugs imported into the United States are in interstate commerce under the Federal Food, Drug, and Cosmetic Act (the act) and therefore are subject to all of the drug provisions of the act, including the provisions on penicillin contamination (21 CFR 211.176) and all other requirements in the CGMP regulations. Foreign drug manufacturers who export products to the United States either are inspected by FDA investigators or, through reciprocal inspection agreements with foreign governments, are inspected by investigators of foreign governments. Before entering into such agreements, FDA reviews the inspection procedures of the foreign country and satisfies itself that its procedures meet FDA standards. The United States currently has reciprocal agreements with Sweden, Switzerland, and Canada. FDA believes that these inspectional procedures for foreign manufacturers are adequate to ensure compliance with CGMP and other regulations.

Moreover, there are addtional safeguards to ensure the safety and effectiveness of imported drugs. If there is any question regarding the safety, identity, strength, quality, or purity of a drug product offered for importation into this country, entry of the article can be denied until an inspection is conducted by FDA or inspectional information is made available to FDA for those firms in countries with which FDA has reciprocal inspection agreements. Examinations and assays of individual drug products are made by FDA on a random basis before allowing the products to be entered into domestic commerce. These procedures have been in effect for many years for nonantibiotic drugs and have been judged to provide a measure of the quality of these drugs without batch-by-batch certification. The agency is confident that they will work equally as well for antibiotics that are exempt from certification.

2. One comment on proposed § 433.2(b) (21 CFR 433.2(b)), which provides for the reimposition of certification where the requirements for exemption are not complied with, expressed concern that FDA would reimpose certification for all manufacturers if only a few manufacturers failed to comply with the applicable requirements for exemption. The comments suggested that the regulation be amended to make clear that this interpretation is not intended. A similar comment was received from a manufacturer of drugs for animal use.

FDA does not interpret § 432.2(b) as requiring FDA to reimpose certification on all manufacturers if only one or a few manufacturers fail to comply with the requirements for exemption. If one or a few isolated manufacturers experience a problem, and the problem is believed to pose a high potential for health risk and certification is the best approach to quality assurance, FDA will reimpose the requirement for certification only on that manufacturer or those manufacturers having the problem. This authority is provided for by § 433.2(b) in the case of drugs for human use, by § 510.521(b) (21 CFR 510.521(b)) for drugs for animal use, and by § 809.6(b) (21 CFR 809.6(b)) for antibiotic susceptibility devices. Only where the problem is believed to be industrywide would the agency reimpose certification for all manufacturers. This authority is provided for by §§ 433.2(a), 510.521(a), and 809.6(a). In either case, the exemption from certification would again be instituted once the problem is resolved. The agency believes that these sections are clear and that revision of the provision is unnecessary.

3. One manufacturer suggested that responsibility for the current monograph system in the Code of Federal Regulations for antibiotics that are exempt from certification be transferred to the USPC. The USPC made a similar comment regarding transfer of responsibility for this antibiotic monograph system, and further recommended that proposed §§ 433.1(b)(2), (3), and (4), and 510.520(a)(2), (3), and (4) (21 CFR 433.1(b)(2), (3), and (4), and 510.520(a)(2), (3), and (4)) be revised to state that exemptions from certification are contingent upon the article's meeting the specifications of packaging and labeling, and standards of identity, strength, quality, and purity contained in the United States Pharmacopeia, rather than those in the Code of Federal Regulations.

The issue of delegating the responsibility for antibiotic monographs and other specifications and standards to an outside group, specifically the USPC, is beyond the scope of this final rule. This issue is, however, under consideration in the agency. A meeting between agency officials and representatives of the USPC has been held to discuss this issue, but the agency has not yet reached a final decision. If the agency concludes that there is no legal bar to the delegation, and that such a delegation would offer some advantage to the public, FDA will revise its regulations as necessary.

4. One comment requested that antibiotic susceptibility discs for use with animals be regulated in the same manner as those for use with humans, i.e., as medical devices, and that they also be exempted from the certification process.

FDA is reviewing the regulatory status of antibiotic susceptibility discs for use in animal medicine. Regardless of whether the products are drugs or devices, however, these regulations exempt them from certification.

5. A manufacturer of animal drugs expressed dissatisfaction at what it describes as FDA's continued endorsement of the provision in section 801(d) of the act (21 U.S.C. 381) that disallows the exportation of any new animal drug, or an animal feed bearing or containing a new animal drug, which is unsafe within the meaning of section 512 of the act (21 U.S.C. 360b). The comment contended that this provision encourages industry to locate manufacturing plants outside the United States, thereby exporting jobs instead of products.

The agency's views on section 801(d) of the act are not relevant to this regulation and therefore were not expressed in the preamble to the proposal. However, it was necessary for the agency to explain in the preamble to the proposal that exemption from certification would not affect the conditions for export of the various classes of antibiotics. As stated in the preamble to the proposal, the conditions for export of antibiotic drugs for animal use will continue to be governed by the separate statutory restrictions contained in section 801(d) of the act, which prohibit the export of a new animal drug that is unsafe within the meaning of section 512 of the act.

6. One manufacturer objected to the proposal to discontinue the policy of reviewing and approving antibiotic Form 5 or Form 6 applications for bulk antibiotic drug substances and the conversion of existing approved antibiotic Form 5 and Form 6 applications for bulk antibiotic drug substances to drug master files. The comment contended that the current policy avoids duplication of agency review, because no further review of the approved bulk antibiotic drug substance is necessary when a manufacturer

wants to use that substance in its product. But in the case of the drug master file system, data on the bulk antibiotic drug substance would be reviewed in the context of each application whenever a dosage form manufacturer wants to use the bulk in its product. The comment also questioned how the agency plans to handle future changes in the drug master files for bulk antibiotic drug substances.

In evaluating the merits of the comment, the agency has carefully reconsidered the need for, and benefits of, incorporating all approved antibiotic Form 5 or Form 6 applications for bulk antibiotic drug substances into the drug master file system. The intent of the proposed policy change was to eliminate the anomaly between antibiotic drugs and nonantibiotic drugs created by the practice of approving antibiotic Form 5 or Form 6 applications for bulk antibiotic drug substances. The agency does not approve new drug applications (NDA's) or abbreviated new drug applications (ANDA's) for bulk nonantibiotic drug substances but handles them through the drug master file system. There is some merit in the comment regarding the possible duplication of agency review time in reviewing the master file data in the context of each antibiotic Form 5 or Form 6 application whenever a manufacturer wants to use the substance in its product, as opposed to the one time review and approval of a Form 5 or Form 6 application for the bulk antibiotic drug substance. This practice could result in some duplication of reviews. There also may be some advantage in the way changes are made in the approved Form 5 or Form 6 application for a bulk antibiotic drug substance as opposed to the procedures used for handling changes to drug master files. In the case of the approved Form 5 or Form 6 application for a bulk antibiotic drug substance, the changes are made by submission of a supplement that must be reviewed and approved by FDA before the change can be made. In the case of a drug master file, the holder simply notifies FDA by letter and institutes the change without the necessity of agency review or approval.

The agency has concluded that it would be premature to discontinue approving Form 5 and Form 6 applications for bulk antibiotic drug substances and converting approved Form 5 and Form 6 applications for bulk antibiotic drug substances to the drug master file system without further comparison of the advantages and disadvantages of the two systems. Therefore, although the agency utilizes the drug master file system for nonantibiotic bulk drug substances, it will continue to accept and approve Form 5 or Form 6 applications for bulk antibiotic drug substances and will continue to maintain the currently approved antibiotic Form 5 of Form 6 applications for bulk antibiotic drug substances. Any changes in the system will be announced in the **Federal Register** as appropriate. Section 433.1(c)(2) has been revised in the final rule to reflect the continuation of the current practice.

7. One manufacturer, while endorsing the proposal, expressed concern that the conditions for exemption from certification may inadvertently permit the marketing of antibiotic drugs that could not now be certified. The comment contended that at present FDA refuses to certify an antibiotic drug if another government agency, such as the U.S. International Trade Commission (ITC), prohibits the importation of that drug or if a court of competent jurisdiction enjoins the manufacture, use, or sale of the drug. The comment suggested that to continue this policy the agency should add, as an additional condition for exemption from certification, that the antibiotic drug not be subject to any import restrictions ordered by ITC or a similar agency, or to an injunction by a court of competent jurisdiction.

FDA does not, as a matter of policy, condition the approval of a drug on a demonstration by the sponsor that all laws other than the act applicable to the drug or to the manufacturer have been complied with. No such condition is found in the regulations governing the approval of nonantibiotic drugs and there is no sound basis for adding such a condition to the regulations for antibiotic drugs. From time to time issues arise concerning the legal status of specific lots of drugs alleged to have been illegally imported. FDA resolves these issues on a case-by-case basis and will continue to do so under the new system established by these regulations. No change in the regulations is called for at this time.

8. One comment suggested that FDA should not exempt antibiotic susceptibility discs from batch certification until it has been shown that manufacturers are capable of making discs to specifications without any involvement by FDA.

Section 507(c) of the act (21 U.S.C. 357(c)) provides that FDA may exempt an antibiotic or class of antibiotics from certification if the manufacturers have demonstrated a level of consistency in production adequate to assure the safety and effectiveness of the products. Manufacturers have reduced the rejection rate of batches of antibiotic susceptibility devices submitted for certification to a level of less than 1 percent. FDA believes that this rejection rate is sufficient to justify the exemption of these products from batch certification. Similarly, FDA is exempting from batch certification the bulk antibiotic drugs used in preparing these devices.

FDA will, however, continue to monitor these products. The antibiotic susceptibility devices and the bulk antibiotic drugs must comply with the applicable monographs. These devices are also subject to other applicable provisions of the act, e.g., the adulteration and misbranding provisions, inspection, and current good manufacturing practice requirements. FDA will collect and test samples, when appropriate.

Antibiotic Susceptibility Devices

As discussed in the preamble to the proposed rule, FDA is establishing in the final rule exemption provisions for antibiotic susceptibility devices for human use, which are subject to section 507 of the act because of section 520(1)(4) of the act (21 U.S.C. 360j(1)(4)). Under section 520(1)(4) of the act, these antibiotic susceptibility devices will continue to be subject to section 507 of the act until the effective date of one of the following: a regulation classifying the device into class I (general controls), a performance standard for the device if it is classified into class II (performance standards) or a requirement to have in effect an approved premarket approval application, if it is classified into class III (premarket approval).

Under these final regulations, antibiotic susceptibility devices continue to be subject to section 507 of the act until one of the above events occurs but are exempted from batch certification under the following conditions:

1. The device is approved for marketing under an appropriate antibiotic Form 5 or 6 application or is the subject of review under the Drug Efficacy Study Implementation program.

2. The device is packaged and labeled for dispensing in accordance with the applicable monograph and both the bulk antibiotic drug used in preparing the device and the device as manufactured meet the standards of identity, strength, quality, and purity specified in the applicable monograph. If a monograph has not been published, the standards and labeling approved in the antibiotic Form 5 or 6 application shall apply.

A device that has been approved for marketing under an appropriate antibiotic Form 5 or 6 application and that has been granted an exemption from batch certification is considered by FDA to have an approved premarket approval application under section 515 of the act (21 U.S.C. 360e). Thus, for such a device, any change that relates to its safety or effectiveness may require the submission to FDA and the approval of a supplemental premarket approval application.

As authorized by section 507(c) of the act, § 809.5(c) (21 CFR 809.5(c)) permits a manufacturer to apply for batch certification for a device even though the device qualifies for exemption from batch certification. A device which has been exempted from batch certification under § 809.5 must comply with the conditions set out in § 809.6 to retain its exemption from batch certification. Also, antibiotic susceptibility devices continue to be subject to all other applicable requirements under the act, as discussed in the response to comment 8, above.

Antibiotic susceptibility devices which come on the market following the enactment of the Medical Device Amendments, May 28, 1976, are not subject to section 507 of the act but are regulated under the other provisions of the act applicable to devices. Devices in this group that are not substantially equivalent to a preamendments device are subject to premarket approval unless reclassified because of the requirements of section 513(f) of the act (21 U.S.C. 360c(f)). Devices that are substantially equivalent to a preamendments device will be classified with the preamendments device and, until classification is completed, are subject only to general controls under the act.

Substantial equivalence is determined by means of premarket notification submissions to FDA under section 510(k) of the act (21 U.S.C. 360(k) and Part 807 of the regulations (21 CFR Part 807).

Drug Products Subject to Drug Reviews

As FDA stated in the proposal, this final rule will not affect findings under the Drug Efficacy Study Implementation (DESI) review or the Over-the-Counter Drug Review for Human Drugs, and any drug product subject to requirements as a result of either of those reviews will still be required to conform to them. Insofar as any such requirements might conflict with the provisions of this final rule, the former will prevail. When this final rule becomes effective, approved antibiotic Form 5 applications will be regarded as approved NDA's and approved antibiotic Form 6 applications as approved ANDA's. Any antibiotic drug product whose effectiveness has not been resolved in the DESI program that is approved through this procedure will have the same status as any other less-than-effective DESI drug that is the subject of an approved or effective NDA under the transitional provisions of the 1962 Drug Amendments to the act (Sec. 107(c), 76 Stat. 780).

The agency has concluded that no Form 6 applications for antibiotic drug products for human use will be approved for antibiotic drugs affected by the DESI program pending a final evaluation with respect to efficacy. Although such Form 6 applications will not be approved, as with nonantibiotic DESI drugs, manufacturers may elect to market these products on their own responsibility pending the outcome of a final agency determination on the products' effectiveness. In accordance with FDA's enforcement priorities for DESI drugs generally, ordinarily no action will be taken against the affected products until the administrative process for those products has been completed. Because the proposed regulations would have required, as one of the conditions for exemption from certification, that the antibiotic drug be approved for marketing under an appropriate antibiotic Form 5 or Form 6 application, the agency has amended § 433.2(b)(1) to provide that exemption from batch certification be conditioned on either the antibiotic drug having an approved Form 5 or Form 6 application or being the subject of review under the DESI program.

As previously stated, antibiotic drug products for animal use are currently required to be the subject of approved new animal drug applications. The status of these approved applications will not be changed as a result of the final rule. Some of these antibiotic drugs for animal use were also subject to review by the National Academy of Sciences/National Research Council (NAS/NRC). For most of these products, the decisions based on this review have been made final. Decisions based on the NAS/NRC review for those products that have not been made final will not be affected by this final rule.

The agency has considered the economic impact of this final rule and has determined that it does not require a regulatory flexibility analysis, as defined with the Regulatory Flexibility Act (Pub. L. 96–354). Specifically, the final rule would eliminate batch certification costs for the manufacturers of antibiotic drugs and antibiotic susceptibility devices. The fees totaled approximately $6.1 million in FY '81 for certification of about 19,000 batches of antibiotic drugs and devices. Approximately $1 million of these fees were paid by 84 small pharmaceutical and device manufacturers. The elimination of these fees, although beneficial to both large and small firms, is a comparatively small financial consideration in the manufacture of antibiotic drugs and antibiotic susceptibility devices, whose total sales are estimated to exceed $1 billion per year. Accordingly, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects

21 CFR Part 314

Administrative practice and procedure, Drugs.

21 CFR Part 433

Antibiotics, Labeling.

21 CFR Part 510

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

21 CFR Part 809

In vitro diagnostic devices, Labeling, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 505, 507, 512(n), 701(f) and (g), 52 Stat. 1050–1053 as amended, 1055–1056 as amended, 59 Stat. 463 as amended, 82 Stat. 350–351 (21 U.S.C. 355, 357, 360b(n), 371(f) and (g))) and under 21 CFR 5.11 as revised (see 47 FR 16010; April 14, 1982), Parts 314, 433, 510, and 809 are amended as follows:

PART 314—NEW DRUG APPLICATIONS

1. Part 314 is amended in § 314.14 by adding new paragraph (j), to read as follows:

§ 314.14 Confidentiality of data and information in a new drug application (NDA) file.

* * * * *

(j) The availability for public disclosure of any record in a file for an antibiotic drug that is exempt from certification under § 433.1 of this chapter shall be determined in accordance with §431.71 of this chapter.

PART 433—EXEMPTIONS FROM ANTIBIOTIC CERTIFICATION AND LABELING REQUIREMENTS

2. Part 433 is amended:

a. By revising § 433.1, to read as follows:

§ 433.1 Exemption of antibiotic drugs for human use from batch certification requirements.

(a) Antibiotic drugs for human use are exempt from the batch certification requirements of Part 431 of this chapter if the conditions of this section are met.

(b) The conditions are as follows:

(1) The antibiotic drug is approved for marketing under an appropriate antibiotic Form 5 or Form 6 application or is the subject of review under the Drug Efficacy Study Implementation Program.

(2) The antibiotic drug is packaged and labeled for dispensing in accordance with the applicable regulation (monograph) in this chapter except where other labeling has been approved in an applicable antibiotic Form 5 or Form 6 application.

(3) The bulk antibiotic drug used in preparing the antibiotic drug product meets the standards of identity, strength, quality, and purity specified in the applicable regulation (monograph) in this chapter except where other standards have been approved in an applicable antibiotic Form 5 or Form 6 application.

(4) The antibiotic drug product meets the standards of identity, strength, quality, and purity specified in the applicable regulation (monograph) in this chapter except where other standards have been approved in an applicable antibiotic Form 5 or Form 6 application.

(c) In accordance with the provisions of section 507(e) of the act, an antibiotic-containing drug for human use exempt from the requirements for batch certification under this section is subject following its approval to section 505 of the act and applicable regulations for new drugs, generally parts 310 through 314 of this chapter. For each antibiotic drug subject to an exemption under this section:

(1) An approved antibiotic Form 5 application is regarded to be an approved new drug application under § 314.1(a) of this chapter.

(2) An approved antibiotic Form 6 application is regarded to be an approved abbreviated new drug application under § 314.1(f) of this chapter.

(d) Nothing in this section prevents a manufacturer from applying for batch certification of an antibiotic drug for human use subject to an exemption under this section as provided in section 507(c) of the act.

(e) All exemptions from batch certification requirements for antibiotic drugs for human use under this section are subject to the conditions of effectiveness under § 433.2.

(f) Reporting/recordkeeping requirements contained in this Part 433 have been approved by the Office of Management and Budget and assigned approval numbers 0910–0007, 0910–0009, and 0910–0055.

b. By revising § 433.2, to read as follows:

§ 433.2 Conditions on the effectiveness of exemptions of antibiotic drugs for human use from batch certification requirements.

(a) If at any time an exemption from batch certification requirements for an antibiotic drug for human use has been granted, the Commissioner finds on the basis of new information before the agency with respect to such exempted drug, evaluated together with the evidence available to the agency when such exemption was granted, that certification of each batch is necessary to ensure its safety and efficacy of use, the Commissioner shall act immediately to revoke all exemptions from batch certification requirements granted for such drug.

(b) If the Commissioner finds that the person granted an exemption from batch certification requirements for an antibiotic drug for human use has failed to comply with the requirements of section 505 of the act and the regulations promulgated thereunder; or if the Commissioner finds that the requirements of § 433.1 have not been met; or if the Commissioner finds that the petition for exemption from batch certification contains any false statements of fact, the Commissioner may revoke the exemption from batch certifications requirements immediately and require batch certification of the drug until such person shows adequate cause why the exemption from batch certification requirements should be reinstated.

(c) If the Commissioner repeals or suspends an exemption from batch certification requirements for an antibiotic drug for human use, a notice to that effect and the reasons therefor will be published in the **Federal Register.**

(d) Any person who contests the revocation or suspension or denial of reinstatement of an exemption from batch certification requirements for an antibiotic drug for human use shall have an opportunity for a regulatory hearing before the Food and Drug Administration under Part 16 of this chapter.

PART 510—NEW ANIMAL DRUGS

3. Part 510 is amended:

a. By adding new § 510.520, to read as follows:

§ 510.520 Exemption from batch certification requirements for antibiotic drugs for animal use subject to section 512(n) of the act.

(a) In addition to the exemptions from certification provided in §§ 510.505, 510.510, and 510.515, antibiotic drugs subject to section 512(n) of the act are also exempt from the batch certification requirements under §§ 514.50 and 514.51 of this chapter, if the following conditions are met:

(1) The antibiotic drug is the subject of a new animal drug application approved under § 514.105 of this chapter.

(2) The antibiotic drug is packaged and labeled in accordance with the conditions of marketing described in the approved new animal drug application.

(3) The bulk antibiotic drug used in preparing the antibiotic drug product meets the standards of identity, strength, quality, and purity specified in the applicable regulation (monograph) in this chapter.

(4) The antibiotic drug product meets the standards of identity, strength, quality, and purity specified in the applicable regulation (monograph) in this chapter.

(b) Nothing in this section prevents a manufacturer from applying for batch certification of an antibiotic drug for animal use subject to an exemption under this section as provided in section 512(n)(3) of the act.

(c) All exemptions from batch certification requirements for antibiotic drugs for animal use under this section are subject to the conditions of effectiveness under § 510.521.

(d) Reporting/recordkeeping requirements contained in this Part 510 have been approved by the Office of Management and Budget and assigned approval numbers 0910–0007, 0910–0009, and 0910–0032.

b. By adding new § 510.521, to read as follows:

§ 510.521 Conditions on the effectiveness of exemptions of antibiotic drugs for animal use from batch certification requirements.

(a) If at any time after an exemption from batch certification requirements for an antibiotic drug for animal use has been granted, the Commissioner finds on the basis of new information before the agency with respect to such exempted drug, evaluated together with the evidence available to the agency when such exemption was granted, that certification of each batch is necessary to ensure its safety and efficacy of use, the Commissioner shall act immediately to revoke all exemptions from batch certification requirements granted for such drug.

(b) If the Commissioner finds that the person granted an exemption from batch certification requirements for an antibiotic drug for animal use subject to section 512(n) of the act has failed to comply with the requirements of section 512 of the act and the regulations promulgated thereunder; or if the Commissioner finds that the requirements of § 510.520 have not been met; or if the Commissioner finds that the petition for exemption from batch certification contains any false statements of fact, the Commissioner may revoke the exemption from batch certification requirements immediately and require batch certification of the drug until such person shows adequate cause why the exemption from batch certification requirements should be reinstated.

(c) If the Commissioner repeals or suspends an exemption from batch certification requirements for an antibiotic drug for animal use, a notice to that effect and the reasons therefor will be published in the **Federal Register.**

(d) Any person who contests the revocation or suspension or denial of reinstatement of an exemption from batch certification requirements for an antibiotic drug for animal use shall have an opportunity for a regulatory hearing before the Food and Drug Administration under Part 16 of this chapter.

PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

4. Part 809 is amended:

a. By adding new § 809.5, to read as follows:

§ 809.5 Exemption from batch certification requirements for in vitro antibiotic susceptibility devices subject to section 507 of the act.

(a) Antibiotic susceptibility devices subject to section 507 of the act are exempt from the batch certification requirements of Part 431 of this chapter if the following conditions are met:

(1) The antibiotic susceptibility device is approved for marketing under an appropriate antibiotic Form 5 or Form 6 application.

(2) The antibiotic susceptibility device is packaged and labeled for dispensing in accordance with the applicable regulation (monograph) in this chapter except where other labeling has been approved in an applicable antibiotic Form 5 or Form 6 application.

(3) The bulk antibiotic drug used in preparing the antibiotic susceptibility device meets the standards of identity, strength, quality, and purity specified in the applicable regulation (monograph) in this chapter except where other standards have been approved in an applicable antibiotic Form 5 or Form 6 application.

(4) The antibiotic susceptibility device meets the standards of identity, strength, quality, and purity specified in the applicable regulation (monograph) in this chapter except where other standards have been approved in an applicable antibiotic Form 5 or Form 6 application.

(b) For each antibiotic susceptibility device subject to an exemption under this section, an approved antibiotic Form 5 or Form 6 application is regarded to be an approved premarket approval application under section 515 of the act.

(c) Nothing in this section prevents a manufacturer from applying for batch certification of an antibiotic susceptibility device as provided in section 507(c) of the act.

(d) All exemptions from batch certification requirements for antibiotic susceptibility devices under this section are subject to the conditions of effectiveness under § 809.6.

b. By adding new § 809.6, to read as follows:

§ 809.6 Conditions on the effectiveness of exemptions of antibiotic susceptibility devices from batch certification requirements.

(a) If at any time after an exemption from batch certification requirements for an antibiotic susceptibility device has been granted, the Commissioner finds on the basis of new information before the agency with respect to such exempted device evaluated together with the evidence available to the agency when such exemption was granted, that certification of each batch is necessary to ensure its safety and efficacy of use, the Commissioner shall act immediately to revoke all exemptions from batch certification requirements granted for such device.

(b) If the Commissioner finds that the person granted an exemption from batch certification requirements for an antibiotic susceptibility device has failed to comply with the requirements of section 507 of the act and the regulations promulgated thereunder; or if the Commissioner finds that the requirements of § 809.5 have not been met; or if the Commissioner finds that the petition for exemption from batch certification contains any false statements of fact, the Commissioner may revoke the exemption from batch certification requirements immediately and require batch certification of the device until such person shows adequate cause why the exemption from batch certification requirements should be reinstated.

(c) If the Commissioner repeals or suspends an exemption from batch certification requirements for an antibiotic susceptibility device, a notice to that effect and the reasons therefor will be published in the **Federal Register.**

(d) Any person who contests the revocation or suspension or denial of reinstatement of an exemption from batch certification requirements for an antibiotic susceptibility device shall have an opportunity for a regulatory hearing before the Food and Drug Administration under Part 16 of this chapter.

Section 10.40(c)(4) of the agency's procedural regulations (21 CFR 10.40(c)(4)) requires the effective date of a final regulation be not less than 30 days after the date of publication in the **Federal Register,** except for a regulation that grants an exemption or relieves a restriction, or for which the Commissioner finds, and states in the notice, good cause for an earlier effective date. Because these regulations grant an exemption and because no significant objections to the exemption were raised in the comments received to the proposal the effective date can be less than 30 days after the date of publication in the **Federal Register.** Therefore, this regulation is effective on October 1, 1982.

Any person who will be adversely affected by this regulation may file objections to it and request a hearing. Reasonable grounds for the hearing must be shown. Any person who decides to seek a hearing must file (1) on or before October 7, 1982, a written notice of participation and request for hearing, and (2) on or before November 8, 1982, the data, information, and analyses on which the person relies to justify a hearing, as specified in 21 CFR 430.20. A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that no genuine and substantial issue of fact precludes the action taken by this order, or if a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who request(s) the hearing, making findings and conclusions and denying a hearing. All submissions must be filed in three copies, identified with the docket

number appearing in the heading of this order and filed with the Dockets Management Branch (address above).

The procedures and requirements governing this order, a notice of participation and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and grant or denial of a hearing are contained in 21 CFR 430.20.

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

Effective date. This regulation shall be effective October 1, 1982.

(Secs. 505, 507, 512(n), 701(f) and (g), 52 Stat. 1050–1053 as amended, 1055–1056 as amended, 59 Stat. 463 as amended, 82 Stat. 350–351 (21 U.S.C. 355, 357, 360b(n), 371(f) and (g)))

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Dated: August 27, 1982.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82-24423 Filed 9-3-82; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR Part 60

[Order No. 987-82]

Offices With Employees Who Are Authorized To Request the Issuance of Search Warrants

AGENCY: Attorney General, Justice.

ACTION: Final rule.

SUMMARY: This rule adds the Office of Inspector General, Department of Agriculture, and the Defense Criminal Investigative Service, Department of Defense, to the list of Government organizations in 28 CFR 60.3 with employees authorized by the Attorney General to request the issuance of search warrants. This list does not itself authorize these employees to seek search warrants, but rather provides public notice that these offices have employees who are authorized under a separate regulation—28 CFR 60.2—to seek the issuance of search warrants.

EFFECTIVE DATE: August 28, 1982.

FOR FURTHER INFORMATION CONTACT: Michael A. Fitts, Attorney-Adviser, Office of Legal Counsel, Department of Justice, Washington, D.C. 20530, tel. (202) 633–4089.

SUPPLEMENTARY INFORMATION: This action is not a rule within the meaning of Executive Order No. 12291 or the Regulatory Flexibility Act, 6 U.S.C. 601 et seq.

List of Subjects in 28 CFR Part 60

Law enforcement officers, Search warrants.

PART 60—AUTHORIZATION OF FEDERAL LAW ENFORCEMENT OFFICERS TO REQUEST THE ISSUANCE OF A SEARCH WARRANT

Accordingly, by the authority vested in me as Attorney General by Rule 41(h) of the Federal Rules of Criminal Procedure, § 60.3(a) (1) and (2) of Title 28, Code of Federal Regulations is revised to read as follows:

§ 60.3 Agencies with authorized personnel.

* * * * *

(a) * * *

(1) Department of Agriculture:
- National Forest Service
- Office of the Inspector General

(2) Department of Defense:
- Defense Criminal Investigative Service
- Defense Investigative Service
- Criminal Investigation Command, United States Army
- Naval Investigative Service, United States Navy
- Office of Special Investigation, United States Air Force

* * * * *

Dated: August 28, 1982.

William French Smith,

Attorney General.

[FR Doc. 82-24468 Filed 9-3-82; 8:45 am]

BILLING CODE 4410-01-M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket S-650]

Hazardous Materials; Attendant Exemption and Latch-Open Devices

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Final rule.

SUMMARY: The Occupational Safety and Health Administration (OSHA) is revising its standard on gasoline nozzles to permit the use of latch-open devices on delivery nozzles used by the public in self-service gasoline stations. OSHA is also revoking a standard that exempts employers with private service stations, not accessible to the public, from having to provide a service station attendant. The exemption is not necessary because there is no requirement in the OSHA standards that an attendant be provided at either public or private service stations.

The two actions announced today will correct problems and conflicts between current OSHA standards and nationally recognized consensus standards used by local code enforcement officials.

EFFECTIVE DATE: This final rule becomes effective September 7, 1982.

FOR FURTHER INFORMATION CONTACT: Mr. Michael B. Moore, Senior Safety Engineer, Occupational Safety and Health Administration, Room N–3463, U.S. Department of Labor, 200 Constitution Avenue, NW. Washington, D.C. 20210, (202) 523–7225.

SUPPLEMENTAL INFORMATION:

I. History

On January 23, 1981, OSHA published an Advance Notice of Proposed Rulemaking (ANPR) in the **Federal Register** (46 FR 7692). This ANPR announced OSHA's plans to revise its safety standards concerning hazardous materials contained in Subpart H of 29 CFR Part 1910. The purpose of the ANPR (Docket S–013) was to solicit public comment on various issues related to the specific standards in Subpart H. In particular, several questions addressed flammable and combustible liquids (Issue 5, 46 FR 7695). Among these issues was one, Issue 5g [46 FR 7696], which requested comment on the use of approved latch-open devices on gasoline delivery nozzles. Section 1910.106(g)(3)(vi) prohibited the use of these devices in self-service gasoline stations open to the public. Several commenters in Docket S–013 (Ex. 3: 11, 16, 18, 19, and others) suggested that OSHA should lift its ban on latch-open devices. The Texas Oil Marketers (TOMA) in their response to the issue urged that OSHA "not simply revise § 1910.106 to allow latch-open devices at industrial accounts, but that the entire prohibition be removed from the OSHA regulations." (Ex. 3: 16). Several others commented in support of TOMA's position (Ex. 3: 7, 11, 18, 19, and 21).

During OSHA's review of the public comments in Docket S–013 which were submitted in response to the ANPR, it became apparent that several unique problems existed with OSHA's prohibition of latch-open devices. Because of these problems, several persons petitioned OSHA either to revise its standard or to publish an internal program directive to provide

relief from this burdensome provision (Ex. 3: 7, 9). In recognition of the arguments raised by the commenters and petitioners, OSHA decided to take immediate action on the issue of latch-open devices.

On Thursday, March 30, 1982, OSHA published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** (47 FR 13386). The purpose of the notice was to solicit public comments on two proposals. First, to revoke an unnecessary exemption pertaining to service station attendants and, second to remove the ban on latch-open devices. Comments were requested by April 29, 1982, Any objections and requests for a hearing on these proposals were also due on that date.

A total of 25 comments were received, most of which supported both of OSHA's proposed actions. There were no hearing requests.

II. Attendant Exemption

In the NPRM (47 FR 13386), OSHA proposed to remove a standard, 29 CFR 1910.106(g)(2), that exempted employers with private service stations, not open to the public, from having to provide a service station attendant. OSHA believes that the exemption was unnecessary because there is no provision in the OSHA standards that requires that either public or private service stations have an attendant.

When OSHA adopted its original standards (Ex. 3: 3) under section 6(a) of the Act, the 1969 Edition of NFPA 30 (Ex. 3: 4) contained both the exemption and a requirement that public service stations have an attendant (Ex. 3: 4; pages 30–68). Under section 6(a) OSHA chose to adopt only the exemption. It did not adopt the requirement for service station attendants because the need for attendants in public service stations was considered to be relevant to public safety, but not to be directly related to employee safety. Therefore, since the standard as adopted under 6(a) did not require an attendant, the exemption appears to be unnecessary.

Several comments addressed this issue (Ex. 2: 11, 14, 19, and 20), all supporting OSHA's proposed action. Since OSHA received no negative comments on this issue and since the exemption is unnecessary and has no application, OSHA is revoking paragraph (g)(2) of § 1910.106, effective today.

III. Latch-Open Devices

OSHA's second proposal was to revise 29 CFR 1910.106(g)(3) to permit the use of listed manual or automatic-closing type hose nozzle valves on dispensers used for dispensing Class I liquids in service stations. It was also proposed to revise the standard to permit the use of listed or approved latch-open devices on automatic-closing gasoline nozzles used by the public.

Latch-open devices are small metal clips attached to the dispensing nozzles of gasoline pumps. They are used to hold the nozzle valve in the open position, thereby allowing the individual using the gasoline pump to perform other services to the vehicle being fueled. The nozzle valve is latched in the open position when an individual engages the device into any one of several hold-open notches built into the nozzle handle. When the flow of gasoline through the nozzle reaches a minimum rate, about 5 gallons per minute, the automatic self-closing nozzle valve closes and the resulting action causes the latch-open device to disengage and release the nozzle valve handle. The flow of gasoline is thereby stopped.

This proposal was developed to deal with problems that existed with the original OSHA standard (§ 1910.106(g)(3)(vi)), which prohibited latch-open devices unless dispensing was done by a service station attendant. The original standard, which was part of the National Fire Protection Association (NFPA) Standard No. 30, *Flammable and Combustible Liquids Code*, 1969 Edition (Ex. 3: 4), was promulgated in 1971 [36 FR 10544] under section 6(a) of the Occupational Safety and Health Act of 1970 (the Act) [84 Stat. 1593; 29 U.S.C. 655].

When OSHA adopted NFPA 30–1969's prohibition on latch-open devices, the self-service operation of gasoline pumps was rather limited. Gasoline delivery, for the most part, was done by service station attendants.

However, since 1969, there has been a significant increase in the number of retail self-service gasoline outlets in the United States and many self-service pumps have been added to previously full-service outlets. The Lundberg Survey, an independent marketing research report which is a widely respected source of information on gasoline marketing, estimates that more than 70% of the volume of gasoline sold in the U.S. is dispensed through self-service pumps (Ex. 3: 25).

Recently, the NFPA Technical Committee responsible for developing national consensus standards for flammable and combustible liquids lifted its ban on the use of approved latch-open devices on pumps to be used by the public in a self-service mode. This determination has been incorporated in the revised NFPA National Consensus Standard, NFPA 30-1981 (Ex. 3: 2). Several reasons have been put forth for this decision (Ex. 3: 1). The most significant of these reasons is that the public has resorted to the unauthorized use of unapproved or unlisted prop-open devices such as gas caps, wooden dowels, penknives, or similar devices (Ex. 2: 25; Ex. 3: 1, 9). The use of such unauthorized devices may result in the improper function of the automatic-closing valve in the gasoline dispensing nozzles (Ex. 3: 9). The potential for a hazardous spill in such a case is increased, as is the associated fire or explosion hazard to employees in the service station.

In brief, OSHA proposed to lift its ban on latch-open devices because it believed that the ban imposed a burdensome requirement on the American consumer; that it was unnecessary for employee safety since employees were already permitted to use latch-open devices on full-service nozzles; and that it addressed the area of public protection—an area outside OSHA's jurisdiction.

All of the twenty-five (25) comments received in response to the NPRM (Ex. 1) addressed this issue. Twenty-one (21) commenters supported OSHA's proposal and four were against it.

Comments supporting OSHA's proposal were received from consumers (Ex. 2: 2, 3, 5, 6, 7) and industrial concerns (Ex. 2: 10, 11, 14, 15, 16). In general, the consumers supported the proposal because it would relieve the burden of holding gas nozzles open by hand and the temptation to use unauthorized prop-open devices. Other consumers cited examples of hazardous situations that they had experienced and that they believed could be eliminated if the devices were permitted. One commenter, David A. Gilliland (Ex. 2: 2), spoke of an incident where another citizen was pumping gas into a car, holding the nozzle open by hand and smoking. The smoking consumer, "not paying attention," overfilled his tank and caused a spill to occur. Mr. Gilliland stated "Possibly if there had been an automatic latch-open device, the customer would not have been pumping gasoline on the pavement and possibly would not have been smoking near the rear of his car." Another consumer (Ex. 2: 3) noted that, "People will find or invent their own devices rather than stand bending over the gas nozzle in ten degree weather." The same commenter admitted using an unauthorized prop-open device that jammed the nozzle open and created a spill when it couldn't be removed.

Several supportive comments were also received from members of the

industrial community. Air Products and Chemicals, Inc. (Ex. 2: 14) commented that their experience shows that the use of latch-open devices will result in a cost savings to them because the employees filling gasoline tanks may do other work while the tank is being filled. They also stated that it will increase safety by reducing the temptation to use unapproved prop-open devices.

Several industry comments (Ex. 2: 15, 18, 22, 25) cited the increased use of unauthorized latch-open devices and their inherent safety hazards as sufficient support for OSHA's proposed action. The OPW Division of the Dover Corporation (Ex. 2: 15) stated that the use of unauthorized clips or other devices for blocking the nozzle open would certainly create more hazards than would ever be encountered with the proper clips. The Society of Independent Gasoline Marketers of America (SIGMA) (Ex. 2: 25) cited the use of "penknives, gasoline caps, or wooden dowels" to prop open nozzles. They stated that, "These makeshift prop-open devices interfere with the proper operation of gasoline nozzles and increase the possibilities of spillage. In contrast, properly designed and installed latch-open devices on self-service gasoline nozzles allow the nozzles to function properly, thus decreasing the risks of spills and injuries to the public and the employees."

OSHA agrees with the comments and recognizes the risks associated with the use of unauthorized latch-open devices. OSHA believes that lifting its ban on the use of approved latch-open devices will reduce the use of and the temptation to use unauthorized prop-open devices.

Other industry comments supported OSHA's proposal because it would make OSHA's standard consistent with NFPA 30–1981 (Ex. 2: 2). Kayo Oil Company (Ex. 2: 10) stated that "the analysis and studies made by the National Fire Protection Association in supporting their change in recommendations (is) adequate, reasonable, and based on appropriate statistical facts." The North Carolina Oil Jobbers Association (Ex. 2: 11) stated that "Such action would make the OSHA regulations conform to recently enacted changes in NFPA Pamphlet 30 provisions which are the foundation for most building and safety codes governing service station construction. This confusion and conflict between local regulatory agencies will be avoided." The Texas Oil Marketers Association (TOMA) (Ex. 2: 24) further cited NFPA 30's recognition of latch-open devices as a strong example of the need for OSHA to do the same.

Likewise, SIGMA (Ex. 2: 25) believes that, "The elimination of the latch-open ban on self-service gasoline nozzles would eliminate considerable confusion among gasoline marketers which has existed since the National Fire Protection Association, * * * revised its *Flammable and Combustible Liquids Code (NFPA 30)* in 1981, to allow the use of latch-open devices on self-service gasoline nozzles."

In recent years, OSHA has made a determined effort in several areas, notably in the revisions of its fire protection and electrical standards, to promulgate standards that are consistent with current State and local government standards, while assuring employee safety. By updating § 1910.106(g)(3)(vi) to conform to NFPA 30–1981, OSHA will further effectuate this policy in the area of fire protection. In this regard, OSHA recognizes that many State and local jurisdictions utilize the most recent revision of NFPA 30 as a source standard for their local fire codes.

Finally, OSHA believes that the issue of latch-open devices is primarily concerned with general public safety and not employee safety. Several commenters agreed with the concept that the devices are installed as a convenience to the public consumer and as such should be regulated for public safety by local jurisdictions. OSHA's proposal would not specifically require or prohibit the use of latch-open devices on self-service nozzles. By lifting its ban, OSHA would leave the decision to use or not to use the device to the local authorities and station operators.

Four (4) commenters did not support OSHA's proposed action (Ex. 2: 4, 12, 17, and 21). In general, these commenters felt that the provision of latch-open devices would increase the hazards of gasoline dispensing. It is, however, our determination and that of the NFPA that there is no record or data on such possible accidents occuring.

The VRAIN Corporation of Martinsville, Virginia, (Ex. 2: 17) disagreed with OSHA's proposal and believes that the devices were originally prohibited for safety reasons. VRAIN believes the standard should be left "as is," in spite of the inconvenience. However, VRAIN provided no additional information or substantiating data on these points.

OSHA has considered the potential problems discussed by these commenters. However, OSHA concurs with NFPA's determination that the use of an approved latch-open device in combination with a properly operating automatic-closing nozzle does not pose a significant risk of fire or explosion. This is particularly true in comparison to the risk posed by the use of unapproved, makeshift devices which can prevent the automatic-closing feature of the nozzle from being activated. Further, the smoking hazard cited by Captain Meyer would appear to be at least as serious, if not more so, where the customer is holding the gasoline nozzle than it is when the latch-open device is used. This is because the latch-open device makes it unnecessary for the customer to stand over the gasoline nozzle, thus minimizing any potential fire or explosion hazard if the customer is smoking. (Of course, fire codes uniformly forbid smoking wherever flammable liquids such as gasoline are pumped, as does § 1910.106(g)(8) of the OSHA standards.)

One objection to the proposal discussed a unique situation in which the use of latch-open devices might pose a different, more significant hazard. This objection concerned the increased use of "pay before you pump" stations. At these stations, a customer pays for a pre-determined dollar amount of gasoline before it is pumped. If the tank is not filled by that amount of gasoline, the shut-off of gasoline flow is provided not by the automatic-closing nozzle, but by the pre-set dollar amount. This operation creates an unusual problem in the use of latch-open devices as was noted with particular concern in the comments submitted by Texaco, Inc. (Ex. 2: 21). Texaco strongly believes that the ban on latch-open devices should not be rescinded for "pay before you pump" stations. Texaco's opposition is premised on the following circumstances:

In "pay before you pump" stations, the customer pays for the gasoline before filling the vehicle. The dispenser pump or valve is operated from the console in the service station office near the service island. If the dispenser hose nozzle were to be equipped with a latch-open device and the device was engaged, the latch-open would not automatically disengage when the predetermined amount of the product had been dispensed. Texaco points out that the customer could then replace the nozzle on the pump with the latch-open device still engaged. Subsequently, when the next customer arrived and paid for a delivery, the service station attendant would then activate the pump from the console with the latch-open engaged. According to Texaco, the flow would start immediately, spraying the consumer, the dispenser, and the dispensing area with gasoline. With the potential for ignition sources around the

service station, the spilled gasoline would constitute a potential fire hazard. Texaco believes that the use of latch-open devices in this context would create a serious hazard, exposing employees to possible injury or death.

OSHA appreciates Texaco's concern and as a result of their comment, has considered the potential for such a scenario to occur. OSHA believes that while such an event is possible, the necessary sequence of events is complicated and its probability of occurrence is low. For example, approved nozzles with latch-open devices are designed and installed so that normal operation of the nozzle will disengage the latch-open device when the nozzle is removed from the fill tube. The normal grasping action and force of the hand on a dispensing nozzle lever when removing the nozzle is sufficient to disengage the latch. Unless the consumer intentionally avoids the natural grasp of the nozzle, the possibility of the latch failing to release is extremely low. Moreover, the lifting of the ban does not mandate the use of latch-open devices, but rather permits the use or non-use at the discretion of the owner. Presumably, Texaco could instruct its owner operators to not use the devices.

The Occupational Safety and Health Act provides for promulgation of safety standards that provide safe and healthful workplaces for employees. Current OSHA standards control sources of ignition in service stations (§ 1910.106(g)(8)), and OSHA believes that these provisions are adequate to minimize employee exposure to potential fire hazards from the use of latch-open devices in "pay before you pump" stations as well. In this regard, it should be emphasized that the standards, as revised, will not make the use of latch-open devices mandatory, but will merely make them permissible. The final decision as to whether these devices will be installed and used will be made by the employer along with State and local authorities.

IV. Regulatory Analysis Assessment

In its NPRM of March 30, 1982, OSHA concluded, based upon the criteria established in Executive Order No. 12291 (46 FR 13193) and the criteria developed by the Department of Labor, that the proposal would not be a "Major" action. Since the final rule is unchanged from the proposal, this determination is unchanged with regard to the final rule being published today.

In addition, OSHA issued a certification pursuant to the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601 et seq.), that the proposal would not have a significant economic impact on a substantial number of small entities. The grounds for this certification of the proposal are equally applicable to today's final rule. OSHA believes that since approximately 90% of the 190,000 retail service stations in the nation employ less than ten (10) employees, the economic effects of this rule are not significant. OSHA also believes that the final rule will reduce regulatory burdens on business and on the public in general by eliminating two standards which are unrelated to and unnecessary for employee safety.

V. List of Index Terms in 29 CFR Part 1910

Fire prevention, Flammable materials, Gases, Hazardous materials, Occupational safety and health, Safety.

VI. Authority

This document was prepared under the direction of Thorne G. Auchter, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Ave., N.W., Washington, D.C. 20210.

For the reasons set forth above and pursuant to section 6(b) of the Occupational Safety and Health Act of 1970 (84 Stat. 1593, 29 U.S.C. 655), Secretary of Labor's Order No. 876 (41 FR 25059), and 29 CFR Part 1911, Part 1910 of Title 29 of the Code of Federal Regulations is amended as follows:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

1. Paragraph (g)(2) of § 1910.106 is removed.

2. Paragraph (g)(3)(vi) of § 1910.106 is revised to read as follows:

§ 1910.106 Flammable and combustible liquids.

* * * * *

(g) *Service stations.* * * *

(3) *Dispensing systems.* * * *

(vi) *Delivery nozzles.* (*a*) A listed manual or automatic-closing type hose nozzle valve shall be provided on dispensers used for the dispensing of Class I liquids.

(*b*) Manual-closing type valves shall be held open manually during dispensing. Automatic-closing type valves may be used in conjunction with an approved latch-open device.

* * * * *

Signed at Washington, D.C., this 1st day of September, 1982.

Thorne G. Auchter,

Assistant Secretary of Labor.

[FR Doc. 82–24543 Filed 9–3–82; 8:45 am]

BILLING CODE 4510–26–M

29 CFR Part 1952

Certification of Completion of Developmental Steps for Puerto Rico State Plan

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Final rule.

SUMMARY: Puerto Rico on or before August 14, 1980, submitted documentation attesting to the completion of all structural and developmental aspects of its approved State occupational safety and health plan. After extensive review and opportunity for State correction, all developmental plan supplements have now been approved. This notice certifies this completion and the beginning of the 18(e) evaluation phase of State plan development. This certification attests only to the fact that Puerto Rico now has in place those structural components necessary for an effective program. It does not render judgment, either positively or negatively, on the adequacy of the State's actual performance. In addition, although State plan commitments on staffing and resources have been met, these initial commitments may not be interpreted as meeting the ultimate requirements of the Occupational Safety and Health Act of 1970 for "sufficient staff" as redefined by the U.S. Court of Appeals decision in "AFL–CIO v. Marshall", 570 F.2d 1030 (1978).

EFFECTIVE DATE: September 7, 1982.

FOR FURTHER INFORMATION CONTACT: Dorothy J. Johnson/John D. Smith, Project Officers, Office of State Programs, Occupational Safety and Health Administration, Room N3619, 200 Constitution Avenue, N.W., Washington, D.C. 20210, (202) 523–8045.

SUPPLEMENTARY INFORMATION:

Background

Section 18 of the Occupational Safety and Health Act of 1970 (hereinafter called the Act) (29 U.S.C. 667) provides that States which desire to assume responsibility for the development and enforcement of occupational safety and health standards shall submit for Federal approval a State plan for such development and enforcement. Part 1902 of Title 29, Code of Federal Regulations sets forth procedures under which the Assistant Secretary of Labor for Occupational Safety and Health (hereinafter called the Assistant Secretary) shall approve such plans. Under the Act and regulations, plan approval is essentially a two-step procedure. A State must first submit its

plan for initial determination under section 18(b) of the Act. If the Assistant Secretary, after reviewing the State's submission, determines that the plan satisfies or will satisfy the criteria set forth in section 18 (c) of the Act, a decision of "initial approval" is issued and the State may begin enforcement of its safety and health standards in accordance with the plan and with concurrent enforcement by the Occupational Safety and Health Administration (OSHA).

A State plan may receive initial approval even though at the time of submission not all essential components of the plan are in place. As provided at 29 CFR 1902.2(b), the Assistant Secretary may initially approve the submission as a "developmental plan" and a schedule within which the State must complete specified "developmental steps" is issued as part of the initial approval decision.

When the Assistant Secretary finds that the State has completed all developmental steps specified in the initial approval decision, a notice of such completion is published in the **Federal Register** (see 29 CFR 1902.34 and 1902.35). Certification of completion of developmental steps initiates a thorough evaluation of the State plan by the Assistant Secretary to determine, on the basis of actual operations, whether the plan adequately protects the safety and health of the State's workers. Certification does not render judgment as to the adequacy of State performance.

The second step of the approval process is final approval of the plan under section 18(e) of the Act and 29 CFR Part 1902. Final approval of the plan may not be granted until at least three years after initial approval and until at least one year after completion of developmental steps. Thereafter, when the Assistant Secretary determines on the basis of actual performance under the plan that the Act's criteria are being applied, a decision of final approval may be granted. This decision is based on a thorough evaluation of the State plan under section 18(e) of the Act and reflects a determination that on the basis of actual operations the plan adequately protects the safety and health of the State's workers. In making this evaluation under section 18(e), the Assistant Secretary must monitor the continuing development of the State program applying criteria which assure that the State will have an at least as effective program for achieving the goals of the Act, except with respect to staffing and funding levels, which must reflect a fully effective program pursuant to "AFL–CIO v. Marshall", 570 F. 2d 1030 (1978).

On August 30, 1977, a notice was published in the **Federal Register** (42 FR 43628) of initial approval of the developmental Puerto Rico plan and the adoption of Subpart FF of Part 1952 containing the decision, a description of the plan and the developmental schedule. During the three year period ending August 14, 1980, the Secretary of Labor and Human Resources, Department of Labor, Puerto Rico, submitted documentation attesting to the completion of each State developmental commitment for review and approval as provided in 29 CFR Part 1953. Following Agency review and subsequent explanation and modification of the State's submissions as deemed appropriate, the Assistant Secretary has approved the completion of all individual Puerto Rico developmental steps.

Completion of Developmental Steps

All developmental steps specified in the August 30, 1977 notice of initial approval have been completed as follows:

(a) In accordance with 29 CFR 1952.383(a), position descriptions of Puerto Rico State plan personnel were approved by the Assistant Secretary on June 11, 1982 (47 FR 25327).

(b) In accordance with 29 CFR 1952.383(b), Puerto Rico's public information program for the private sector was approved by the Assistant Secretary on June 11, 1982 (47 FR 25327).

(c) In accordance with 29 CFR 1952.383(c), Puerto Rico's analysis for inspection scheduling in the private sector was approved by the Assistant Secretary on June 11, 1982 (47 FR 25327).

(d) In accordance with 29 CFR 1952.383(d), Puerto Rico's administrative regulations were approved by the Assistant Secretary on June 11, 1982 (47 FR 25327).

(e) In accordance with 29 CFR 1952.383(e), Puerto Rico's affirmative action plan was approved by the Assistant Secretary on June 11, 1982 (47 FR 25327).

(f) In accordance with 29 CFR 1952.383(f), Puerto Rico standards identical to Federal standards have been promulgated, subsequently amended to reflect changes in and additions to Federal standards, and approved by the Regional Administrator on July 14, 1978 (43 FR 37233), June 18, 1979 (44 FR 71470), June 12, 1979 (44 FR 33751), April 17, 1979 (44 FR 22830), and October 23, 1981 (46 FR 52060).

(g) In accordance with 29 CFR 1952.383(g), Puerto Rico's adoption of the Federal OSHA Field Operations Manual was approved by the Assistant Secretary on June 11, 1982 (47 FR 25327).

(h) In accordance with 29 CFR 1952.383(h), Puerto Rico's participation in the Federal OSHA Management Information System was approved by the Assistant Secretary on June 11, 1982 (47 FR 25327).

(i) In accordance with 29 CFR 1952.383(i), Puerto Rico's internal training schedule was approved by the Assistant Secretary on June 11, 1982 (47 FR 25327).

(j) In accordance with 29 CFR 1952.383(j), Puerto Rico's employer/employee training schedule was approved by the Assistant Secretary on June 11, 1982 (47 FR 25327).

(k) In accordance with 29 CFR 1952.383(k), Puerto Rico's public information program for the government sector was approved by the Assistant Secretary on June 11, 1982 (47 FR 25327).

(l) In accordance with 29 CFR 1952.383(l), Puerto Rico's analysis for inspection scheduling in the government sector was approved by the Assistant Secretary on June 11, 1982 (47 FR 25327).

(m) In accordance with 29 CFR 1952.383(m), Puerto Rico's implementation of its public employee program was approved by the Assistant Secretary on June 11, 1982 (47 FR 25327).

(n) In accordance with 29 CFR 1952.383(n), Puerto Rico's on-site consultation regulations were approved by the Assistant Secretary on June 11, 1982 (47 FR 25327).

(o) In accordance with 29 CFR 1952.383(o), Puerto Rico's industrial hygiene laboratory was approved by the Assistant Secretary on June 11, 1982 (47 FR 25327).

(p) In accordance with 29 CFR 1952.383(p), Puerto Rico's safety and health posters for private and public employment were approved by the Assistant Secretary on July 2, 1979 (44 FR 41427).

(q) In accordance with 29 CFR 1952.383(q), Puerto Rico submitted its boiler and elevator program on November 28, 1979. Puerto Rico's subsequent deletion of the boiler and elevator program from its plan, as recommended by OSHA, was approved by the Assistant Secretary on June 11, 1982 (47 FR 25327).

(r) In accordance with 29 CFR 1952,383(r), Puerto Rico's meeting of staffing levels set out in its plan for the on-site consultation program and the industrial hygiene laboratory and the deletion of staffing for the boiler and elevator program were approved by the Assistant Secretary on June 11, 1982 (47 FR 25327).

This certification covers all occupational safety and health issues covered under the Federal program, as well as the State's program covering State and local government employees, except all industries included within the classification of Marine Cargo Handling (SIC 4463) and Shipbuilding and Repairing (SIC 3713).

Location of the plan and its Supplements for Inspection and Copying

A copy of the approved supplements along with the approved plan may be inspected and copied during normal business hours at the following locations:

Office of State Programs, Occupational Safety and Health Administration, Room N3619, 200 Constitution Avenue, N.W., Washington, D.C. 20210

Office of the Regional Administrator, Occupational Safety and Health Administration, 1515 Broadway (1 Astor Plaza) Room 3445, New York, New York 10036

Puerto Rico Department of Labor, Prudencio Rivera Martinez Building, 505 Munoz Rivera Avenue, Hato Rey, Puerto Rico 00918

Effect of Certification

The Puerto Rico plan is certified effective September 7, 1982, as having completed all developmental steps on or before August 14, 1980. This certification attests to structural completion, but does not render judgment on adequacy of performance.

The Puerto Rico occupational safety and health program will be monitored and evaluated for a period of not less than one year after publication of the certification to determine whether the State program in operation provides for an effective program of enforcement including the requirement set out in "AFL–CIO v. Marshall" cited above. The Assistant Secretary will then determine whether Federal authority should be withdrawn with respect to issues covered by the plan pursuant to section 18(e) of the Act.

Level of Federal Enforcement

In accordance with 29 CFR 1902.35 Federal enforcement authority under sections 5(a)(2), 8, 9, 10, 13, and 17 of the Act (29 U.S.C. 654(a)(2), 657, 658, 659, 662, and 666) and Federal standards authority under section 6 of the Act (29 U.S.C. 655) will not be relinquished during the evaluation period. However, under the terms of an operational status agreement entered into between OSHA and the Puerto Rico Department of Labor and Human Resources effective December 8, 1981, the exercise of this authority will continue to be limited to, among other things: complaints about employee discrimination; enforcement of new Federal standards including temporary emergency standards until adopted by the State, enforcement of standards in areas excluded from plan coverage; investigations for fulfillment of monitoring obligations under sections 18 (e) and (f) of the Act; and abatement dates from OSHA-issued citations, which extend beyond the date of State assumption of inspection responsibility. Pursuant to 29 CFR 1953.3(f)(1) the agreement provides for resumption of Federal enforcement activity for failure to substantially comply with the provisions of the agreement or as a result of evaluation or other factors.

Public Participation

Under 29 CFR 1953.2(c), the Assistant Secretary may prescribe alternative procedures to expedite the review process or for other good cause which may be consistent with applicable laws. The Assistant Secretary finds good cause for not publishing this certification as a proposed rule and making it effective upon publication because the State program elements described herein were adopted in accordance with State procedures including opportunity for public comment; further public participation is therefore unnecessary.

List of Subjects in 29 CFR Part 1952

Intergovernmental relations, Law enforcement, Occupational safety and health.

PART 1952—APPROVED STATE PLANS FOR ENFORCEMENT OF STATE STANDARDS

In accordance with this certification 29 CFR 1952.383 is hereby amended to reflect successful completion of the developmental period by changing the title of the section and by adding a paragraph (s) as follows:

§ 1952.383 Completion of developmental steps and certification.

* * * * *

(s) In accordance with § 1902.34 of this Chapter, the Puerto Rico occupational safety and health plan was certified effective September 7, 1982, as having completed all developmental steps specified in the plan as approved on August 15, 1977 on or before August 14, 1980. This certification attests to structural completion, but does not render judgment on adequacy of performance.

(Sec. 18, Pub. L. 91–596, 84 Stat. 1608 (29 U.S.C. 667).

Signed at Hato Rey, Puerto Rico, this 5th day of August 1982.

Mark D. Cowan,

Deputy Assistant Secretary.

[FR Doc. 82–24497 Filed 9–3–82; 8:45 am]

BILLING CODE 4510–26–M

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 724

Naval Discharge Review Board; Standards for Discharge Review; Amendment

AGENCY: Department of the Navy, DoD.

ACTION: Final rule.

SUMMARY: Pursuant to the July 16, 1982, order of the United States District Court for the District of Columbia in *Walters* v. *Secretary of Defense* (Civil Action No. 81–0962), the procedure for the Naval Discharge Review Board is amended. The amendment sets forth the standards and procedures to be used in the review of less than honorable discharges that were issued as the result of an administrative proceeding in which the Navy or the Marine Corps introduced evidence developed by or as a result of compelled urinalysis testing administered for the purpose of identifying drug abusers.

EFFECTIVE DATE: The amendment is effective as of August 23, 1982, and will apply to all applications pending before the Naval Discharge Review Board on that date, as well as to new applications.

FOR FURTHER INFORMATION CONTACT: LCOL Stephen A. Bamberger, USMC, Legal Advisor, Naval Discharge Review Board, Room 905, Ballston #2, Arlington, VA, 22203, Telephone number (202) 696–4366.

SUPPLEMENTARY INFORMATION: Pursuant to the authority cited below, the Department of the Navy amends 32 CFR Part 724. Inasmuch as the United States District Court for the District of Columbia has ordered the Department of the Navy to publish this final rule without latitude as to its contents, it has been determined that invitation of public comment prior to adoption under the public rulemaking provisions of 32 CFR Parts 296 and 701 is unnecessary. The Department of the Navy is presently seeking to appeal the district court order that requires promulgation of this amendment. If, as a result of the appeal,

the district court order is stayed, modified, or vacated, this rule may be revised or revoked, and actions taken on applications submitted pursuant thereto may be modified or reversed.

List of Subjects in 32 CFR Part 724

Administrative practice and procedures, Military personnel.

PART 724—NAVAL DISCHARGE REVIEW BOARD

Accordingly, 32 CFR Part 724 is amended as follows:

1. The authority citation for Part 724 reads as follows:

Authority: 10 U.S.C. 1553, unless otherwise noted.

2. A new § 724.904 is added to Subpart I which reads as follows:

§ 724.904 Special standards.

(a) Pursuant to the order of the United States District Court for the District of Columbia in *Walters* v. *Secretary of Defense* (Civil Action No. 81–0962), a former Navy or Marine Corps servicemember who presently possesses a less than honorable administrative discharge, which was characterized as less than honorable in an administrative proceeding in which evidence was introduced that was developed by, or as a result of, compelled urinalysis testing administered for the purpose of identifying drug abusers, is entitled to special processing.

(b) Applicants who believe that they fall within the scope of paragraph (a) of this section should place the words "CATEGORY W" in block 8, DD Form 293, Application For Review of Discharge or Dismissal From the Armed Forces of the United States. Such applications shall be reviewed expeditiously by a designated official who will either cause the individual to be sent an honorable discharge certificate or will forward the application and the service personnel and medical records to the military service concerned to determine whether a new administrative proceeding should be convened to determine whether a less than honorable discharge can be justified. Applicants determined not to qualify for either of the foregoing forms of processing will have their applications forwarded to the Naval Discharge Review Board for appropriate review and action.

The action of the designated official shall not constitute an action or decision by the Naval Discharge Review Board.

Dated: September 1, 1982.

F. N. Ottie,

Lieutenant Commander, JAGC, U.S. Navy, Alternate Federal Register Liaison Officer.

[FR Doc. 82–24482 Filed 9–3–82; 8:45 am]

BILLING CODE 3810–AE–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[A–5–FRL 2182–8]

Approval and Promulgation of Implementation Plans; Indiana

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rulemaking.

SUMMARY: On March 12, 1982 (47 FR 10813), EPA conditionally approved the Lake County, Indiana State Implementation Plan (SIP) for sulfur dioxide (SO_2), including a stack height increase for the Northern Indiana Public Service Company's (NIPSCO) Mitchell Power Plant. Subsequently, NIPSCO informed EPA that increasing the stack height would endanger airplanes landing at the nearby Gary Municipal Airport. EPA reviewed the information and is rescinding its approval of the Mitchell stack height increase. Additionally, EPA is adding another condition to its previous conditional approval of the Lake County SIP. The condition is that Indiana must address the Mitchell stack height issue in Indiana's responses to EPA conditional approval for the Lake County SIP.

DATE: This action is effective November 8, 1982, unless notice is received within 30 days that someone wishes to submit adverse or critical comments.

ADDRESSES: Copies of the materials relating to this rulemaking are available for inspection at the following addresses: (It is recommended that you telephone Robert B. Miller at (312) 886–6031 before visiting the Region V Office).

The Office of the Federal Register, 1100 L Street, N.W., Rm. 8401, Washington, D.C. 20408

Air Programs Branch (5AP–11), 230 South Dearborn Street, Chicago, Illinois 60604

Environmental Protection Agency, Public Information Reference Unit, 401 M Street, S.W., Washington, D.C. 20460

Indiana Air Pollution Control Division, Indiana State Board of Health, 1330 West Michigan Street, Indianapolis, Indiana 46206

Written comments should be sent to: Gary Gulezian, Chief, Regulatory Analysis Section, Air Programs Branch (5AP–11), Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Robert B. Miller, Air Programs Branch, Environmental Protection Agency, Region V, Chicago, Illinois 60604, (312) 886–6031.

SUPPLEMENTARY INFORMATION: Under Section 107 of the Clean Air Act (CAA), EPA has designated certain areas in Indiana as not attaining National Ambient Air Quality Standards (NAAQS) for SO_2. See 43 FR 8962 (March 3, 1978) and 43 FR 45993 (October 5, 1978). For these areas, Part D of the CAA requires that the State revise its SIP to provide for attaining the primary SO_2 NAAQS by December 31, 1982. These SIP revisions must also provide for attaining the secondary NAAQS as soon as practicable. The requirements for an approvable SIP are described in a "General Preamble" for Part D rulemakings published at 44 FR 20372 (April 4, 1979), 44 FR 38583 (July 2, 1979), 44 FR 50371 (August 28, 1979), 44 FR 53761 (September 17, 1979), and 44 FR 67182 (November 23, 1979).

The Lake County SO_2 SIP strategy was developed by the Lake County Task Force using computer dispersion modeling. This strategy was adopted by the State of Indiana and, on June 26, 1979, was submitted to EPA as a revision to Indiana's SIP. EPA reviewed these revisions and proposed them for conditional approval on March 27, 1980 (45 FR 20432). In response to this proposal, on August 27, 1980 and July 16, 1981, Indiana committed itself to submit additional data and regulations, if necessary, to fulfill EPA's conditions. At a later date Indiana agreed to meet its commitments by November 1982. EPA reviewed Indiana's commitments and the comments received in response to EPA's notice of proposed rulemaking, and on March 12, 1982, EPA conditionally approved the Lake County SO_2 plan as meeting the requirements of Part D of the Clean Air Act (47 FR 10813). Additionally, EPA proposed on March 12, 1982 to approve the November 1982 date by which Indiana committed itself to fulfill the conditions (47 FR 10860). EPA will take final rulemaking at a later time on the date by which Indiana committed itself to respond to the Part D SO_2 conditions.

Indiana's strategy for Lake County includes an increase in the NIPSCO Mitchell Station's stacks from 71.9 meters to 104 meters and on a status quo emission limitation of 1.2 pounds of SO_2 per million British Thermal Units (lbs/

MMBTU). Because the strategy is based on these assumptions, a change in either of them would require the strategy to be reexamined to assure that the NAAQS remain protected.

Subsequent to EPA's conditional approval of the Lake County SO_2 plan, NIPSCO informed EPA on April 26, 1982, that the stack height increase for NIPSCO's Mitchell Station could conflict with Federal Aviation Administration Regulations (14 CFR Part 77) and the City of Gary Zoning Ordinances. EPA has examined the potential for conflict and rescinds its approval of the stack height increase at Mitchell Station. EPA's action on the stack height does not affect its approval of Mitchell Station's 1.2 lbs/MMBTU emission limitation.

EPA's March 12, 1982 conditional approval of the Lake County strategy is based on the requirement that the State submit additional data; including a determination that the 24-hour strategy is constraining, a justification of the background level, a revised emission inventory, and an adequate receptor network. Additionally, if in the State's analysis of these additional data the State determines that change in its regulations are necessary, the State has committed itself to revise its regulations and submit them to EPA as a revision to the SIP. Indiana has informed EPA that Lake County currently is being reanalyzed to meet the above conditions. Because the present Mitchell Station stack height may require changes in the Lake County strategy, EPA is adding a condition to its previous conditional approval of the Lake County strategy that the State must address the Mitchell Station stack height in its revised analysis of Lake County. EPA proposed on March 12, 1982 that the Lake County reanalysis is due by November 1982. This proposal is still applicable, and EPA will take final action on the date by which the conditions must be fulfilled in a future **Federal Register** notice. For a discussion of conditional approvals and their practical effect, see 44 FR 38583 (July 2, 1979) and 43 FR 67182 (November 23, 1979).

Because EPA considers today's action noncontroversial, we are approving it today without prior proposal. The action will become effective 60 days from the date of this notice. However, if we receive notice by 30 days from the date of this notice that someone wishes to submit critical comments, then EPA will publish a notice that (1) withdraws EPA's final action and (2) begins a new rulemaking by proposing the action and establishing a comment period.

Under 5 U.S.C. 605(b), the Administrator has certified that SIP approvals do not have a significant economic impact on a substantial number of small entities. (See 46 FR 8709).

Under Executive Order 12291, today's action is not "Major". It has been submitted to the Office of Management and Budget (OMB) for review.

Under Section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit within 60 days of today. This action may not be challenged later in proceedings to enforce its requirements. (See sec. 307(b)(2).)

List of Subjects in 40 CFR Part 52

Air pollution control, Ozone, Sulfur oxides, Nitrogen dioxide, Lead, Particulate matter, Carbon monoxide, Hydrocarbons, Intergovernmental relations.

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

(Sec. 110 and 172 of the Clean Air Act, as amended (42 U.S.C. 7410 and 7502))

Dated: August 24, 1982.

John W. Hernandez, Jr.,

Acting Administrator.

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Indiana

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

1. Section 52.770 is amended by revising paragraph (c)(19) as follows:

§ 52.770 Identification of plan.

* * * * *

(c) * * *

(19) On June 26, 1979, the Governor submitted a revised sulfur dioxide strategy, including regulation APC 13 with appendix, which was promulgated by the State on June 19, 1979 for all areas of the State. This included the Part D sulfur dioxide regulations for Lake, LaPorte, and Marion Counties. On August 27, 1980 and July 16, 1981 the State committed itself to correct conditionally approved items within their strategy. On October 6, 1980, the State submitted a recodified version of APC 13 which was promulgated by the State on August 27, 1980. This included 325 IAC 7, 325 IAC 1.1–6, 325 IAC 1.1–7–2 and 4, 325 IAC 12–5–1 and 2(a), 325 IAC 12–9–1 and 4, and 325 IAC 12–18–1 and 2. EPA is not taking action on: (1) 325 IAC 7 as it applies to Floyd and Vigo Counties, (2) the 30-day averaging compliance method contained in 325 IAC 7–1–3, and (3) the Mitchell Station stack height provision in the Lake County SO_2 strategy.

* * * * *

2. Section 52.795 is amended by revising paragraph (e)(1) as follows:

§ 52.795 Control strategy: Sulfur dioxide.

* * * * *

(e) * * *

(1) Lake County—The plan must either contain an acceptable demonstration that the 24-hour standard is the constraining standard or 3-hour and annual attainment analyses must be provided. The plan must justify appropriate SO_2 background levels for all averaging periods. These must be used in all analyses. The plan must contain a complete emission inventory, including process sources. This inventory must be appropriately used in all analyses. Adequate receptor resolution must be used in the attainment analyses. The plan must be based on NIPSCO Mitchell Station's existing stack height. If revisions to the Lake County limitations are necessary, they must be submitted as revisions to the SIP.

* * * * *

[FR Doc 82-24456 Filed 9-3-82; 8:45 am]

BILLING CODE 6560-50-M

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40 CFR Part 61

[AD-FRL-2070-8]

Appendix B; Test Methods; Revised Methods 106 and 107; and Appendix C, Quality Assurance Procedures 1 and 2; Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Revised Test Methods 106 and 107 for vinyl chloride were proposed in the **Federal Register** on November 18, 1980 (45 FR 76346). This action promulgates the revised test methods. The intended effect of this action is to require all sources of vinyl chloride specified to conduct emission tests under Subparts A and F of 40 CFR Part 61 to hereafter (see effective date below) use these methods for determining compliance.

Appendix C, Quality Assurance Procedures 1 and 2, was proposed in the **Federal Register** on April 18, 1980 (45 FR 26682). This action promulgates

Procedures 1 and 2 of Appendix C. The intended effect of Procedure 1 is to provide a method for determination of gas chromatograph (GC) column resolution, and the intended effect of Procedure 2 is to provide a method for auditing GC sample analysis.

EFFECTIVE DATE: September 7, 1982.

Under Section 307(b)(1) of the Clean Air Act, judicial review of this rulemaking 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 Clean Air Act, the requirements that are the subject of today's notice may not be challenged later in civil or criminal proceedings brought by EPA to enforce these requirements.

ADDRESSES: *Summary of Comments and Responses.* The summary of comments and responses for the proposed test methods may be obtained from the U. S. EPA Library (MD–35), Research Triangle Park, North Carolina 27711, telephone number (919) 541–2777. Please refer to "Revised Test Methods 106 and 107—Summary of Comments and Responses, EPA 450/3–82–002." The document contains (1) a summary of the changes made to the test methods since proposal and (2) a summary of all the public comments made on the proposed revised methods and the Administrator's responses to the comments.

Docket. A docket, number A–80–50, containing information considered by EPA in the development of the test methods and docket number OAQPS 79–3 Part 2 that contains background information pertaining to Appendix C are available for public inspection between 8:00 a.m. and 4:00 p.m., Monday through Friday, at EPA's Central Docket Section (A–130), West Tower Lobby, Gallery 1, 401 M Street, S.W., Washington, D.C. 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Roger T. Shigehara, Emission Measurement Branch, Emission Standards and Engineering Division (MD–19), U. S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone (919) 541–2237.

Public Participation

The revised test methods were proposed and published in the **Federal Register** on November 18, 1980 (45 FR 76346). Public comments were solicited at the time of proposal. The public comment period was from November 18, 1980, to January 19, 1981, with an extension to February 19, 1981.

Five comment letters were received concerning issues relative to the proposed test methods. The comments have been carefully considered; and where determined to be appropriate by the Administrator, changes have been made in the proposed revisions to the test methods.

Procedures 1 and 2 of Appendix C were proposed and published in the **Federal Register** April 18, 1980 (45 FR 26660). Public comments were solicited at the time of proposal. The public comment period was from April 18, 1980, to August 21, 1980.

No comment letters were received.

Significant Comments and Changes to the Proposed Test Methods

Comments on the proposed revisions to the test methods were received from industry, industry counsel, engineering firms, and equipment manufacturers. A detailed discussion of these comments and responses can be found in the summary of comments and responses which is referred to in the **ADDRESSES** section of this preamble. The summary of comments and responses serves as the basis for the revisions which have been made to the test methods between proposal and promulgation. The major comments and responses are summarized in this preamble. Most of the comment letters contained multiple comments. The comments have been divided into the following areas:

Proposal of Revised Test Methods 106 and 107

One commenter felt that EPA should publish a notice in the **Federal Register** to clarify the November 18, 1980, notice on Test Methods 106 and 107 (45 FR 76346) as to whether the changes in the methods were proposed or final amendments. The EPA considered the suggestion to be reasonable; and a notice was published in the **Federal Register** on January 6, 1981 (46 FR 1318) to clarify that the changes in Methods 106 and 107 published on November 18, 1980, were proposed changes.

Sample Analysis Procedure—Method 106

One commenter suggested that Section 7.2.2, Preparation of Chromatograph Calibration Curve, be changed to require calibration at least once every 8 hours of continuous operation of the chromatograph, whereas the method requires daily calibration. The EPA has decided it would be an unnecessary burden to arbitrarily set 8 hours as a cutoff point for valid calibration. However, the comment has identified the need for instruction in the method as to the use of multiple calibration curves in data interpretation, and Section 7.2.2 has been revised to provide that instruction.

One commenter questioned the use of Figure 106–2 because it appeared to illustrate a standards preparation procedure different from the one described in the method. Figure 106–2 did illustrate a different sample preparation procedure and has been deleted from the method.

Sample Collection and Analysis Procedure—Method 107

One commenter questioned the need for the sample prepressurization procedure that is included in the revised test method. The Agency believes the prepressurization procedure is valid as prepressurization of sample vials prior to analysis has been shown to produce k_p values which agree with theoretical values. A paper describing a study of this technique has been added to the bibliography section of the method as an aid in the use of this procedure.

Quality Assurance—Method 106

One commenter requested that Section 5.2.4, Audit Cylinder Standards, further describe commercial gas manufacturers as an alternative source of these standards. The Agency considered the request to be reasonable, and Section 5.2.4 has been revised to define the acceptability of audit cylinders obtained from commercial gas manufacturers.

Docket

The docket is an organized and complete file of all the information considered by EPA in the development of this rulemaking. The docket is a dynamic file, since material is added throughout the rulemaking development. The docketing system is intended to allow members of the public and industries involved to readily identify and locate documents so that they can intelligently and effectively participate in the rulemaking process. Along with the statement of basis and purpose of the proposed and promulgated test methods and 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)].

Miscellaneous

This rulemaking does not impose any additional emission measurement requirements on facilities affected by this rulemaking. Rather, this rulemaking revises the test methods to which the

affected facilities are already subject. The revisions do not affect the present emission standards. If future standards impose emission measurement requirements, the impacts of the revised test methods promulgated today will be evaluated during development of those standards.

Under Executive Order 12291, EPA must judge whether a regulation is "major" and, therefore, subject to the requirement of a regulatory impact analysis. This regulation is not major because it will not have an annual effect on the economy of $100 million or more; it will not result in a major increase in costs or prices; and there will be no significant effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The regulation was submitted to the Office of Management and Budget for review as required by Executive Order 12291.

Pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that the attached rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 40 CFR Part 61

Air pollution control, Asbestos, Beryllium, Hazardous materials, Mercury, Vinyl chloride.

(Secs. 112, 114, 301(a) of the Clean Air Act, as amended (42 U.S.C. 7412, 7414, 7601(a))

Dated: August 24, 1982.

John W. Hernandez,

Acting Administrator.

PART 61—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS

40 CFR Part 61 is amended by revising Test Methods 106 and 107 of Appendix B to read as follows:

Appendix B—Test Methods

* * * * *

Method 106—Determination of Vinyl Chloride From Stationary Sources

Introduction

Performance of this method should not be attempted by persons unfamiliar with the operation of a gas chromatograph (GC) nor by those who are unfamiliar with source sampling, because knowledge beyond the scope of this presentation is required. Care must be exercised to prevent exposure of sampling personnel to vinyl chloride, a carcinogen.

1. Applicability and Principle

1.1 Applicability. The method is applicable to the measurement of vinyl chloride in stack gases from ethylene dichloride, vinyl chloride, and polyvinyl chloride manufacturing processes. The method does not measure vinyl chloride contained in particulate matter.

1.2 Principle. An integrated bag sample of stack gas containing vinyl chloride (chloroethene) is subjected to GC analysis using a flame ionization detector (FID).

2. Range and Sensitivity

This method is designed for the 0.1 to 50 ppm range. However, common GC instruments are capable of detecting 0.02 ppm vinyl chloride. With proper calibration, the upper limit may be extended as needed.

3. Interferences

The chromatographic columns and the corresponding operating parameters herein described normally provide an adequate resolution of vinyl chloride; however, resolution interferences may be encountered on some sources. Therefore, the chromatograph operator shall select the column and operating parameters best suited to his particular analysis requirements, subject to the approval of the Administrator. Approval is automatic, provided that the tester produces confirming data through an adequate supplemental analytical technique, such as analysis with a different column or GC/mass spectroscopy, and has the data available for review by the Administrator.

4. Apparatus

4.1 Sampling (see Figure 106–1). The sampling train consists of the following components:

4.1.1 Probe. Stainless steel, Pyrex glass, or Teflon tubing (as stack temperature permits) equipped with a glass wool plug to remove particulate matter.

4.1.2 Sample Lines. Teflon, 6.4-mm outside diameter, of sufficient length to connect probe to bag. Use a new unused piece for each series of bag samples that constitutes an emission test, and discard upon completion of the test.

4.1.3 Quick Connects. Stainless steel, male (2) and female (2), with ball checks (one pair without), located as shown in Figure 106–1.

4.1.4 Tedlar Bags. 50- to 100-liter capacity, to contain sample. Aluminized Mylar bags may be used if the samples are analyzed within 24 hours of collection.

4.1.5 Bag Containers. Rigid leak-proof containers for sample bags, with covering to protect contents from sunlight.

4.1.6 Needle Valve. To adjust sample flow rates.

4.1.7 Pump. Leak-free, with minimum of 2-liter/min capacity.

4.1.8 Charcoal Tube. To prevent admission of vinyl chloride and other organics to the atmosphere in the vicinity of samplers.

4.1.9 Flowmeter. For observing sampling flow rate; capable of measuring a flow range from 0.10 to 1.00 liter/min.

4.1.10 Connecting Tubing. Teflon, 6.4-mm outside diameter, to assemble sampling train (Figure 106–1).

4.1.11 Tubing Fittings and Connectors. Teflon or stainless steel, to assemble sampling train.

4.2 Sample Recovery. Teflon tubing, 6.4-mm outside diameter, to connect bag to GC sample loop for sample recovery. Use a new unused piece for each series of bag samples that constitutes an emission test, and discard upon conclusion of analysis of those bags.

4.3 Analysis. The following equipment is required:

4.3.1 Gas Chromatograph. With FID, potentiometric strip chart recorder and 1.0- to 5.0-ml heated sampling loop in automatic sample valve. The chromatographic system shall be capable of producing a response to 0.1-ppm vinyl chloride that is at least as great as the average noise level. (Response is measured from the average value of the base line to the maximum of the wave form, while standard operating conditions are in use.)

4.3.2 Chromatographic Columns. Columns as listed below. The analyst may use other columns provided that the precision and accuracy of the analysis of vinyl chloride standards are not impaired and he has available for review information confirming that there is adequate resolution of the vinyl chloride peak. (Adequate resolution is defined as an area overlap of not more than 10 percent of the vinyl chloride peak by an interferent peak. Calculation of area overlap is explained in Appendix C, Procedure 1: "Determination of Adequate Chromatographic Peak Resolution.")

4.3.2.1 Column A. Stainless steel, 2.0 m by 3.2 mm, containing 80/100-mesh Chromasorb 102.

4.3.2.2 Column B. Stainless steel, 2.0 m by 3.2 mm, containing 20 percent GE SF-96 on 60/80-mesh Chromasorb P AW; or stainless steel, 1.0 m by 3.2 mm containing 80/100-mesh Porapak T. Column B is required as a secondary column if acetaldehyde is present. If used, column B is placed after column A. The combined columns should be operated at 120° C.

4.3.3 Flowmeters (2). Rotameter type, 100-ml/min capacity, with flow control valves.

4.3.4 Gas Regulators. For required gas cylinders.

4.3.5 Thermometer. Accurate to 1° C, to measure temperature of heated sample loop at time of sample injection.

4.3.6 Barometer. Accurate to 5 mm Hg, to measure atmospheric pressure around GC during sample analysis.

4.3.7 Pump. Leak-free, with minimum of 100-ml/min capacity.

4.3.8 Recorder. Strip chart type, optionally equipped with either disc or electronic integrator.

4.3.9 Planimeter. Optional, in place of disc or electronic integrator on recorder, to measure chromatograph peak areas.

4.4 Calibration. Sections 4.4.2 through 4.4.4 are for the optional procedure in Section 7.1.

4.4.1 Tubing. Teflon, 6.4-mm outside diameter, separate pieces marked for each calibration concentration.

4.4.2 Tedlar Bags. Sixteen-inch-square size, with valve; separate bag marked for each calibration concentration.

4.4.3 Syringes. 0.5-ml and 50-μl, gas tight, individually calibrated to dispense gaseous vinyl chloride.

4.4.4 Dry Gas Meter, with Temperature and Pressure Gauges. Singer model DTM–115 with 802 index, or equivalent, to meter nitrogen in preparation of standard gas mixtures, calibrated at the flow rate used to prepare standards.

5. Reagents

Use only reagents that are of chromatograph grade.

5.1 Analysis. The following are required for analysis.

5.1.1 Helium or Nitrogen. Zero grade, for chromatographic carrier gas.

5.1.2 Hydrogen. Zero grade.

5.1.3 Oxygen or Air. Zero grade, as required by the detector.

5.2 Calibration. Use one of the following options: either 5.2.1 and 5.2.2, or 5.2.3.

5.2.1 Vinyl Chloride. Pure vinyl chloride gas certified by the manufacturer to contain a minimum of 99.9 percent vinyl chloride, for use in the preparation of standard gas mixtures in Section 7.1. If the gas manufacturer maintains a bulk cylinder supply of 99.9+ percent vinyl chloride, the certification analysis may have been performed on this supply rather than on each gas cylinder prepared from this bulk supply. The date of gas cylinder preparation and the certified analysis must have been affixed to the cylinder before shipment from the gas manufacturer to the buyer.

5.2.2 Nitrogen. Zero grade, for preparation of standard gas mixtures as described in Section 7.1.

5.2.3 Cylinder Standards (3). Gas mixture standards (50-, 10-, and 5-ppm vinyl chloride in nitrogen cylinders). The tester may use cylinder standards to directly prepare a chromatograph calibration curve as described in Section 7.2.2, if the following conditions are met: (a) The manufacturer certifies the gas composition with an accuracy of ±3 percent or better (see Section 5.2.3.1). (b) The manufacturer recommends a maximum shelf life over which the gas concentration does not change by greater than ±5 percent from the certified value. (c) The manufacturer affixes the date of gas cylinder preparation, certified vinyl chloride concentration, and recommended maximum shelf life to the cylinder before shipment to the buyer.

5.2.3.1 Cylinder Standards Certification. The manufacturer shall certify the concentration of vinyl chloride in nitrogen in each cylinder by (a) directly analyzing each cylinder and (b) calibrating his analytical procedure on the day of cylinder analysis. To calibrate his analytical procedure, the manufacturer shall use, as a minimum, a three-point calibration curve. It is recommended that the manufacturer maintain (1) a high-concentration calibration standard (between 50 and 100 ppm) to prepare his calibration curve by an appropriate dilution technique and (2) a low-concentration calibration standard (between 5 and 10 ppm) to verify the dilution technique used. If the difference between the apparent concentration read from the calibration curve and the true concentration assigned to the low-concentration calibration standard exceeds 5 percent of the true concentration, the manufacturer shall determine the source of error and correct it, then repeat the three-point calibration.

5.2.3.2 Verification of Manufacturer's Calibration Standards. Before using a standard, the manufacturer shall verify each calibration standard (a) by comparing it to gas mixtures prepared (with 99 mole percent vinyl chloride) in accordance with the procedure described in Section 7.1 or (b) calibrating it against vinyl chloride cylinder Standard Reference Materials (SRM's) prepared by the National Bureau of Standards, if such SRM's are available. The agreement between the initially determined concentration value and the verification concentration value must be within ±5 percent. The manufacturer must reverify all calibration standards on a time interval consistent with the shelf life of the cylinder standards sold.

5.2.4 Audit Cylinder Standards (2). Gas mixture standards with concentrations known only to the person supervising the analysis of samples. The audit cylinder standards shall be identically prepared as those in Section 5.2.3 (vinyl chloride in nitrogen cylinders). The concentrations of the audit cylinder should be: one low-concentration cylinder in the range of 5 to 20 ppm vinyl chloride and one high-concentration cylinder in the range of 20 to 50 ppm. When available, the tester may obtain audit cylinders by contacting: Environmental Protection Agency, Environmental Monitoring Systems Laboratory, Quality Assurance Division (MD–77), Research Triangle Park, North Carolina 27711. Audit cylinders obtained from a commercial gas manufacturer may be used provided: (a) the gas manufacturer certifies the audit cylinder as described in Section 5.2.3.1, and (b) the gas manufacturer obtains an independent analysis of the audit cylinders to verify this analysis. Independent analysis is defined here to mean analysis performed by an individual different than the individual who performs the gas manufacturer's analysis, while using calibration standards and analysis equipment different from those used for the gas manufacturer's analysis. Verification is complete and acceptable when the independent analysis concentration is within ±5 percent of the gas manufacturer's concentration.

6. Procedure

6.1 Sampling. Assemble the sample train as shown in Figure 106–1. A bag leak check should have been performed previously according to Section 7.3.2. Join the quick connects as illustrated, and determine that all connection between the bag and the probe are tight. Place the end of the probe at the centroid of the stack and start the pump with the needle valve adjusted to yield a flow that will fill over 50 percent of bag volume in the specific sample period. After allowing sufficient time to purge the line several times, change the vacuum line from the container to the bag and evacuate the bag until the rotameter indicates no flow. Then reposition the sample and vacuum lines and begin the actual sampling, keeping the rate proportional to the stack velocity. At all times, direct the gas exiting the rotameter away from sampling personnel. At the end of the sample period, shut off the pump, disconnect the sample line from the bag, and disconnect the vacuum line from the bag container. Protect the bag container from sunlight.

6.2 Sample storage. Keep the sample bags out of direct sunlight. When at all possible, analysis is to be performed within 24 hours, but in no case in excess of 72 hours of sample collection. Aluminized Mylar bag samples must be analyzed within 24 hours.

6.3 Sample Recovery. With a new piece of Teflon tubing identified for that bag, connect a bag inlet valve to the gas chromatograph sample valve. Switch the valve to receive gas from the bag through the sample loop. Arrange the equipment so the sample gas passes from the sample valve to 100-ml/min rotameter with flow control valve followd by a charcoal tube and a 1-in. H_2O pressure gauge. The tester may maintain the sample flow either by a vacuum pump or container pressurization if the collection bag remains in the rigid container. After sample loop purging is ceased, allow the pressure gauge to return to zero before activating the gas sampling valve.

6.4 Analysis. Set the column temperature to 100° C and the detector temperature to 150° C. When optimum hydrogen and oxygen flow rates have been determined, verify and maintain these flow rates during all chromatography operations. Using zero helium or nitrogen as the carrier gas, establish a flow rate in the range consistent with the manufacturer's requirements for satisfactory detector operation. A flow rate of approximately 40 ml/min should produce adequate separations. Observe the base line periodically and determine that the noise level has stabilized and that base line drift has ceased. Purge the sample loop for 30 seconds at the rate of 100 ml/min, shut off flow, allow the sample loop pressure to reach atmospheric pressure as indicated by the H_2O manometer, then activate the sample valve. Record the injection time (the position of the pen on the chart at the time of sample injection), sample number, sample loop temperature, column temperature, carrier gas flow rate, chart speed, and attenuator setting. Record the barometeric pressure. From the chart, note the peak having the retention time corresponding to vinyl chloride as determined in Section 7.2.1. Measure the vinyl chloride peak area, A_m, by use of a disc integrator, electronic integrator, or a planimeter. Measure and record the peak heights, H_m. Record A_m and retention time. Repeat the injection at least two times or until two consecutive values for the total area of the vinyl chloride peak do not vary more than 5 percent. Use the average value for these two total areas to compute the bag concentration.

Compare the ratio of H_m to A_m for the vinyl chloride sample with the same ratio for the standard peak that is closest in height. If these ratios differ by more than 10 percent, the vinyl chloride peak may not be pure (possibly acetaldehyde is present) and the secondary column should be employed (see Section 4.3.2.2).

6.5 Determination of Bag Water Vapor Content. Measure the ambient temperature

and barometric pressure near the bag. From a water saturation vapor pressure table, determine and record the water vapor content of the bag as a decimal figure. (Assume the relative humidity to be 100 percent unless a lesser value is known.)

7. Preparation of Standard Gas Mixtures, Calibration, and Quality Assurance

7.1 Preparation of Vinyl Chloride Standard Gas Mixtures. (Optional Procedure—delete if cylinder standards are used.) Evacuate a 16-inch square Tedlar bag that has passed a leak check (described in Section 7.3.2) and meter in 5.0 liters of nitrogen. While the bag is filling, use the 0.5-ml syringe to inject 250 μl of 99.9+ percent vinyl chloride gas through the wall of the bag. Upon withdrawing the syringe, immediately cover the resulting hole with a piece of adhesive tape. The bag now contains a vinyl chloride concentration of 50 ppm. In a like manner use the 50 μl syringe to prepare gas mixtures having 10- and 5-ppm vinyl chloride concentrations. Place each bag on a smooth surface and alternately depress opposite sides of the bag 50 times to further mix the gases. These gas mixture standards may be used for 10 days from the date of preparation, after which time new gas mixtures must be prepared. (Caution: Contamination may be a problem when a bag is reused if the new gas mixture standard is a lower concentration than the previous gas mixture standard.)

7.2 Calibration.

7.2.1 Determination of Vinyl Chloride Retention Time. (This section can be performed simultaneously with Section 7.2.2.) Establish chromatograph conditions identical with those in Section 6.4 above. Determine proper attenuator position. Flush the sampling loop with zero helium or nitrogen and activate the sample valve. Record the injection time, sample loop temperature, column temperature, carrier gas flow rate, chart speed, and attenuator setting. Record peaks and detector responses that occur in the absence of vinyl chloride. Maintain conditions with the equipment plumbing arranged identically to Section 6.3, and flush the sample loop for 30 seconds at the rate of 100 ml/min with one of the vinyl chloride calibration mixtures. Then activate the sample valve. Record the injection time. Select the peak that corresponds to vinyl chloride. Measure the distance on the chart from the injection time to the time at which the peak maximum occurs. This quantity divided by the chart speed is defined as the retention time. Since other organics may be present in the sample, positive identification of the vinyl chloride peak must be made.

7.2.2 Preparation of Chromatograph Calibration Curve. Make a GC measurement of each gas mixture standard (described in Section 5.2.3 or 7.1) using conditions identical with those listed in Sections 6.3 and 6.4. Flush the sampling loop for 30 seconds at the rate of 100 ml/min with one of the standard mixtures, and activate the sample valve. Record the concentration of vinyl chloride injected (C_c), attenuator setting, chart speed, peak area, sample loop temperature, column temperature, carrier gas flow rate, and retention time. Record the barometric pressure. Calculate A_c, the peak area multiplied by the attenuator setting. Repeat until two consecutive injection areas are within 5 percent, then plot the average of those two values versus C_c. When the other standard gas mixtures have been similarly analyzed and plotted, draw a straight line through the points derived by the least squares method. Perform calibration daily, or before and after the analysis of each emission test set of bag samples, whichever is more frequent. For each group of sample analyses, use the average of the two calibration curves which bracket that group to determine the respective sample concentrations. If the two calibration curves differ by more than 5 percent from their mean value, then report the final results by both calibration curves.

7.3 Quality Assurance.

7.3.1 Analysis Audit. Immediately after the preparation of the calibration curve and prior to the sample analyses, perform the analysis audit described in Appendix C, Procedure 2: "Procedure for Field Auditing GC Analysis."

7.3.2 Bag Leak Checks. Checking of bags for leaks is required after bag use and strongly recommended before bag use. After each use, connect a water manometer and pressurize the bag to 5 to 10 cm H_2O (2 to 4 in. H_2O). Allow to stand for 10 min. Any displacement in the water manometer indicates a leak. Also, check the rigid container for leaks in this manner. (Note: An alternative leak check method is to pressurize the bag to 5 to 10 cm H_2O and allow it to stand overnight. A deflated bag indicates a leak.) For each sample bag in its rigid container, place a rotameter in line between the bag and the pump inlet. Evacuate the bag. Failure of the rotameter to register zero flow when the bag appears to be empty indicates a leak.

8. *Calculations.*

8.1 Determine the sample peak area, A_c, as follows:

$$A_c = A_m A_f \qquad \text{Eq. 106-1}$$

Where:

A_m = Measured peak area.

A_f = Attenuation factor.

8.2 Vinyl Chloride Concentrations. From the calibration curves described in Section 7.2.2, determine the average concentration value of vinyl chloride, C_c, that corresponds to A_c, the sample peak area. Calculate the concentration of vinyl chloride in the bag, C_b, as follows:

$$C_b = \frac{C_c P_r T_i}{P_i T_r (1 - B_{wb})} \qquad \text{Eq. 106-2}$$

Where:

P_r = Reference pressure, the laboratory pressure recorded during calibration, mm Hg.

T_i = Sample loop temperature on the absolute scale at the time of analysis, °K.

P_i = Laboratory pressure at time of analysis, mm Hg.

T_r = Reference temperature, the sample loop temperature recorded during calibration, °K.

B_{wb} = Water vapor content of the bag sample, as analyzed.

9. *Bibliography.*

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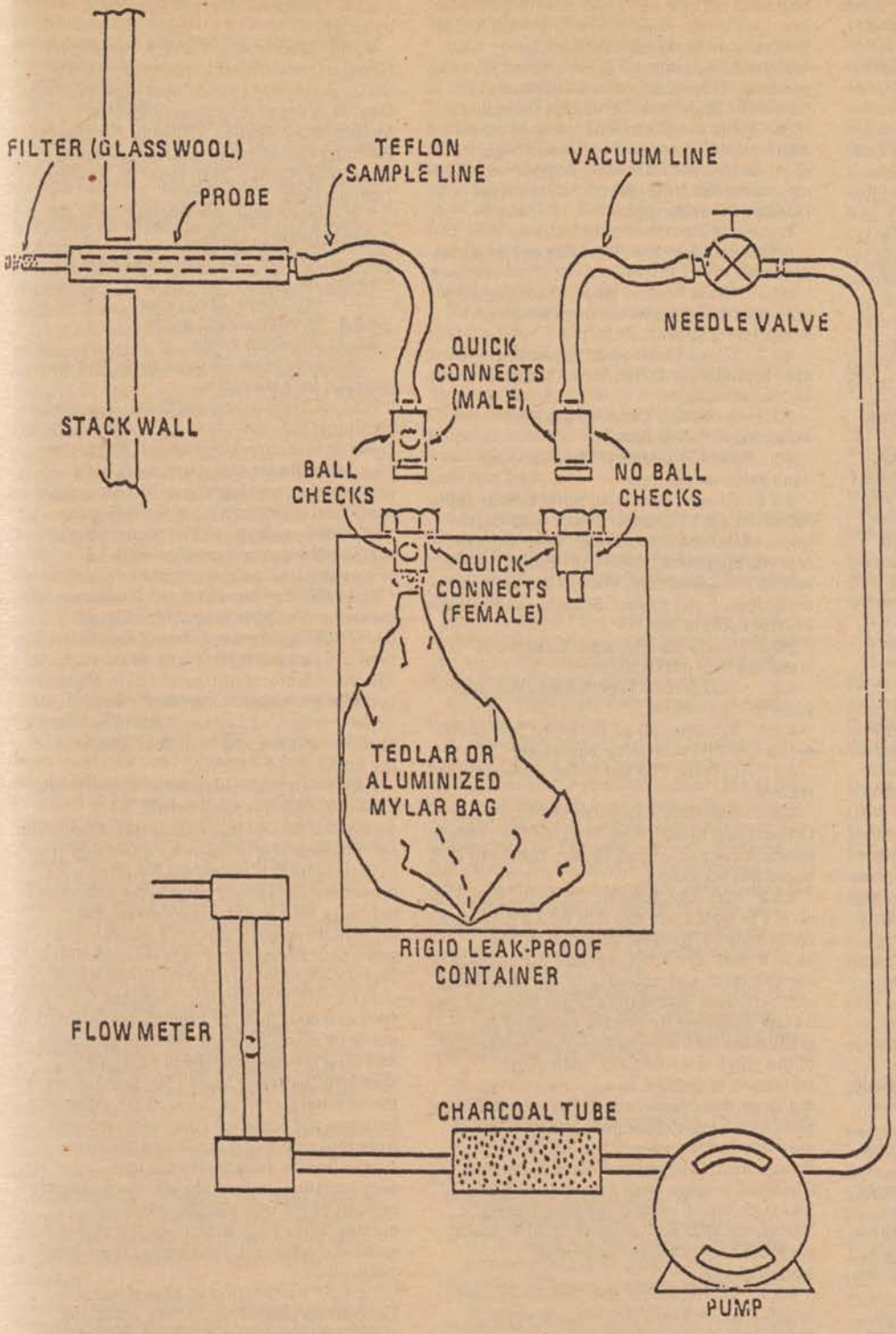


Figure 106-1. Integrated-bag sampling train. (Mention of trade names or specific products does not constitute endorsement by the Environmental Protection Agency.)

Method 107—Determination of Vinyl Chloride Content of Inprocess Wastewater Samples, and Vinyl Chloride Content of Polyvinyl Chloride Resin, Slurry, Wet Cake, and Latex Samples

Introduction

Performance of this method should not be attempted by persons unfamiliar with the operation of a gas chromatograph (GC), nor by those who are unfamiliar with source sampling, because knowledge beyond the scope of this presentation is required. Care must be exercised to prevent exposure of sampling personnel to vinyl chloride, a carcinogen.

1. *Applicability and Principle.*

1.1 Applicability. This method applies to the measurement of the vinyl chloride monomer (VCM) content of inprocess wastewater samples, and the residual vinyl chloride monomer (RVCM) content of polyvinyl chloride (PVC) resins, wet cake, slurry, and latex samples. It cannot be used for polymer in fused forms, such as sheet or cubes. This method is not acceptable where methods from Section 304(h) of the Clean Water Act, 33 U.S.C. 1251 et seq. (the Federal Water Pollution Control Amendments of 1972 as amended by the Clean Water Act of 1977) are required.

1.2 Principle. The basis for this method relates to the vapor equilibrium that is established between RVCM, PVC resin, water, and air in a closed system. The RVCM in a PVC resin will equilibrate rapidly in a closed vessel, provided that the temperature of the PVC resin is maintained above the glass transition temperature of that specific resin.

2. Range and Sensitivity. The lower limit of detection of vinyl chloride will vary according to the chromatograph used. Values reported include 1×10^{-7} mg and 4×10^{-7} mg. With proper calibration, the upper limit may be extended as needed.

3. *Interferences.* The chromatograph columns and the corresponding operating parameters herein described normally provide an adequate resolution of vinyl chloride; however, resolution interferences may be encountered on some sources. Therefore, the chromatograph operator shall select the column and operating parameters best suited to his particular analysis requirements, subject to the approval of the Administrator. Approval is automatic provided that the tester produces confirming data through an adequate supplemental analytical technique, such as analysis with a different column or GC/mass spectroscopy, and has the data available for review by the Administrator.

4. *Precision and Reproducibility.* An interlaboratory comparison between seven laboratories of three resin samples, each split into three parts, yielded a standard deviation of 2.63 percent for a sample with a mean of 2.09 ppm, 4.16 percent for a sample with a mean of 1.66 ppm, and 5.29 percent for a sample with a mean of 62.66 ppm.

5. *Safety.* Do not release vinyl chloride to the laboratory atmosphere during preparation of standards. Venting or purging with VCM/air mixtures must be held to a minimum. When they are required, the vapor must be routed to outside air. Vinyl chloride, even at low ppm levels, must never be vented inside the laboratory. After vials have been analyzed, the gas must be vented prior to removal of the vial from the instrument turntable. Vials must be vented through a hypodermic needle connected to an activated charcoal tube to prevent release of vinyl chloride into the laboratory atmosphere. The charcoal must be replaced prior to vinyl chloride breakthrough.

6. *Apparatus.*

6.1 Sampling. The following equipment is required:

6.1.1 Glass bottles. 60-ml (2-oz) capacity, with wax-lined screw-on tops, for PVC samples.

6.1.2 Glass Vials. 50-ml capacity Hypo-vial, sealed with Teflon faced Tuf-Bond discs, for water samples.

6.1.3 Adhesive Tape. To prevent loosening of bottle tops.

6.2 Sample Recovery. The following equipment is required:

6.2.1 Glass Vials. With butyl rubber septa, Perkin-Elmer Corporation Nos. 0105–0129 (glass vials), B001–0728 (gray butyl rubber septum, plug style), 0105–0131 (butyl rubber septa), or equivalents. The seals must be made from butyl rubber. Silicone rubber seals are not acceptable.

6.2.2 Analytical Balance. Capable of weighing to ±0.0001 gram.

6.2.3 Vial Sealer. Perkin-Elmer No. 105–0106, or equivalent.

6.2.4 Syringe. 100-μl capacity, precision series "A" No. 010025, or equivalent.

6.3 Analysis. The following equipment is required:

6.3.1 Gas Chromatograph. Perkin-Elmer Corporation Model F–40, F–42, or F–45 Head-Space Analyzer, or equivalent. Equipped with backflush accessory.

6.3.2 Chromatographic Columns. Stainless steel 1 m by 3.2 mm and 2 m by 3.2 mm, both containing 50/80-mesh Porapak Q. The analyst may use other columns provided that the precision and accuracy of the analysis of vinyl chloride standards are not impaired and he has available for review information confirming that there is adequate resolution of the vinyl chloride peak. (Adequate resolution is defined as an area overlap of not more than 10 percent of the vinyl chloride peak by an interferent peak. Calculation of area overlap is explained in Appendix C, Procedure 1: "Determination of Adequate Chromatographic Peak Resolution.") Two 1.83 m columns, each containing 1 percent Carbowax 1500 on Carbopak B, have been suggested for samples containing acetaldehyde.

6.3.3 Thermometer. 0 to 100° C, accurate to ±0.1° C, Perkin-Elmer No. 105–0109, or equivalent.

6.3.4 Sample Tray Thermostat System. Perkin-Elmer No. 105–0103, or equivalent.

6.3.5 Septa. Sandwich type, for automatic dosing, 13 mm, Perkin-Elmer No. 105–1008, or equivalent.

6.3.6 Integrator-Recorder. Hewlett-Packard Model 3380A, or equivalent.

6.3.7 Filter Drier Assembly (3). Perkin-Elmer No. 2230117, or equivalent.

6.3.8 Soap Film Flowmeter. Hewlett Packard No. 0101–0113, or equivalent.

6.3.9 Regulators. For required gas cylinders.

6.3.10 Headspace Vial Pre-Pressurizer. Nitrogen pressurized hypodermic needle inside protective shield. (Blueprint available from Test Support Section, Emission Measurement Branch, Office of Air Quality Planning and Standards, Environmental Protection Agency, Mail Drop 19, Research Triangle Park, N.C. 27711.)

7. *Reagents.* Use only reagents that are of chromatographic grade.

7.1 Analysis. The following items are required for analysis:

7.1.1 Hydrogen. Zero grade.

7.1.2 Nitrogen. Zero grade.

7.1.3 Air. Zero grade.

7.2 Calibration. The following items are required for calibration:

7.2.1 Cylinder Standards (4). Gas mixture standards (50-, 500-, 2000- and 4000-ppm vinyl chloride in nitrogen cylinders). The tester may use cylinder standards to directly prepare a chromatograph calibration curve as described in Section 9.2, if the following conditions are met: (a) The manufacturer certifies the gas composition with an accuracy of ±3 percent or better (see Section 7.2.1.1). (b) The manufacturer recommends a maximum shelf life over which the gas concentration does not change by greater than ±5 percent from the certified value. (c) The manufacturer affixes the date of gas cylinder preparation, certified vinyl chloride concentration, and recommended maximum shelf life to the cylinder before shipment to the buyer.

7.2.1.1 Cylinder Standards Certification. The manufacturer shall certify the concentration of vinyl chloride in nitrogen in each cylinder by (a) directly analyzing each cylinder and (b) calibrating his analytical procedure on the day of cylinder analysis. To calibrate his analytical procedure, the manufacturer shall use, as a minimum, a 3-point calibration curve. It is recommended that the manufacturer maintain (1) a high-concentration calibration standard (between 4000 and 8000 ppm) to prepare his calibration curve by an appropriate dilution technique and (2) a low-concentration calibration standard (between 50 and 500 ppm) to verify the dilution technique used. If the difference between the apparent concentration read from the calibration curve and the true concentration assigned to the low-concentration calibration standard exceeds 5 percent of the true concentration, the manufacturer shall determine the source of error and correct it, then repeat the 3-point calibration.

7.2.1.2 Verification of Manufacturer's Calibration Standards. Before using, the manufacturer shall verify each calibration standard by (a) comparing it to gas mixtures prepared (with 99 mole percent vinyl chloride) in accordance with the procedure described in Section 7.1 of Method 106 or by (b) calibrating it against vinyl chloride cylinder Standard Reference Materials (SRM's) prepared by the National Bureau of Standards, if such SRM's are available. The agreement between the initially determined concentration value and the verification concentration value must be within +5

percent. The manufacturer must reverify all calibration standards on a time interval consistent with the shelf life of the cylinder standards sold.

8. *Procedure.*

8.1 Sampling.

8.1.1 PVC Sampling. Allow the resin or slurry to flow from a tap on the tank or silo until the tap line has been well purged. Extend and fill a 60-ml sample bottle under the tap, and immediately tighten a cap on the bottle. Wrap adhesive tape around the cap and bottle to prevent the cap from loosening. Place an identifying label on each bottle, and record the date, time, and sample location both on the bottles and in a log book.

8.1.2 Water Sampling. Prior to use, the 50-ml vials (without the discs) must be capped with aluminum foil and heated in a muffle furnace at 400° C for at least 1 hour to destroy or remove any organic matter that could interfere with analysis. At the sampling location fill the vials bubble-free to overflowing so that a convex meniscus forms at the top. The excess water is displaced as the sealing disc is carefully placed, with the Teflon side down, on the opening of the vial.

Place the aluminum seal over the disc and the neck of the vial, and crimp into place. Affix an identifying label on the bottle, and record the date, time, and sample location both on the vials and in a log book. All samples must be kept refrigerated until analyzed.

8.2 Sample Recovery. Samples must be run within 24 hours.

8.2.1 Resin Samples. The weight of the resin used must be between 3.5 and 4.5 grams. An exact weight must be obtained (±0.0001 g) for each sample. In the case of suspension resins, a volumetric cup can be prepared for holding the required amount of sample. When the cup is used, open the sample bottle, and add the cup volume of resin to the tared sample vial (tared, including septum and aluminum cap). Obtain the exact sample weight, add 100μl or about two equal drops of distilled water, and immediately seal the vial. Report this value on the data sheet; it is required for calculation of RVCM. In the case of dispersion resins, the cup cannot be used. Weigh the sample in an aluminum dish, transfer the sample to the tared vial, and accurately weigh it in the vial. After prepressurization of the samples, condition them for a minimum of 1 hour in the 90° C bath. Do not exceed 5 hours.

Note.—Some aluminum vial caps have a center section that must be removed prior to placing into sample tray. If the cap is not removed, the injection needle will be damaged.

8.2.2 Suspension Resin Slurry and Wet Cake Samples. Decant the water from a wet cake sample, and turn the sample bottle upside down onto a paper towel. Wait for the water to drain, place approximately 0.2 to 4.0 grams of the wet cake sample in a tared vial (tared, including septum and aluminum cap) and seal immediately. Then determine the sample weight (±0.0001 g). All samples must be prepressurized and then conditioned for 1 hour at 90° C. A sample of wet cake is used to determine total solids (TS). This is required for calculating the RVCM.

8.2.3 Dispersion Resin Slurry and Geon Latex Samples. The materials should not be filtered. Sample must be thoroughly mixed. Using a tared vial (tared, including septum and aluminum cap) add approximately eight drops (0.25 to 0.35 g) of slurry or latex using a medicine dropper. This should be done immediately after mixing. Seal the vial as soon as possible. Determine sample weight (±0.0001 g). After prepressurization, condition the vial for 1 hour at 90° C in the analyzer bath. Determine the TS on the slurry sample (Section 8.3.5).

8.2.4 Inprocess Wastewater Samples. Using a tared vial (tared, including septum and aluminum cap) quickly add approximately 1 cc of water using a medicine dropper. Seal the vial as soon as possible. Determine sample weight (±0.0001 g). Prepressurize the vial, and then condition for 1 to 2 hours as required at 90° C in the analyzer bath.

8.3 Analysis.

8.3.1 Preparation of Equipment. Install the chromatographic column and condition overnight at 160° C. In the first operation, Porapak columns must be purged for 1 hour at 230° C.

Do not connect the exit end of the column to the detector while conditioning. Hydrogen and air to the detector must be turned off while the column is disconnected.

8.3.1.1 Flow Rate Adjustments. Adjust flow rates as follows:

a. Nitrogen Carrier Gas. Set regulator on cylinder to read 50 psig. Set regulator on chromatograph to produce a flow rate of 30.0 cc/min. Accurately measure the flow rate at the exit end of the column using the soap film flowmeter and a stopwatch, with the oven and column at the analysis temperature. After the instrument program advances to the "B" (backflush) mode, adjust the nitrogen pressure regulator to exactly balance the nitrogen flow rate at the detector as was obtained in the "A" mode.

b. Vial Prepressurizer Nitrogen. After the nitrogen carrier is set, solve the following equation and adjust the pressure on the vial prepressurizer accordingly.

$$P = \frac{T_1}{T_2}\left[P_1 - \frac{P_{w1} - P_{w2}}{7.50}\right] - 10 \text{ k Pa}$$

Where:

T_1 = Ambient temperature, °K.

T_2 = Conditioning bath temperature, °K.

P_1 = Gas chromatograph absolute dosing pressure (analysis mode), k Pa.

P_{w1} = Water vapor pressure @ 90° C (525.8 mm Hg).

P_{w2} = Water vapor pressure @ 22° C (19.8 mm Hg).

7.50 = mm Hg per k Pa.

10 k Pa = Factor to adjust the prepressurized pressure to slightly less than the dosing pressure.

Because of gauge errors, the apparatus may over-pressurize the vial. If the vial pressure is at or higher than the dosing pressure, an audible double injection will occur. If the vial pressure is too low, errors will occur on resin samples because of inadequate time for headspace gas equilibrium. This condition can be avoided by running several standard gas samples at various pressures around the calculated pressure, and then selecting the highest pressure that does not produce a double injection. All samples and standards must be pressurized for 60 seconds using the vial prepressurizer. The vial is then placed into the 90° C conditioning bath and tested for leakage by placing a drop of water on the septum at the needle hole. A clean, burr-free needle is mandatory.

c. Burner Air Supply. Set regulator on cylinder to read 50 psig. Set regulator on chromatograph to supply air to burner at a rate between 250 and 300 cc/min. Check with bubble flowmeter.

d. Hydrogen Supply. Set regulator on cylinder to read 30 psig. Set regulator on chromatograph to supply approximately 35 ± 5 cc/min. Optimize hydrogen flow to yield the most sensitive detector response without extinguishing the flame. Check flow with bubble meter and record this flow.

8.3.1.2 Temperature Adjustments. Set temperatures as follows:

a. Oven (chromatograph column), 140° C.

b. Dosing Line, 150° C.

c. Injection Block, 170° C.

d. Sample Chamber, Water Temperature, 90° C ± 1.0° C.

8.3.1.3 Ignition of Flame Ionization Detector. Ignite the detector according to the manufacturer's instructions.

8.3.1.4 Amplifier Balance. Balance the amplifier according to the manufacturer's instructions.

8.3.2 Programming the Chromatograph. Program the chromatograph as follows:

a. I—Dosing or Injection Time. The normal setting is 2 seconds.

b. A—"Analysis Time." The normal setting is approximately 70 percent of the VCM retention time. When this timer terminates, the programmer initiates backflushing of the first column.

c. B—Backflushing Time. The normal setting is double the "analysis time."

d. W—Stabilization Time. The normal setting is 0.5 min to 1.0 min.

e. X—Number of Analyses Per Sample. The normal setting is one.

8.3.3 Preparation of Sample Turntable. Before placing any sample into turntable, be certain that the center section of the aluminum cap has been removed. All samples and standards must be pressurized for 60 seconds by using the vial prepressurizer. The numbered sample vials should be placed in the corresponding numbered positions in the turntable. Insert samples in the following order:

Position 1 and 2—Old 2000-ppm standards for conditioning. These are necessary only after the analyzer has not been used for 24 hours or longer.

Position 3—50-ppm standard, freshly prepared.

Position 4—500-ppm standard, freshly prepared.

Position 5—2000-ppm standard, freshly prepared.

Position 6—4000-ppm standard, freshly prepared.

Position 7—Sample No. 7 (This is the first sample of the day, but is given as 7 to be consistent with the turntable and the integrator printout.)

After all samples have been positioned, insert the second set of 50-, 500-, 2000-, and 4000-ppm standards. Samples, including standards, must be conditioned in the bath of 90° C for 1 hour (not to exceed 5 hours).

8.3.4 Start Chromatograph Program. When all samples, including standards, have been conditioned at 90° C for 1 hour, start the analysis program according to the manufacturer's instructions. These instructions must be carefully followed when starting and stopping a program to prevent damage to the dosing assembly.

8.3.5 Determination of TS. For wet cake, slurry, resin solution, and PVC latex samples, determine TS for each sample by accurately weighing approximately 3 to 4 grams of sample in an aluminum pan before and after placing in a draft oven (105 to 110° C). Samples must be dried to constant weight. After first weighing, return the pan to the oven for a short period of time, and then reweigh to verify complete dryness. The TS are then calculated as the final sample weight divided by initial sample weight.

9. *Calibration.* Calibration is to be performed each 8-hour period when the instrument is used. Each day, prior to running samples, the column should be conditioned by running two 2000-ppm standards from the previous day.

9.1 Preparation of Standards. Calibration standards are prepared as follows: Place 100μl or about two equal drops of distilled water in the sample vial, then fill the vial with the VCM/nitrogen standard, rapidly seat the septum, and seal with the aluminum cap. Use a ⅛-in. stainless steel line from the cylinder to the vial. Do not use rubber or tygon tubing. The sample line from the cylinder must be purged (into a properly vented hood) for several minutes prior to filling the vials. After purging, reduce the flow rate to 500 to 1000 cc/min. Place end of tubing into vial (near bottom). Position a septum on top of the vial, pressing it against the ⅛-in. filling tube to minimize the size of the vent opening. This is necessary to mimimize mixing air with the standard in the vial. Each vial is to be purged with standard for 90 seconds, during which time the filling tube is gradually slid to the top of the vial. After the 90 seconds, the tube is removed with the septum, simultaneously sealing the vial. Practice will be necessary to develop good technique. Rubber gloves should be worn during the above operations. The sealed vial must then be pressurized for 60 seconds using the vial prepressurizer. Test the vial for leakage by placing a drop of water on the septum at the needle hole.

9.2 Preparation of Chromatograph Calibration Curve.

Prepare two 50-, 500-, 2000-, and 4000-ppm standard samples. Run the calibration samples in exactly the same manner as regular samples. Plot A_s, the integrator area counts for each standard sample, versus C_c, the concentration of vinyl chloride in each standard sample. Draw a straight line through the points derived by the least squares method.

10. *Calculations.*

10.1 Response Factor. If the calibration curve described in Section 9.2 passes through zero, a response factor, R_f, may be used to compute vinyl chloride concentrations. To compute a response factor, divide any particular A_s by the corresponding C_c.

$$R_f = \frac{A_s}{C_c} \qquad \text{Eq. 107-1}$$

Where:

A_s = Chromatograph area counts of vinyl chloride for the sample.

P_a = Ambient atmospheric pressure, mm Hg.

R_f = Response factor in area counts per ppm VCM.

T_1 = Ambient laboratory temperature, °K.

M_v = Molecular weight of VCM, 62.5 g/mole.

V_g = Volume of the vapor phase, cm^3.

R = Gas constant, (62360 cm_3) (mm Hg/mole) (°K).

m = Sample weight, g.

K_p = Henry's Law Constant for VCM in PVC @ 90° C, 6.52×10^{-6} g/g/mm Hg.

If the calibration curve does not pass through zero, the calibration curve must be employed to calculate each sample concentration unless the error introduced by using a particular R_f is known.

10.2 Residual Vinyl Chloride Monomer Concentration, (C_{rvc}) or Vinyl Chloride Monomer Concentration. Calculate C_{rvc} in ppm or mg/kg as follows:

$$C_{rvc} = \frac{A_s\ P_a}{R_f\ T_1}\left[\frac{M_v\ V_g}{R\ m} + K_p\ (TS)\ T_2 + K_w\ (1 - TS)\ T_2\right] \qquad \text{Eq. 107-2}$$

Results calculated using these equations represent concentration based on the total sample. To obtain results based on dry PVC content, divide by TS.

TS = Total solids expressed as a decimal fraction.

T_2 = Equilibrium temperature, °K.

K_w = Henry's Law Constant for VCM in water @ 90° C, 7×10^{-7} g/g/mm Hg.

Assuming the following conditions are met, these values can be substituted into Equation 107-2:

P_a = 750 mm Hg.

V_g = Vial volume—sample volume (Fisher vials are 22.0 cm^3 and Perkin-Elmer vials are 21.8 cm^3).

T_1 = 23° C or 296° K.

T_2 = 90° C or 363° K.

$$C_{rvc} = \frac{A_s\ 750}{R_f\ 296}\left[\frac{65.5\left(21.8 - \frac{m(TS)}{1.36} - \frac{m(1-TS)}{0.9653}\right)}{62360\ m} + 6.25 \times 10^{-6}(TS)(363) + 7.0 \times 10^{-7}\ (1-TS)(363)\right]$$

11. *References.*

1. B.F. Goodrich, Residual Vinyl Chloride Monomer Content of Polyvinyl Chloride Resins, Latex, Wet Cake, Slurry and Water Samples. B.F. Goodrich Chemical Group Standard Test Procedure No. 1005–E. B.F. Goodrich Technical Center, Avon Lake, Ohio. October 8, 1979.

2. Berens, A.R. The Diffusion of Vinyl Chloride in Polyvinyl Chloride. ACS—Division of Polymer Chemistry, Polymer Preprints *15* (2):197. 1974.

3. Berens, A.R. The Diffusion of Vinyl Chloride in Polyvinyl Chloride. ACS—Division of Polymer Chemistry, Polymer Preprints *15* (2):203. 1974.

4. Berens, A.R., L.B. Crider, C.J. Tomanek, and J.M. Whitney. Analysis for Vinyl Chloride in PVC Powders by Head—Space Gas Chromatography. Journal of Applied Polymer Science. *19*:3169–3172. 1975.

5. Mansfield, R.A. The Evaluation of Henry's Law Constant (Kp) and Water Enhancement in the Perkin-Elmer Multifract F–40 Gas Chromatograph. B.F. Goodrich. Avon Lake, Ohio. February 10, 1978.

40 CFR Part 61 is amended by adding Appendix C as follows:

Appendix C.—Quality Assurance Procedures

* * * * *

Procedure 1—Determination of Adequate Chromatographic Peak Resolution

In this method of dealing with resolution, the extent to which one chromatographic peak overlaps another is determined.

For convenience, consider the range of the elution curve of each compound as running from -2σ to $+2\sigma$. This range is used in other resolution criteria, and it contains 95.45 percent of the area of a normal curve. If two

peaks are separated by a known distance, b, one can determine the fraction of the area of one curve that lies within the range of the other. The extent to which the elution curve of a contaminant compound overlaps the curve of a compound that is under analysis is found by integrating the contaminant curve over the limits $b-2\sigma_s$ to $b+2\sigma_s$, where σ_s is the standard deviation of the sample curve.

This calculation can be simplified in several ways. Overlap can be determined for curves of unit area; then actual areas can be introduced. Desired integration can be resolved into two integrals of the normal distribution function for which there are convenient calculation programs and tables. An example would be Program 15 in Texas Instruments Program Manual ST1, 1975, Texas Instruments, Inc., Dallas, Texas 75222.

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$$\frac{1}{\sqrt{2\Pi}\sigma_c}\int_{b-2\sigma_s}^{b+2\sigma_s} e^{\left(\frac{-t_c^2}{2\sigma_c}\right)}dt = \frac{1}{\sqrt{2\Pi}}\int_{\frac{b-2\sigma_s}{\sigma_c}}^{\infty} e^{\left(\frac{-x^2}{2}\right)}dx - \frac{1}{\sqrt{2\Pi}}\int_{\frac{b+2\sigma_s}{\sigma_c}}^{\infty} e^{\left(\frac{-x^2}{2}\right)}dx$$

The following calculation steps are required:*

1. $2\sigma_s = t_s/\sqrt{2 \ln 2}$
2. $\sigma_c = t_c/2\sqrt{2 \ln 2}$
3. $x_1 = (b-2\sigma_s)/\sigma_c$
4. $x_2 = (b+2\sigma_s)/\sigma_c$
5. $Q(x_1) = \frac{1}{\sqrt{2\Pi}}\int_{x_1}^{\infty} e^{\left(\frac{-x^2}{2}\right)}dx$
6. $Q(x_2) = \frac{1}{\sqrt{2\Pi}}\int_{x_2}^{\infty} e^{\left(\frac{-x^2}{2}\right)}dx$
7. $I_o = Q(x_1) - Q(x_2)$
8. $A_o = I_o A_c/A_s$
9. Percentage overlap = $A_o \times 100$,

where:

A_s = Area of the sample peak of interest determined by electronic integration or by the formula $A_s = h_s t_s$.

A_c = Area of the contaminant peak, determined in the same manner as A_s.

b = Distance on the chromatographic chart that separates the maxima of the two peaks.

H_s = Peak height of the sample compound of interest, measured from the average value of the baseline to the maximum of the curve.

t_s = Width of sample peak of interest at 1/2 peak height.

t_c = Width of the contaminant peak at 1/2 of peak height.

σ_s = Standard deviation of the sample compound of interest elution curve.

σ_c = Standard deviation of the contaminant elution curve.

$Q(x_1)$ = Integral of the normal distribution function from x_1 to infinity.

$Q(x_2)$ = Integral of the normal distribution function from x_2 to infinity.

I_o = Overlap integral.

A_o = Area overlap fraction.

*In most instances, $Q(x_2)$ is very small and may be neglected.

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In judging the suitability of alternate GC columns or the effects of altering chromatographic conditions, one can employ the area overlap as the resolution parameter with a specific maximum permissible value.

The use of Gaussian functions to describe chromatographic elution curves is widespread. However, some elution curves are highly asymmetric. In cases where the sample peak is followed by a contaminant that has a leading edge that rises sharply but the curve then tails off, it may be possible to define an effective width for t_c as "twice the distance from the leading edge to a perpendicular line through the maxim of the contaminant curve, measured along a perpendicular bisection of that line."

Procedure 2—Procedure for Field Auditing GC Analysis

Responsibilities of audit supervisor and analyst at the source sampling site include the following:

A. The audit supervisor verifies that audit cylinders are stored in a safe location both before and after the audit to prevent vandalism.

B. At the beginning and conclusion of the audit, the analyst records each cylinder number and pressure. An audit cylinder is never analyzed when the pressure drops below 200 psi.

C. During the audit, the analyst performs a minimum of two consecutive analyses of each audit cylinder gas. The audit must be conducted to coincide with the analysis of source test samples, normally immediately after GC calibration and prior to sample analyses.

D. At the end of audit analyses, the audit supervisor requests the calculated concentrations from the analyst and compares the results with the actual audit concentrations. If each measured concentration agrees with the respective actual concentration within ±10 percent, he directs the analyst to begin analyzing source samples. Audit supervisor judgment and/or supervisory policy determine action when agreement is not within ±10 percent. When a consistent bias in excess of 10 percent is found, it may be possible to proceed with the sample analysis, with a corrective factor to be applied to the results at a later time. However, every attempt should be made to locate the cause of the discrepancy, as it may be misleading. The audit supervisor records each cylinder number, cylinder pressure (at the end of the audit), and all calculated concentrations. The individual being audited must not under any circumstance be told actual audit concentrations until calculated concentrations have been submitted to the audit supervisor.

Field Audit Report

Part A.—To be filled out by organization supplying audit cylinders.

1. Organization supplying audit sample(s) and shipping address

_____

2. Audit supervisor, organization, and phone number

_____

_____

3. Shipping instructions: Name, Address, Attention

_____

_____

_____

4. Guaranteed arrival date for cylinders———

5. Planned shipping date for cylinders———

6. Details on audit cylinders from last analysis

	Low conc.	High conc.
a. Date of last analysis		
b. Cylinder number		
c. Cylinder pressure, psi		
d. Audit gas(es)/balance gas		
e. Audit gas(es), ppm		
f. Cylinder construction		

Part B.—To be filled out by audit supervisor.

1. Process sampled———

_____

2. Audit location———

_____

3. Name of individual audit———

4. Audit date———

5. Audit results:

	Low conc. cylinder	High conc. cylinder
a. Cylinder number		
b. Cylinder pressure before audit, psi		
c. Cylinder pressure after audit, psi		
d. Measured concentration, ppm Injection #1* Injection #2* Average		
e. Actual audit concentration, ppm (Part A, 6e)		
f. Audit accuracy:[1]		
Low Conc. Cylinder		
High Conc. Cylinder		

$$\text{Percent [1] accuracy} = \frac{\text{Measured Conc.} - \text{Actual Conc.}}{\text{Actual Conc.}} \times 100$$

g. Problems detected (if any		

[1] Results of two consecutive injections that meet the sample analysis criteria of the test method.

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BILLING CODE 6560-50-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 65

[Docket No. FEMA-6399]

List of Communities With Special Hazard Areas Under the National Flood Insurance Program

AGENCY: Federal Emergency Management Agency.

ACTION: Final rule.

SUMMARY: This rule identifies communities with areas of special flood, mudslide, or erosion hazards as authorized by the National Flood Insurance Program. The identification of such areas is to provide guidance to communities on the reduction of property losses by the adoption of appropriate flood plain management or other measures to minimize damage. It will enable communities to guide future construction, where practicable, away from locations which are threatened by flood or other hazards.

EFFECTIVE DATES: The effective date shown at the top right of the table or October 7, 1982, whichever is later.

FOR FURTHER INFORMATION CONTACT: Mr. Richard E. Sanderson, Chief, Natural Hazards Division, (200) 287-0270, 500 C Street Southwest, Donohoe Building, Room 505, Washington, DC 20472.

SUPPLEMENTARY INFORMATION: The Flood Disaster Protection Act of 1973 (Pub. L. 93-234) requires the purchase of flood insurance on and after March 2, 1974, as a condition of receiving any form of Federal or federally related financial assistance for acquisition or construction purposes in an identified flood plain area having special flood hazards that is located within any community participating in the National Flood Insurance Program.

One year after the identification of the community as flood prone, the requirement applies to all identified special flood hazard areas within the United States, so that, after the date, no such financial assistance can legally be provided for acquisition and construction in these areas unless the community has entered the program. The prohibition, however, does not apply in respect to conventional mortgage loans by federally regulated, insured, supervised, or approved lending institutions.

This 30 day period does not supersede the statutory requirement that a community, whether or not participating in the program, be given the opportunity for a period of six months to establish that it is not seriously flood prone or that such flood hazards as may have existed have been corrected by floodworks or other flood control methods. The six months period shall be considered to begin 30 days after the date of publication in the **Federal Register** or the effective date of the Flood Hazard Boundary Map, whichever is later. Similarly, the one year period a community has to enter the program under section 201(d) of the Flood Disaster Protection Act of 1973 shall be considered to begin 30 days after publication in the **Federal Register** or the effective date of the Flood Hazard Boundary Map, whichever is later.

This identification is made in accordance with Part 64 of Title 44 of the Code of Federal Regulations as

authorized by the National Flood Insurance Program (42 U.S.C. 4001–4128).

Pursuant to the provisions of 5 U.S.C. 605(b), the Associate Director, State and Local Programs and Support, to whom authority has been delegated by the Director, Federal Emergency Management Agency, hereby certifies that this rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. This rule provides routine legal notice of technical amendments made to designated special flood hazard areas on the basis of updated information or regarding the completed stages of engineering tasks in delineating the special flood hazard areas of the specified community. This rule imposes no requirements or regulation on participating communities.

List of Subjects in 44 CFR Part 65

Flood Insurance, Flood plains.

PART 65—IDENTIFICATION AND MAPPING OF SPECIAL HAZARD AREAS

Section 65.3 is amended by adding in alphabetical sequence a new entry to the table:

§ 65.3 List of communities with special hazard areas (FHBMs in effect).

BILLING CODE 6718-03-M

EFFECTIVE DATE August 6, 1982

1 STATE	2 IDENT. NUMBER	3 COMMUNITY NAME & COUNTY NAME	4 PANELS PRINTED (# AND SUFFIX)	5 INLAND/ COASTAL	6 HAZARD	7 60.3 CODE	8 PROGRAM STATUS	9 STATUS OF FHBM	9 STATUS OF FIRM	10 PREVIOUS MAP DATES FHBM	10 PREVIOUS MAP DATES FIRM	11 REVISION CODE(S)	12 RESCISSION	13 FLOODWAYS PANELS PRINTED	14 LOCATION OF MAP REPOSITORY
[1	170400	La Salle County Unincorporated Areas Index Cont'd. 0009B, thru 0012B, 0014B, 0015B & 0017B	Index 0001B thru 0004B 0006B 0007B	I	FL	B	4	3	1	5/26/78	N/A	10	N/A	N/A	Orlando Smith, Chairman County Board LaSalle County Courthouse Ottawa, IL 61350 815-434-8242
WV	540114	McDowell County Unincorporated Areas	0001A thru 0009A	I	FL	B	1	3	1	1/10/75	N/A	9 10 16	N/A	N/A	Jenning Boyd, President County Commissioners Box 967, Welch, WV 24801 304-436-6218 EFFECTIVE DATE: August 10, 1982
TX	480279	City of Memphis Hall County	0001B	I	FL	B	1	3	1	12/10/76	N/A	9 10	N/A	N/A	A. L. Gailey, Mayor 721 Robertson St. Memphis, TX 79245 806-259-2001 EFFECTIVE DATE: August 13. 1982
OK	400485	Canadian County Unincorporated Areas Index-0025A, 0050A, 0075A, 0100A, 0125A, 0150A, 0175A, 0200A & 0225A		I	FL	B	1	2	1	N/A	N/A	N/A	N/A	N/A	Troy Denwalt County Commissioner County Courthouse EL Reno, OK 73036 EFFECTIVE DATE: August 17, 1982
ID	160193	Soda Springs, City of Caribou County	0001B	I	FL	B	1	3	1	6/27/75 3/11/80	N/A	9	N/A	N/A	David H. Clegg, Mayor 9 West 2nd South Soda Springs, ID 83276 208-547-2151
MT	300183	Town of Neihart Cascade County	0001A	I	FL	B	4	2	1	N/A	N/A	N/A	N/A	N/A	Susan Paddock, Town Clerk Box 36 Neihart, MT 59465 406-235-5335

EFFECTIVE DATE August 17, 1982

1 STATE	2 IDENT. NUMBER	3 COMMUNITY NAME & COUNTY NAME	4 PANELS PRINTED (# AND SUFFIX)	5 INLAND/ COASTAL	6 HAZARD	7 60.3 CODE	8 PROGRAM STATUS	9 STATUS OF FHBM	9 STATUS OF FIRM	10 PREVIOUS MAP DATES FHBM	10 PREVIOUS MAP DATES FIRM	11 REVISION CODE(S)	12 RESCISSION	13 FLOODWAYS PANELS PRINTED	14 LOCATION OF MAP REPOSITORY
OK	400494	Pittsburg County Unincorporated Areas	0001A thru 0016A	I	FL	B	4	2	1	N/A	N/A	N/A	N/A	N/A	John Whetsel, Chairman County Commissioners Pittsburg,County Courthouse McAlester, OK 74501 918-423-1338 EFFECTIVE DATE: August 31, 1982
MT	300147	Custer County Unincorporated Areas	0014B	I	FL	B	1	3	1	6/26/79	N/A	N/A	N/A	N/A	Maurice Fleming 614 South Jordan Miles City, MT 59301 406-232-5001
WY	560085	Park County Unincorporated Areas. Index-0001B, 0002B, 0004B, 0008B thru 0012B, 0017B, 0018B, 0021B, 0024B, 0027B, 0028B, 0030B		I	FL	B	4	3	1	4/25/78	N/A	N/A	N/A	N/A	Phyllis M. Smith County Clerk, County Seat, Cody, WY 82414 307-587-2204

EFFECTIVE DATE September 7, 1982

1 STATE	2 IDENT. NUMBER	3 COMMUNITY NAME & COUNTY NAME	4 PANELS PRINTED (# AND SUFFIX)	5 INLAND/ COASTAL	6 HAZARD	7 60.3 CODE	8 PROGRAM STATUS	9 STATUS OF		10 PREVIOUS MAP DATES		11 REVISION CODE(S)	12 RESCISSION	13 FLOODWAYS PANELS PRINTED	14 LOCATION OF MAP REPOSITORY
								FHBM	FIRM	FHBM	FIRM				
CA	060703	City of Santee San Diego County	0002A	I	FL	B	1	2	1	N/A	N/A	N/A	N/A	N/A	Robert Summers, City Engin San Diego Co. Dept. of Public 5555 Overland Ave. San Diego, CA 92123 714-565-5865
ID	160136	City of Firth Bingham Co.	0001A	I	FL	B	4	2	1	N/A	N/A	N/A	N/A	N/A	Lonnie R. Bowne, Mayor P. O. Box 37 Firth, ID 83236
WA	530245	City of Dupont Pierce County	0001A	I	FL	B	4	2	1	N/A	N/A	N/A	N/A	N/A	Pola A. Andre, Mayor P. O. Box 159 Barksdale & Steilacoom Roads Dupont, WA 98327 206-964-8121
WY	560092	Town of Mountain View Uinta County	560092	I	FL	B	1	3	1	N/A	N/A	9 10	N/A	N/A	Casey Davis, Mayor P. O. Box 249 Mountain View, WY 82939
													EFFECTIVE DATE: September 10, 1982		
NC	370266	Marion, City of McDowell Co.	0005A	I	MF	B	1	2	1	N/A	N/A	N/A	N/A	N/A	James Segars, Mayor P.O. Drawer 700 City Hall Marion, NC 28752
													EFFECTIVE DATE: September 14, 1982		
ID	160205	Boise County Unincorporated Areas	0003A 0004A 0008A 0009A 0013A 0014A 0019A 0022A	I	FL	B	4	2	1	N/A	N/A	N/A	N/A	N/A	Elzie Yensen, Chairman Boise Co. Bd. of Commissioners P.O. Box 157 Idaho City, ID 83631 208-392-4431

EFFECTIVE DATE September 17, 1982

1 STATE	2 IDENT. NUMBER	3 COMMUNITY NAME & COUNTY NAME	4 PANELS PRINTED (# AND SUFFIX)	5 INLAND/ COASTAL	6 HAZARD	7 60.3 CODE	8 PROGRAM STATUS	9 STATUS OF		10 PREVIOUS MAP DATES		11 REVISION CODE(S)	12 RESCISSION	13 FLOODWAYS PANELS PRINTED	14 LOCATION OF MAP REPOSITORY
								FHBM	FIRM	FHBM	FIRM				
MD	240089	Charles County Unincorporated Areas	0001A thru 0010A	I	FL	B	1	3	1	2/7/75	N/A	9 10 16	N/A	N/A	Christopher Chinault Co. Administrator P. O. Box 8, Courthouse La Plata, MD 20646 301-654-0600
MD	240045	Kent County Unincorporated Areas	0001A thru 0008A	I	FL	B	1	3	1	4/25/75	N/A	9 10 16	N/A	N/A	Wallace Miller, President County Commissioners Courthouse Chestertown, MD 21620 301-778-4600
													EFFECTIVE DATE: September 21, 1982		
TX	481048	City of Round Rock Williamson Co.	0001B 0002B	I	FL	B	1	3	1	9/13/77	N/A	8 10	N/A	N/A	Larry L. Tonn, Mayor 214 East Main St. Round Rock, TX 78664 512-255-3612
													EFFECTIVE DATE: September 24, 1982		
VA	510201	James City County Unincorporated Areas	0001A thru 0006A	I	FL	B	1	3	1	7/18/75	N/A	9 10 16	N/A	N/A	James B. Oliver County Administrator Planning Dept. P. O. Box 3C Williamsburg, VA 23187
													EFFECTIVE DATE: September 28, 1982		
IA	190434	City of Wyoming Jones County	0001A	I	FL	B	1	3	1	11/12/76	N/A	9 10	N/A	N/A	Lyman D. Thompson, Mayor City Hall Wyoming, IA 52362 319-488-3970

BILLING CODE 6718-03-C

Community Map Actions

(Codes: Where no entry is necessary use N/A)

Column Code:

1. Two letter state designator.
2. FIA Community 6-digit identity number.
3. Community name, County(ies) name.
4. Four digit number and suffix of each FIRM or FHBM panel printed.
5. INL/COAST:
I=Inland
C=Coastal
W=Wave Height
6. Hazard:
FL=Flood
MS=Mudslide
ER=Erosion
NF=Non Flood Prone
MF=Minimally Flood Prone
7. 60.3 Code:
A=Special Hazard not defined, no elevation data (No FHBM)
B=Special Hazard Designated, no elevation data (FHBM)
C=Firm, No Floodway or Coastal High Hazard
*D=Firm, Regulatory Floodway Designated
*E=Firm, Coastal High Hazard
*Dual entry is available.
8. Program Status:
1=Emergency
2=Regular
3=Not Participating, no Map
4=Not Participating, With Map
5=Withdrew
6=Suspended
9. FHBM Status:
1=Never Mapped
2=Original
3=Revised
4=Rescinded
5=Superceded by Firm
10. Firm Status:
1=Never Mapped
2=Original
3=Revised
4=Rescinded
5=All Zone C–No Published Firm
6=All Zone A and C–No Elevations Determined
11. Dates of all previous maps.
12. Revision Codes:
1. 67 BFE (Base Flood Elevation) Decrease
2. 67 BFE Increase
3. 65 SFHA (Special Flood Hazard Area) Change
4. Change of Zone Designation; revised FIRM
5. Curvilinear
6. 64 Incorporation
7. 64 Discorporation
8. 64 Annexation
9. SFHA Reduction
10. Non-67 SFHA Increase Without Numbered Zones
11. Non 67 SFHA Increase With Numbered Zones
12. Drafting Correction; Printing Errors
13. Suffix Change ONLY
14. Change to Uniform Zone Designations (7/1/74)
15. Revisions Withdrawn
16. Refunds Possible
17. Letter of Map Amendment (70)
18. Letter of Map Amendment (70 without Federal Register publication)
19. Federal Register Ommission
20. Attention. A previous map (or maps) has been rescinded or withdrawn for this community. This may have affected the sequence of suffixes.
21. Miscellaneous
13. List of Numbered Floodway Panels Printed.
14. Address of Community Map Repository.

(National Flood Insurance Act of 1968 (title XIII of the Housing and Urban Development Act of 1968); effective Jan. 28, 1969 (33 FR 17804, Nov. 28, 1968), as amended, 42 U.S.C. 4001–4128; Executive Order 12127, 44FR 19367; and delegation of authority to the Associate Director, State and Local Programs and Support)

Issued: August 20, 1982.

Lee M. Thomas,

Associate Director, State and Local Programs and Support.

[FR Doc. 82-24378 Filed 9-3-82; 8:45 am]

BILLING CODE 6718-03-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[BC Docket No. 82-261; RM-4079]

Radio Broadcast Services; FM Broadcast Station in Soldotna, Alaska

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: Action taken herein assigns Channel 269A to Soldotna, Alaska, in response to a petition filed by Peninsular Communications, Inc. The assigned channel could provide a first FM service to Soldotna.

DATE: Effective October 26, 1982.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Mark N. Lipp, Broadcast Bureau, (202) 632–7792.

SUPPLEMENTARY INFORMATION:

List of Subjects in 47 CFR Part 73

Radio broadcasting.

In the matter of Amendment of § 73.202(b), Table of Assignments, FM Broadcast Stations. (Soldotna, Alaska); BC Docket No. 82–261, RM–4079.

Report and Order (Proceeding Terminated)

Adopted: August 18, 1982.

Released: August 26, 1982.

By the Chief, Policy and Rules Division:

1. The Commission has under consideration a notice of proposed rule making, 47 FR 22124, published May 21, 1982, proposing the assignment of Channel 269A to Soldotna, Alaska, as that community's first FM assignment in response to a petition filed by Peninsular Communications, Inc. ("petitioner"). Petitioner filed comments in support of the proposal and reaffirmed its interest in applying for the channel, if assigned. No oppositions to the proposal were received.

2. A site restriction of 2.2 miles southwest of Soldotna is necessary to meet the mileage separation for existing Station KGOT (Channel 267), Anchorage, Alaska.

3. The Commission has determined that the public interest would be served by assigning Channel 269A to Soldotna, Alaska, since it would provide that community with its first FM service.

4. Accordingly, pursuant to the authority contained in sections 4(i), 5(d)(1), 303(g) and (r) and 307(b) of the Communications Act of 1934, as amended, §§ 0.281 and 0.204(b) of the Commission's Rules, it is ordered, That effective October 26, 1982, § 73.202(b) of the Commission's Rules is amended with respect to the following community:

City	Channel
Soldotna, Alaska	269A

5. It is further ordered, That this proceeding is terminated.

6. For further information contact Mark N. Lipp, Broadcast Bureau, (202) 632–7792.

(Secs. 4, 303, 48 Stat., as amended, 1066, 1082; 47 U.S.C. 154, 303)

Federal Communications Commission.

Roderick K. Porter,

Chief, Policy and Rules Division, Broadcast Bureau.

[FR Doc. 82-24491 Filed 9-3-82; 8:45 am]

BILLING CODE 6712-01-M

INTERSTATE COMMERCE COMMISSION

49 CFR Part 1057

[Ex Parte MC 43 (Sub-7A)]

Lease and Interchange of Vehicles (Leases Involving Carrier Agents)

Decided: August 26, 1982.

AGENCY: Interstate Commerce Commission.

ACTION: Extension of effective date for final rules.

SUMMARY: By decision entered June 22, 1982, the Commission amended its leasing rules to clarify further which parties and leases are subject to them and which are not (47 FR 28396, June 30, 1982). The changes were to go into effect August 30, 1982. However, The American Movers Conference has requested an extension to December 31, 1982, of the date for compliance with new regulation 49 CFR 1057.12(n). Although the relief will be granted, further requests for extension of compliance with the new regulation will not be looked on with favor.

EFFECTIVE DATE: December 31, 1982.

FOR FURTHER INFORMATION CONTACT:
Ombudsman's Office, (202) 275–7863
Howell I. Sporn, (202) 275–7691

By the Commission, Chairman Taylor, Vice Chairman Gilliam, Commissioners Sterrett, Andre, Simmons and Gradison. Commisioner Andre concurs in the extension. Commissioner Sterrett was absent and did not participate.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82–24460 Filed 9–3–82; 8:45 am]

BILLING CODE 7035–01–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 611

[Docket No. 2827–169]

Foreign Fishing, Groundfish of the Gulf of Alaska, and Groundfish of the Bering Sea and Aleutian Islands Area

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of inseason adjustment.

SUMMARY: This document announces the apportionment of reserve amounts of Alaska groundfish that were eligible in June 1982 for apportionment to the total allowable level of foreign fishing and to the domestic annual harvest, under provisions of the fishery management plans (FMPs) for Groundfish of the Bering Sea and Aleutian Islands Area, and for the Groundfish of the Gulf of Alaska. Apportionment is prescribed by regulations implementing those FMPs. The intended effects of this action are to assure optimum use of groundfish resources and to allow the foreign and domestic fisheries to proceed without interruption to achieve optimum yield.

EFFECTIVE DATES: August 31, 1982 through December 31, 1982.

FOR FURTHER INFORMATION CONTACT:
Robert W. McVey, Director, Alaska Region National Marine Fisheries Service, 907–586–7221.

SUPPLEMENTARY INFORMATION:

Background

Optimum yields (OY) for various groundfish are established by the fishery management plan (FMP) for the Groundfish of the Bering Sea and Aleutian Islands Area and by the FMP for the Groundfish of the Gulf of Alaska. The FMPs were developed under the Magnuson Fishery Conservation and Management Act, and are implemented by rules appearing at 50 CFR 611.92 and 611.93 and 50 CFR Parts 672 and 675. The OYs are apportioned initially to domestic annual harvest (DAH), reserve, and total allowable level of foreign fishing (TALFF). Each reserve amount, in turn, is to be apportioned to DAH and/or TALFF during the fishing year, under 50 CFR 611.92(c) and 611.93(b) and 50 CFR Parts 672 and 675. In addition, portions of DAH may be apportioned to TALFF during the fishing year under those same regulations. It is under these authorities that the following reserve adjustments are made.

In April 1982, 40 percent of the initial reserves for all groundfish species in the Gulf of Alaska were apportioned to TALFF with the following exceptions (47 FR 27862). The entire pollock reserve amount in the Central Regulatory Area was apportioned to DAH. In addition, 40 percent of the reserve amounts for Pacific cod and sablefish in the Western Regulatory Area were retained.

The current action pertains to the reserve amounts eligible for apportionment in June and to reserve amounts eligible for apportionment in April that were retained in the reserve.

All groundfish reserve amounts were retained for the Bering Sea and Aleutian Islands area on the first and second scheduled dates for apportionment, February 2, 1982 (47 FR 7674), and April 2, 1982 (47 FR 27862). Those reserve amounts, together with the reserve amounts available for apportionment in June, are also the subject of the current action; hence, 75 percent of the initial reserves are now eligible for apportionment. Moreover, portions of the initial DAH are subject to apportionment by this action.

Determination of Reserve Releases

1. Bering Sea and Aleutian Islands Area

The U.S. fishing effort has been expanding in the Bering Sea and Aleutian Islands area for more than two months and this effort is expected to increase through the summer. Because substantial joint venture catches of yellowfin sole, other flounders, and Atka mackerel are expected to continue during 1982, all of the scheduled reserve amounts for these species (75 percent of the initial reserves) are retained at this time. To allow for a possible increase in the amount of pollock available for joint ventures, only 50 percent of the initial reserve amount of pollock, or 25,000 metric tons (mt), will be released to TALFF at this time. It is not anticipated that U.S. fishermen will harvest more than the current DAH amounts for all other groundfish species in the Bering Sea and Aleutian Islands area; therefore, 75 percent of the initial reserve amounts of these other groundfish species will be released to TALFF at this time (see the Table of Apportionments to TALFF).

Uncertainties as to the amounts to be taken by joint ventures and other domestic effort through the summer make it impracticable to release any portion of DAH to TALFF at this time.

2. Gulf of Alaska

Western Regulatory Area. A U.S. catcher-processor vessel has harvested large amounts of Pacific cod in the Western Regulatory Area; furthermore, a major U.S. effort to harvest Pacific cod for salt-production is expected to begin. Therefore, the entire Western Regulatory Area reserve (or 100 percent of the initial reserve amount) of Pacific cod is apportioned to the DAP component of DAH. The scheduled amount of pollock reserve and a small portion (86 mt) of the amount of sablefish reserve available for apportionment are retained to provide for possible incidental catch needs of the domestic Pacific cod fisheries. The balance of the amount of sablefish reserve available for apportionment, or 250 mt., is apportioned to TALFF at this time.

It is not anticipated that U.S. fishermen will harvest more than the initial DAH specifications for other categories of groundfish in the Western Regulatory Area. Therefore, 40 percent of the initial reserves for those other species is apportioned to TALFF (see Table of Apportionments to TALFF).

Central Regulatory Area. The entire reserve of pollock was apportioned to the JVP component of DAH in the April 1982 apportionment. It is not anticipated that U.S. fishermen will harvest more than the initial DAH specifications for the other groundfish species in the Central Regulatory Area. Therefore, 40 percent of the reserves for these species is apportioned to TALFF (see the Table of Apportionments to TALFF).

Eastern Regulatory Area. With the exception of sablefish, it is not anticipated that U.S. fishermen will harvest more than the amounts specified as initial DAH for groundfish species in the Eastern Regulatory Area. Therefore, 40 percent of the initial reserves for all species, except sablefish in the Yakutat District of the Eastern Regulatory area, is apportioned to TALFF (see the Table of Apportionments to TALFF). Fifty U.S. vessels affected by the August 2, 1982, closure of the Southeast Outside District of the Eastern Regulatory area (47 FR 33972, August 5, 1982) will be required to move west into the Yakutat District in order to continue fishing for sablefish. Accordingly, the sablefish reserves for the Yakutat District of the Eastern Regulatory Area are retained.

Gulf-Wide. It is not anticipated that U.S. fishermen will harvest more than the Gulf-wide specifications of the initial DAH for "other rockfish," thornyhead rockfish, squid, and "other species." Therefore, 40 percent of the reserve amounts for these species are apportioned to TALFF (see the Table of Apportionments to TALFF).

3. Summary Table of Apportionments to TALFF (Metric Tons)

	Bering Sea	Aleutians	Western	Central	Eastern	Gulf-wide
Pollock	25,000				1,328	
Turbots	3,375					
Pacific ocean perch	122	281	216	632	70	
Pacific cod	2,951			2,683	791	
Sablefish	262	112	250	304		
Atka mackerel			375	1,667	255	
Flounders			832	1,176	672	
Rockfish	375					608
Thornyhead rockfish						300
Squid	375					400
Other species	2,784					1,296
Subtotal	35,244	393	1,673	6,462	3,116	2,604
Total						49,492

4. Summary Table of Apportionment to DAH (Metric Tons)

Gulf of Alaska—Western Regulatory Area	Reserve amount apportioned	DAH, as adjusted	DAP, as adjusted
Pacific Cod	3,312	5,192	3,552

Response to Public Comments

In accordance with 50 CFR 611.92(c), 611.93(b), 672.20(c), and 675.20(b), recent aggregated reports were made available for public inspection regarding the level of catch and effort by U.S vessels fishing for Alaska groundfish and the amounts of U.S.-harvested groundfish processed by U.S. processors or foreign vessels. In addition, those provisions afforded the public an opportunity to submit timely comments on the extent to which U.S. vessels will harvest the Alaska groundfish reserves or DAH amounts and to which U.S. fish processors will process these amounts. No comments were received during the comment periods provided.

Classification

The apportionment to TALFF of reserve amounts of groundfish is hereby announced by amending portions of Appendix 1 to 50 CFR § 611.20, which Appendix contains current specifications of OY, DAH, DAP, JVP, DNP, reserve, and TALFF for the various fisheries. The apportionment to DAH of reserve amounts of groundfish is announced in this document without amendment to 50 CFR § 672.20, Table 1, since that Table specifies initial rather than current DAH, DAP, JVP, DNP, reserve, and TALFF amounts (as of January 1 for the relevant fishing year).

This action is taken under the authority of 50 CFR 611.92(c), 611.93(b), 672.20(c), and 675.20(b), and is taken in compliance with Executive Order 12291.

In view of the prior notice provided in the underlying regulations regarding the dates after which apportionment of reserves is to occur, together with the need to avoid disruption of United States and foreign fisheries and the obligation to afford a reasonable opportunity to achieve optimum yield, the Agency has determined that to delay the effectiveness of this rule would be impracticable, unnecessary, and contrary to the public interest.

List of Subjects in 50 CFR Part 611

Fish, Fisheries, Foreign relations, Reporting requirements.

Dated: August 30, 1982.

William G. Gordon,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

PART 611—FOREIGN FISHING

For reasons set forth in the preamble, 50 CFR Part 611 is amended as follows:

1. The authority citation for Part 611 reads as follows:

Authority: 16 U.S.C. 1801 et seq., unless otherwise noted.

§ 611.20 Appendix 1 [Amended]

2. In § 611.20, Appendix 1, the Alaska entries designated A (Bering Sea and Aleutian Islands groundfish fishery) and E (Gulf of Alaska groundfish fishery) for Alaska fisheries are revised to read as follows:

* * * * *

APPENDIX 1.—OPTIMUM YIELD (OY), DOMESTIC ANNUAL HARVEST (DAH), DOMESTIC ANNUAL PROCESSING (DAP), JOINT VENTURE PROCESSING (JVP), DOMESTIC NONPROCESSED FISH (DNP), RESERVE, AND TOTAL ALLOWABLE LEVEL OF FOREIGN FISHING (TALFF), ALL IN METRIC TONS. OY = DAH + RESERVE + TALFF. DAH = DAP + JVP + DNP

Species	Species code	Areas	OY	DAH	DAP	JVP	DNP	Reserve	TALFF
*	*	*	*	*	*	*			
A. Bering Sea and Aleutian Islands Groundfish Fishery:									
Pollock:	701								
Bering Sea[1]			1,000,000	19,550	10,000	9,050	500	25,000	955,450
Aleutians[2]			100,000	.....	.....	0	.....	.....	100,000
Yellowfin Sole	720		117,000	26,200	1,000	25,000	200	5,850	84,950
Turbots	721,118		90,000	1,075	1,000	75	.....	1,125	87,800
Other Flatfishes	129		61,000	4,200	1,000	3,000	200	3,050	53,750
Pacific Cod	702		78,700	43,265	26,000	17,065	200	984	34,451
Pacific Ocean Perch:[4]	780								
Bering Sea[1]			3,250	1,380	550	830	.....	40	1,830
Aleutians[2]			7,500	1,380	550	830	.....	94	6,026
Other Rockfish	849		7,727	1,550	1,100	450	.....	125	6,052

APPENDIX 1.—OPTIMUM YIELD (OY), DOMESTIC ANNUAL HARVEST (DAH), DOMESTIC ANNUAL PROCESSING (DAP), JOINT VENTURE PROCESSING (JVP), DOMESTIC NONPROCESSED FISH (DNP), RESERVE, AND TOTAL ALLOWABLE LEVEL OF FOREIGN FISHING (TALFF), ALL IN METRIC TONS. OY = DAH + RESERVE + TALFF. DAH = DAP + JVP + DNP—Continued

Species	Species code	Areas	OY	DAH	DAP	JVP	DNP	Reserve	TALFF
Sablefish:	703								
Bering Sea[1]			3,500	700	500	200		88	2,712
Aleutians[2]			1,500	700	500	200		38	762
Atka Mackerel	207		24,800	100	0	100		1,240	23,460
Squid	509		10,000	50	0	50		125	9,825
Other Species[3]	499		74,249	2,000	1,400	200	400	928	71,321
B. * * *									
C. * * *									
D. * * *									
E. Gulf of Alaska Groundfish Fishery:									
Pollock	701	Western [3]	57,000	5,775	25	5,750		6,840	44,385
		Central [3]	95,200	32,360	5,380	26,980		0	62,840
		Eastern [3]	16,600	2,215	695	1,520		664	13,721
		Total	168,800	40,350				7,504	120,946
Pacific Cod	702	Western	16,560	5,192	3,552	1,040	600	0	11,368
		Central	33,540	6,050	3,480	1,370	1,200	1,342	26,148
		Eastern	9,900	2,070	280	590	1,200	397	7,433
		Total	60,000	13,312				1,739	44,949
Flounders	129	Western	10,400	700	100	600		416	9,284
		Central	14,700	1,120	300	820		580	12,992
		Eastern	8,400	1,360	900	460		336	6,704
		Total	33,500	3,180				1,340	24,980
Pacific Ocean Perch[4]	780	Western	2,700	345	25	320		108	2,247
		Central	7,900	1,255	295	960		316	6,329
		Eastern	875	500	300	200		35	340
		Total	11,475	2,100				459	8,916
Other Rockfish [4]	849	Total	7,600	900	700	200		304	6,396
Sablefish [1]	703	Western	2,100	270	100	170		170	1,160
		Central	3,800	1,220	1,000	220		152	2,428
		Yakutat District [5]	3,400	1,380	1,180	200		852	1,168
		Southeast Outside [5]	3,000	2,910	2,820	90		0	90
		Total	12,300	5,780				1,174	5,346
Atka Mackerel	207	Western	4,678	290	0	290		187	4,201
		Central	20,836	1,080	0	1,080		833	18,923
		Eastern	3,186	700	0	700		127	2,359
		Total	28,700	2,070				1,147	25,483
Squid	509	Total	5,000	150	0	150		200	4,650
Other Species [3]	499	Total	16,200	1,720	300	620	800	648	13,632
Thornyhead Rockfish	749	Total	3,750	6	6	0		150	3,594
*	*	*	*	*	*	*	*	*	*

[FR Doc. 24346 Filed 8-31-82; 4:55 pm]

BILLING CODE 3510-22-M

Proposed Rules

Federal Register
Vol. 47, No. 173
Tuesday, September 7, 1982

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 82-NM-60-AD]

Airworthiness Directives: Boeing Model 707, 727C, and 727-100C Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes a new Airworthiness Directive (AD) which would require inspection and repair, if necessary, or the main cargo door structure on certain Boeing Model 707, 727C, and 727-100C series airplanes. The proposed AD is prompted by reports of skin cracking and door frame failures. Failure to detect the cracking prior to reaching critical length could result in rapid decompression or loss of a portion of the main cargo door.

DATE: Comments due November 8, 1982.

ADDRESSES: The applicable service bulletins may be obtained upon request from the Boeing Commercial Airplane Company, P.O. Box 3707, Seattle, Washington 98124. This information also may be examined at FAA Northwest Mountain Region, Seattle Area Aircraft Certification Office, 9010 East Marginal Way South, Seattle, Washington.

FOR FURTHER INFORMATION CONTACT: Mr. Don Gonder, Airframe Branch, ANM-120S, at the above address, telephone (206) 767-2516. Mailing Address: Seattle Area Aircraft Certification Office, FAA Northwest Mountain Region, 17900 Pacific Hwy. South, C-68966, Seattle, Washington 98168.

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 regulatory docket or notice number and be submitted to the address specified below. All communications received on or before the closing date for comments will be considered by the Administrator before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. 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 the proposed AD will be filed in the Rules Docket.

Availability of NPRMS

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Northwest Mountain Region, Office of the Regional Counsel, Attention: Airworthiness Rules Docket No. 82-NM-60-AD, 17900 Pacific Hwy. South, C-68966, Seattle, Washington 98168.

DISCUSSION: The Boeing Company has conducted a structural reassessment of the B-707 and B-727 airplanes as part of their program to develop a supplemental inspection document (SID) for these airplanes. In conducting this reassessment Boeing used advanced analysis techniques which were not available during the original design and certification of these airplanes and used as guidelines the requirements of FAR 25.571 (25-45). The reassessment included structural details that have a history of cracking. The analysis has revealed that certain of these details should receive increased emphasis in the maintenance program of operators to maintain the structural integrity of the airplane. The main cargo door skin is one such detail.

The FAA issued Advisory Circular AC 91-56 on May 6, 1981, which provides guidelines for the development and implementation of supplemental inspection programs for large transport category airplanes. AC 91-56 in part states "any service bulletin or other service information publications found to be essential for safety during the initial SID assessment process should be implemented by AD action."

There have been two reports of main cargo door skin cracks and frame failures on certain Boeing 707 and 727 airplanes. One report involved a cargo door skin failure along the upper portion of the main cargo door between BS 530 and BS 540 during pressurized operation at 25,000 feet. The skin failure initiated at the second row of fasteners below the door hinge. Also, the door frames at BS 540, BS 550 and BS 560 failed at the frame top lightening holes. The frame cracks were determined to be caused by a manufacturing defect; the frame cracks precipitated the skin crack. Another report involved a ten-inch crack in the door skin between the frames at BS 540 and BS 550. The door structure on the affected B-707 and B-727 models is identical.

Boeing has issued Service Bulletins No's 2999 and 727-52-79, which describe the inspection and repair procedures for the affected structure. The structural reassessment established appropriate inspection thresholds and repeat intervals necessary for detecting cracks prior to reaching critical lengths. Failure to detect cracking prior to reaching critical lengths may result in rapid decompression or loss of a portion of the main cargo door.

The FAA has determined, based on the guidelines of AC 91-56 and the structural reassessment of the B-727, that AD action for this area is required. The proposed AD would require inspection and repair, if necessary, of the main deck cargo door structure on Boeing Model 707 and 727 series airplanes.

There are approximately 147 B-707 and 81 B-727 airplanes totaling 228 airplanes of U.S. registry which would be affected by this proposal. Any one of three inspection methods (visual, eddy current or X-ray) is acceptable; however, an X-ray inspection would be the most expensive. It is estimated that a X-ray inspection would require three manhours per airplane. It is further estimated that labor would cost $40 per manhour. Based on these figures, the total labor cost impact of this AD per inspection cycle is estimated to be $29,000 if all operators elect to use the more expensive X-ray inspection method. For these reasons, the proposed rule is not considered to be a major rule under the criteria of Executive Order 12291. Few, if any, small entities within the meaning of the Regulatory Flexibility Act would be affected.

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

The Proposed Amendment

Accordingly, the Federal Aviation Administration proposes to amend § 39.13 of Part 39 of the Federal Aviation

Regulations (14 CFR 39.13) by adding the following new Airworthiness Directive:

Boeing: Applies to Boeing Model 707, 727C, and 727–100C series airplanes certified in all categories, listed in Boeing Service Bulletin Nos. 2999, Rev. 3; and 727–52–79, Rev. 4; or later FAA approved revisions.

Compliance is required as indicated, unless already accomplished.

To detect cracking of the main cargo door skin and frames and to prevent rapid decompression or loss of a portion of the door accomplish the following in accordance with Boeing Service Bulletin 2999, Rev. 3; or 727–52–79, Rev. 4, or later FAA approved revisions.

A. Within the next 500 landings after the effective date of this AD, unless accomplished within the last 500 lands, or prior to accumulating 10,000 landings, whichever occurs later, inspect for cracks in the main cargo door skin between B.S. 505 and B.S. 595 from the lower edge of the door hinge downwards a minimum of six inches, and six inches above and three inches below the center line of stringer 10. Inspect either visually or using eddy current or X-ray procedures as specified in the applicable service bulletin.

B. Repeat the inspections at intervals not to exceed one of the following until the airplane is modified in accordance with the applicable service bulletin listed in paragraph D.

1. 500 landings if visually inspected.
2. 750 landings if eddy current inspected.
3. 1,000 landings if X-ray inspected.

C. Cracks are to be repaired prior to further pressurized flight in accordance with the following service bulletins:

1. For Boeing Model 707 series airplanes: Boeing Service Bulletin No. 2999, Rev. 3, or later FAA approved revisions.

2. For Boeing Model 727 series airplanes: Boeing Service Bulletin No. 727–52–79, Rev. 4, or later FAA approved revisions.

D. Modification in accordance with Boeing Service Bulletin Nos. 2999, Revision 3; or 727–52–79, Revision 4; or later FAA approved revisions, constitutes terminating action for this AD.

E. For the purpose of this AD, and when approved by an FAA maintenance inspector, the number of landings may be computed by dividing each airplane's time-in-service by the operator's fleet average time from takeoff to landing for the aircraft type.

F. Aircraft may be ferried to a maintenance base for repair in accordance with FAR 21.197 and 21.199.

G. Alternate means of compliance which provide an equivalent level of safety may be used when approved by the Chief, Seattle Area Aircraft Certification Office, FAA Northwest Mountain Region.

The manufacturer's specification and procedures identified and described in this directive are incorporated herein and made a part hereof pursuant to 5 U.S.C. 552(a)(1).

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

(Secs. 313(a), 601 and 603, Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421, and 1423); Sec. 6(c) Department of Transportation Act (49 U.S.C. 1655(c)); and 14 CFR 11.85)

Note.—For the reasons discussed earlier in the preamble: the FAA has determined that this document (1) Involves a proposed regulation which is not major under Executive Order 12291, and (2) is not a significant rule pursuant to the Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and it is certified under the criteria of the Regulatory Flexibility Act that this proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. A regulatory evaluation has been prepared and has been placed in the public docket.

Issued in Seattle, Wash., on August 26, 1982.

Charles R. Foster,

Director, Northwest Mountain Region.

[FR Doc. 82–24189 Filed 9–3–82; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 71

[Airspace Docket No. 82–ASW–60]

Designation of Federal Airways, Area Low Routes, Controlled Airspace, and Reporting Points; Proposed Designation of Transition Area: Hampton, AR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Aviation Administration proposes to designate a transition area at Hampton, AR. The intended effect of the proposed action is to provide controlled airspace for aircraft executing a new instrument approach procedure to the Hampton Airport. This action is necessary since there is a new proposed standard instrument approach procedure (SIAP) using a nondirectional radio beacon (NDB) located on the airport.

DATE: Comments due Oct. 7, 1982.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Airspace and Procedures Branch, Air Traffic Division, Southwest Region, Federal Aviation Administration, P.O. Box 1689, Fort Worth, TX 76101.

The official docket may be examined in the Rules Docket, weekdays, except Federal holidays, between 8 a.m. and 4:30 p.m. The FAA Rules Docket is located in the Office of the Regional Counsel, Southwest, Region, Federal Aviation Administation, 4400 Blue Mound Road, Fort Worth, TX.

FOR FURTHER INFORMATION CONTACT: Kenneth L. Stephenson, Airspace and Procedures Branch, ASW–535, Air Traffic Division, Southwest Region, Federal Aviation Administration, P.O. Box 1689, Fort Worth, TX 76101; telephone: (817) 624–4911, extension 302.

SUPPLEMENTARY INFORMATION:

History

Federal Aviation Regulations Part 71, Subpart G 71.181 as republished in Advisory Circular AC 70–3 dated January 29, 1982, contains the description of transition areas designated to provide controlled airspace for the benefit of aircraft conducting instrument flight rules (IFR) activity. Designation of the transition area at Hampton, AR, will necessitate an amendment to this subpart. This amendment will be required at Hampton, AR, since there is a proposed IFR procedure to the Hampton Airport.

Comments Invited

Interested persons are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposals. (Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposal.) Communications should identify the airspace docket and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 82–ASW–60." The postcard will be date/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in the light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM

Any person may obtain a copy of this notice of proposed rulemaking (NPRM) by submitting a request to the Manager, Airspace and Procedures Branch, Air Traffic Division, Southwest Region, Federal Aviation Administration, P.O. Box 1689, Fort Worth, TX 76101, or by calling (817) 624–4911, extension 302. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should contact the office listed above.

List of Subjects in 14 CFR Part 71

Control zones, Transition areas.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the FAA proposes to amend 71.181 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71) as follows:

Hampton, AR [New]

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Hampton Airport (latitude 33°31'30"N., longitude 92°27'30"W.) and 3 miles each side of a 007° bearing from the airport to 8.5 miles north.

(Sec. 307(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a)); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); and 14 CFR 11.61(c))

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

Issued in Fort Worth, TX, on August 26, 1982.

F. E. Whitfield,

Acting Director, Southwest Region.

[FR Doc. 82-24183 Filed 9-3-82; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 922

National Marine Sanctuary Program Regulations

AGENCY: Office of Coastal Zone Management (OCZM), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule.

SUMMARY: These proposed regulations revise existing procedures for identifying and selecting potential marine sanctuary candidiates, as well as for designating these sites as national marine sanctuaries. The regulations refect a management-oriented approach to protecting special marine areas. They reflect the refinements and programmatic policies outlined in the Program Development Plan (PDP) for the National Marine Sanctuary Program (January 1982).The rules will amend existing procedures by providing greater selectivity in initially identifying and processing potential national marine sanctuaries. They are intended to reduce delay and uncertainty in the site selection and approval process.

DATES: Comments will be accepted until November 8, 1982. After the close of the comment period and review of comments received, final regulations will be published in the **Federal Register**.

ADDRESS: Send comments to: Dr. Nancy Foster, Deputy Director, Sanctuary Programs Office, Office of Coastal Zone Management, NOAA, 3300 Whitehaven Street, NW., Washington, D.C. 20235.

FOR FURTHER INFORMATION CONTACT: John Epting, (202) 634–4236.

SUPPLEMENTARY INFORMATION: NOAA is publishing revised reguations for implementing the National Marine Sanctuary Program, pursuant to Title III of the Marine Protection, Research and Sanctuaries Act, as amended in 1980, 16 U.S.C. 1431–1434, (the Act). Since its establishment in 1972, the National Marine Sanctuary Program has had a number of years of operating experience. Through this experience and considerable commentary on the Program, a number of refinedments in operational policy and procedure have been designed. These refinements are discussed at length in the PDP for the National Marine Sanctuary Program. The PDP describes the Program's mission and goals; changes in the site identification and selection criteria; the nomination and designation process; and the components and purposes of site-specific managment plans.

The proposed regulations implement these refinements, which include:

I. Adoption of the Mission and Goals for the Program

The Mission Statement and Goals for the continued implementation of the National Marine Sanctuary Program stress the importance of comprehensive long-term management. Although broad in scope, they establish a framework within which specify program activities are conducted. The Mission Statement and Goals are adopted by the revised regulations (§ 922.1).

II. Revision of the Procedures for Initially Identifying Potential Sanctuary Candidates

(A) Elimination of the List of Recommended Areas.

In regulations published on July 31, 1979 (44 FR 44531), NOAA established the List of Recommended Areas (LRA) as a means of eliminating clearly inappropriate proposals, advising the public at large of recommended sites, cataloging potentially significant marine sites, and soliciting information on those sites. The LRA, however, did not totally fulfill these purposes. Since the LRA site evaluation criteria were broad and allowed marginally acceptable nominations to qualify for further consideration, the procedure resulted in much unnecessary controversy over the Program as a whole. A great number of nominations were received, many of which were minimally acceptable, in some instances incorporating large areas of Outer Continental Shelf waters and encompassing thousands of square miles. This caused substantial confusion and concern over the status of sites on the LRA and the likelihood of further action. Even though the majority of the listed sites would never become active candidates, the LRA has often been perceived as the blueprint for the sanctuary program. These regulations elmininate the LRA process from the program, and replace it with the procedure set forth below:

(B) Establishment of a Site Evaluation List.

The Site Evaluation List (SEL) process, described in section 922.20(a), is proposed to eliminate the problems created by the LRA. Under this process, NOAA is using regional resource evaluation teams, comprised of knowledgeable scientists, to identify, evaluate, and recommend sites suitable for sanctuary consideration in accordance with redefined site identification and evaluation criteria. The criteria and methodology have been refined to focus more clearly on those sites with special resource and human use values that have a high likelihood of eventual designation. The revised criteria and an explanation of their application are provided in Appendix 1. By actively seeking sites based on sound criteria, resource data and scientific experts; and by assuring early public review at the regional level, highly-qualified marine sites can be identified. The regional resource evaluation teams recommend the final sites to NOAA; final selection for placement on the SEL will be made by NOAA and published in the **Federal Register** by March 1983.

After NOAA adopts the SEL, it will review an additional site only if it is an important new discovery of national significance. NOAA will make this determination in consultation with appropriate scientists and resource manager. If the newly discovered site is determined to be of national significance, the selection criteria

specified in Appendix I will be applied, and qualified sites will be placed on the Site Evaluation List for further evaluation as a national marine sanctuary, consistent with the procedures in § 922.21.

III. Selection of Active Candidates and the Actual Designation of Marine Sanctuaries

Selection of a site from the SEL to be an active candidate is the second step in evaluating a site for potential designation (section 922.21). Only a limited number of sites at a time will be selected as active candidates and evaluated by NOAA for possible sanctuary designation. NOAA's selection and scheduling of sites from the SEL for active candidate evaluation necessarily involves a balancing of ecological factors and relevant policy considerations including: ecological conditions, immediacy of need, timing and practicality, and public comment.

IV. Enforcement Activities

Subpart D has been revised to reflect the 1980 amendments to the Act explicitly authorizing NOAA to utilize the resources of other agencies including State agencies for enforcement purposes (section 922.30).

V. Other Actions Associated With the Notice of Final Rulemaking

(A) Classification Under Executive Order 12291.

NOAA has concluded that these regulations are not major because they will *not* result in:

(1) An annual effect on the economy of $100 million or more;

(2) A major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or

(3) Significant adverse effects on competition, employment investment, productivity, innovation or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The final rules amend existing procedures by providing greater selectivity in initially identifying and processing potential national marine sanctuaries in accordance with the recent Program Development Plan for the National Marine Sanctuary Program. These rules establish a revised process for identifying, designating, and managing national marine sanctuaries. They will not result in any direct economic or environmental effects nor will they lead to any major indirect economic or environmental impacts. They are intended to reduce delay and uncertainty in the site selection and approval process.

(B) Regular Flexibility Analysis.

A Regulatory Flexibility Analysis is not required for this notice of proposed rulemaking. The regulations set forth procedures for identifying, selecting, and, if designated, managing national marine sanctuaries. These rules do not directly affect "small government jurisdictions" as defined by Pub. L. 96–354, the Regulatory Flexibility Act, and the rules will have no effect on small businesses.

(C) Paper Work Reduction Act of 1980 (Pub. L. 96–511).

These regulations will impose no information collection requirements of the type covered by Pub. L. 96–511.

(D) National Environmental Policy Act.

NOAA has concluded that publication of the proposed rules does not constitute a major Federal action significantly affecting the quality of the human environment. Therefore, an environmental impact statement is not required.

List of Subjects in 15 CFR Part 922

Administrative practice and procedure, Environmental protection, Marine resources, Natural resources.

Dated: July 9, 1982.

William Matuszeski,

Acting Assistant Administrator for Coastal Zone Management.

(Federal Domestic Assistance Catalog Number 11.419 Coastal Zone Management Program Administration)

Accordingly, it is proposed that 15 CFR Part 922 be revised as follows:

PART 922—NATIONAL MARINE SANCTUARY PROGRAM

Subpart A—General

Sec.

922.1 Mission and goals.
922.2 Definitions.
922.10 Effect of national marine sanctuary designation.

Subpart B—Potential Sanctuary Sites

922.20 Site evaluation list.

Subpart C—Selection of Active Candidates and the Designation of National Marine Sanctuaries

922.21 Selection of active candidates.
922.22 Designation process.
922.23 Coordination with States.

Subpart D—Enforcement

922.30 Enforcement entities.
922.31 Penalties.
922.32 Notice of violation.
922.33 Enforcement hearings.
922.34 Determinations.
922.35 Final action.

Appendix 1—Selection Criteria.

Authority: Title III, Public Law 95–532, as amended, (16 U.S.C. 1431–1434).

Subpart A—General

§ 922.1 Mission and goals.

(a) The mission of the National Marine Sanctuary Program is the establishment of a system of national marine sanctuaries based on the identification, designation, and comprehensive management of special marine areas for the long-term benefit and enjoyment of the public. The goals of the Program are to carry out this mission by designating national marine sanctuaries to:

(1) Enhance resource protection through the implementation of a comprehensive, long-term management plan tailored to the specific resources;

(2) Promote and coordinate research to expand scientific knowledge of significant marine resources and improve management decisionmaking;

(3) Enhance public awareness, understanding, and wise use of the marine environment through public interpretive and recreational programs; and

(4) Provide for optimum compatible public and private use of special marine areas.

(b) The National Marine Sanctuary Program will seek maximum public participation throughout all the stages that may lead to the designation of a sanctuary.

§ 922.2 Definitions.

(a) "Act" means Title III of the Marine Protection, Research and Sanctuaries Act of 1972, as amended, 16 U.S.C. 1431–1434.

(b) "Active Candidate" means a site selected by NOAA from the Site Evaluation List for further consideration leading to possible designation.

(c) "Affected State" means any State in which a proposed marine sanctuary includes waters lying within the territorial limits of that State or superjacent to the subsoil and seabed within the seaward boundary of that coastal State.

(d) "Administrator" means the Administrator of the National Oceanic and Atmospheric Administration, United States Department of Commerce.

(e) "Assistant Administrator" means the Assistant Administrator for Coastal Zone Management, National Oceanic and Atmospheric Administration, United States Department of Commerce, or his successor or designee.

(f) "Person" means any private individual, partnership, corporation, or other entity; or any officer, employee, agent, department, agency or

instrumentality of the Federal government, or any State, local or regional unit of government.

(g) "Secretary" means the Secretary of the U.S. Department of Commerce.

(h) "Site Evaluation List" means that list of high resource and human use value sites having met program identification criteria and qualifying for further evaluation as a potential national marine sanctuary.

§ 922.10 Effect of national marine sanctuary designation.

The designation of a national marine sanctuary, and the management plan implementing it (including regulations, if applicable), are binding on any person subject to the jurisdiction of the United States. Designation does not constitute any claim to territorial jurisdiction on the part of the United States, and the management plan implementing it applies to foreign citizens only to the extent consistent with recognized principles of international law or otherwise authorized by international agreement.

Subpart B—Potential Sanctuary Sites

§ 922.20 Site evaluation list.

(a) The Assistant Administrator (AA) will establish a Site Evaluation List (SEL) comprising the most highly qualified marine sites identified and recommended by the regional resource evaluation teams in accordance with the Program's mission and goals set forth in section 922.1 and the site identification criteria set forth in Appendix 1. The SEL will be published in the **Federal Register.** NOAA will prepare a written analysis of each site on the SEL describing the relation of the sites to the selection criteria and evaluation matrix described in Appendix 1. Such analysis shall be part of the administrative record for that site. The List of Recommended Areas is abolished.

(b) The AA will consider future recommendations of potential sanctuary sites only if such sites are important new discoveries of national significance. NOAA determines whether the newly discovered site is of national significance in consultation with appropriate scientists and resource managers. If the site is so determined, the selection criteria specified in Appendix 1 will be applied; qualified sites will be placed on the Site Evaluation List for further evaluation as a national marine sanctuary, consistent with the procedures in § 922.21.

Subpart C—Selection of Active Candidates and the Designation of National Marine Sanctuaries

§ 922.21 Selection of active candidates.

(a) Only a limited number of sites at one time will be selected as active candidates and further evaluated for possible sanctuary designation. The AA will select sites from the SEL for active candidate evaluation based both on the value of the site as determined by the written analysis described in § 920.20(a) and on a balancing of relevant considerations including: (1) Ecological conditions; (2) immediacy of need; (3) timing and practicality; and (4) public comment.

(b) Before selecting a site as an active candidate, the AA shall undertaken preliminary consultation on the considerations described in subsection (a) with relevant local, State, and national government agencies and appropriate regional fishery management councils. The AA shall request additional comments from the public and any relevant international agencies. NOAA's written analysis described in § 922.20(a) will be provided for review. Notice of such preliminary consultation shall be published in the **Federal Register.**

(c) Within 90 days of initiating preliminary consultation, the AA shall determine whethr to select the site as an active candidate and publish a notice of this determination in the **Federal Register.** If the site is not selected, a short statement of the reasons for the determination shall be specified in the notice.

§ 922.22 Designation process.

(a) After selecting a site as an active candidate, the AA shall prepare a draft designation document and draft management plan to implement the designation in consultation with relevant Federal, State, and local agencies, Regional Fishery Management Council members, and other interested persons. Management plans generally shall include sections on: goals and objectives; management responsibilities; resource studies; interpretive and educational programs; and regulations (where applicable). Where a proposal for a sanctuary requires the preparation of a draft environmental impact statement (DEIS) under the National Environmental Policy Act, the designation document and management plan, including regulations if applicable, shall be included in the DEIS.

(b) The terms of designation shall include the geographic area included within the Sanctuary; the characteristics of the area that give it conservation, recreational, ecological, or esthetic values; and the types of activities that will be subject to regulation in order to protect those characteristics. The terms of the designation may be modified only by the same procedures through which the original designation was made. If regulations are promulgated, they shall be consistent with and implement the terms of the Desigtion. All amendments to these regulations must remain consistent with the Designation.

(c) Where essential to prevent immediate, serious and irreversible damage to the resources of a sanctuary, activities other than those listed in the Designation may be regulated within the limits of the Act on an emergency basis for an interim period not to exceed 120 days, during which time an appropriate amendment of the Designation will be sought.

(d) Early in the development of the sanctuary documents and the DEIS, if required, meetings shall be held in the area or areas most affected to solicit public and government input on the significant issues related to the proposed action.

(e) The AA will publish the draft designation and a summary of the management plan including the draft regulations, where applicable, in the **Federal Register.** If a DEIS is required, the **Federal Register** notice shall be published concurrently with the Environmental Protection Agency (EPA) Notice of Availability of the DEIS. Not less than 30 days after publication of the applicable documents, the AA shall hold at least one public hearing in the area or areas most affected by the proposed designation in accordance with section 302(e) of the Act.

(f) After final consultation with all appropriate Federal agencies, including the Departments of State, Defense, the Interior, Transportation, Energy, and the Environmental Protection Agency, and publication of a final environmental impact statement where necessary the Secretary shall transmit the proposed Designation to the President for approval. Where sites include state waters, the applicable documents will be sent to the Governor of the State for final consultation, as provided under subsection (h)(1) below.

(g) The AA shall announce the designation of a Sanctuary and publish the designation document and implementing regulations in the **Federal Register.**

(h) A designation shall become effective unless either:

(1) The Governor of any affected State, as defined in § 922.2(c) certifies to the Secretary, before the end of the

sixty-day period beginning on the date of the publication of the designation, that the designation or any of its terms described in subsection (b), are unacceptable to the State, in which case those terms certified as unacceptable will not be effective in the waters described in § 922.2(c) until the Governor withdraws his certification of unacceptability; or

(2) both Houses of Congress adopt a concurrent resolution, consistent with section 302(h) of the Act, within sixty calendar days of continuous session of Congress after the date on which the designation was transmitted, which disapproves the designation or any of its terms described in subsection (b).

§ 922.23 Coordination with States.

(a) The AA shall make every effort to consult and cooperate with affected States throughout the entire national marine sanctuary review and consideration process. In particular the AA shall:

(1) Consult with the relevant state officials prior to selecting any site on the SEL as an Active Candidate, pursuant to § 922.21(b), especially concerning the relationship of any site to state waters and the consistency of the proposed designation with an approved State Coastal Zone Management Program.

(2) Ensure that any relevant state agency is consulted prior to holding any meeting pursuant to § 922.22(d) or public hearing pursuant to § 922.22(e).

(3) Provide the Governor an opportunity to certify the designation as unacceptable as specified in § 922.22(h).

Subpart D—Enforcement

§ 922.30 Enforcement entities.

(a) The AA is responsible for enforcing the provisions of the Act and is authorized to enter into agreements with federal or state agencies as may be necessary to carry out the enforcement responsibilities of the Act.

(b) The U.S. Coast Guard is the primary enforcement agency for the National Marine Sanctuary Program in accordance with section 302(f)(4) of the Act. In high use areas or where the need for additional enforcement arises, State law enforcement entities may be deputized consistent with subsection (c). The Coast Guard retains concurrent enforcement authority whenever a state law enforcement entity is deputized to assist in sanctuary enforcement.

(c) Where the need arises and a state agency possesses appropriate law enforcement capabilities which could assist the AA in carrying out the Act's law enforcement responsibilities, these state law enforcement officers may be deputized as Federal law enforcement agents and authorized to enforce those provisions of the Act and applicable regulations. State enforcement activities shall be conducted in accordance with any guidelines or limitations which the AA may, from time to time, impose.

(1) State enforcement officials shall prepare such reports as may be required by the AA relating to contacts made, documentation or written warnings issued and suspected violations, locations and times of patrols, and other actions taken pursuant to the Act.

(2) The state shall immediately notify the AA of any violation issued pursuant to the Act and shall submit an investigation report within 15 days of issuance.

(3) Any vessel, fish, or cargo seized by a State enforcement officer under the Act may be delivered to a U.S. Government official designated by the AA or other appropriate Federal authority. If such official, however, is unable to properly provide for the care, handling, and preservation as evidence of such seized property, employees of the State will be expected to make reasonable arrangements for such care, handling, and preservation as evidence. Costs to third parties with whom arrangements for the care, handling, and preservation of seized property are made under this paragraph shall be considered as separate items for payment by the AA and will not be the responsibility of the State.

§ 922.31 Penalties.

Any person subject to the jurisdiction of the United States who violates any regulation issued pursuant to the Act shall be liable for a civil penalty of not more than $50,000 for each such violation. Each day of a continuing violation shall constitute a separate violation. No penalty may be assessed under this section until the person charged has been given notice and an opportunity to be heard. Upon failure of the offending party to pay an assessed penalty, the Attorney General, at the request of the AA, will commence action in the appropriate district court of the United States in order to collect the penalty and to seek such other relief as may be necessary. A vessel used in the violation of a regulation issued pursuant to the Act will be liable in rem for any civil penalty assessed for such violation and may be proceeded against in any District Court of the United States having jurisdiction. Pursuant to section 303(a) of the Act, the District Courts of the United States have jurisdiction to restrain a violation of the regulations issued pursuant to the Act, and to grant such other relief as may be appropriate.

§ 922.32 Notice of violation.

Upon receipt of information that any person has violated any provision of the Act, the AA shall notify such person in writing of the violation with which charged, and of the right to demand a hearing to be held in accordance with § 922.33. The notice of violation shall inform the person of the procedures for requesting a hearing and may provide that, after a period of 30 days from receipt of the notice, any right to a hearing will be deemed to have been waived.

§ 922.33 Enforcement hearings.

Hearings requested under § 922.32 shall be held not less than 60 days after the request is received. Such hearings shall be on the record before a hearing officer. Parties may be represented by counsel, and shall have the right to submit motions, to present evidence in their own behalf, to cross-examine adverse witnesses, to be apprised of all evidence considered by the hearing officer, and, upon payment of appropriate costs, to receive copies of the transcript of the proceedings. The hearing officer shall rule on all evidentiary matters and on all motions, which shall be subject to review pursuant to § 922.34.

§ 922.34 Determinations.

Within 30 days following conclusion of the hearing, the hearing officer shall make findings of facts and recommendations to the AA, unless such time limit is extended by the AA for good cause. When appropriate, the hearing officer may recommend a penalty, after consideration of the gravity of the violation, prior violations by the person charged, and the demonstrated good faith by such person in attempting to achieve compliance with the provisions of the Act and regulations issued pursuant to it. A copy of the findings and any recommendation of the hearing officer shall be provided to the person charged at the same time they are forwarded to the AA. Within 30 days of the date on which the hearing officer's findings and recommendations are forwarded to the AA, any objecting party may file written exceptions with the AA.

§ 922.35 Final action.

A final order on a proceeding under this part shall be issued by the AA no later than 30 days following receipt of the findings and recommendations of the hearing officer. A copy of the final order shall be served by registered mail (return receipt requested) to the person charged or his/her representative.

Appendix 1.—Selection Criteria

A. NATIONAL MARINE SANCTUARY SITE IDENTIFICATION CRITERIA

During summer 1981, the National Marine Sanctuary Program Draft Site Identification Criteria were reviewed and refined by three marine scientists: Drs. Walter H. Adey, Rezneat M. Darnell, and G. Carlton Ray. Taking their recommendations into consideration, the criteria presented below and the Site Evaluation Matrix in Appendix 1.B were developed.

The site identification criteria are directly related to the Program's purposes: (1) That the system of sanctuaries established is illustrative of the variety of ecosystems found in the United States; (2) that sanctuaries allow, to the maximum extent feasible, multiple use for public and private interests; (3) that sanctuaries are designated for the purpose of protecting or restoring conservation, recreational, ecological, or esthetic values; and (4) that sanctuaries are established to serve as a conservation component, or a management tool, in a broad national-interest approach to marine resource development, conservation, and utilization. The criteria are grouped accordingly into four categories: (1) Natural resource values; (2) human use values; (3) potential activity impacts; and (4) management concerns. The criteria under each category reflect concerns significant to the Program.

Sites initially identified using the Sanctuary Program Classification System in the PDP are evaluated in terms of these criteria (i.e., to see which criteria are met). Appendix 1.B. describes how sites are further assessed to identify priority sites. The Regional Resource Evaluation Teams utilize these criteria in their site evaluations.

I. Natural Resource Values

A. *Subregional Representation.* The area under consideration is representative of the biogeographic subregion in which it is located. (Reference: Sanctuary Program Classification System in the PDP).

Examples: This criterion would apply to an area containing species assemblages which are especially characteristic of the Oregonian subregion of the British Columbian region. Another example would be an area containing species assemblages which are especially characteristic of the Floridian or American Atlantic Antillean subregion of the West Indian region.

B. *Community Representation.* The area under consideration is significant in relation to the ecological communities which are found within the specified habitat type or within the biogeographic region or subregion (i.e., on a macroscale, communities are assemblages of species populations within a prescribed area or habitat).

Examples: (1) The wide spectrum of marine habitats in the Channel Islands National Marine Sanctuary in California created by accentuated bottom relief, varied bottom substrates, and gradation in water depth from island shorelines to deep coastal basins support a variety of ecological communities.

(2) Coral reef, grass bed, soft bottom, and open-bay habitat areas in the Key Largo National Marine Sanctuary support a variety of ecological communities associated with the east Florida reef tract.

C. *Biological Productivity.* The area under consideration is significant in relation to its level of primary and/or secondary production.

Examples: (1) East Breaks at the edge of the outer continental shelf off Corpus Christi, Texas is characterized by intense local upwelling, high primary productivity, and exceptional fish production.

(2) In the Gray's Reef National Marine Sanctuary, much production may be imported; outcroppings of limestone rocks may serve to entrap, conserve, and circulate detritus and plankton which provide energy sources for reef invertebrates, which in turn support marine fisheries and sea turtles.

(3) In the Channel Islands National Marine Sanctuary, the cold waters of the California Current flowing north meet the warm waters of the California Counter Current flowing south to create upwellings of cold nutrient-rich waters that enhance the biological productivity of the area. (Note: This example also meets Criterion I.F.)

(4) In many cases, coral reefs are not only energetically self-sustaining (i.e., they produce locally enough food to support the community), but they are also specifically organized to entrap, hoard, and recycle materials received from the surrounding waters (i.e., products that are imported and conserved).

D. *Biotic Character/Species Representation.* The area under consideration is of special interest because it supports:

(1) Ecologically limited species;

(2) Ecologically important species; or

(3) Unique species associations or biological assemblages.

Examples: (1) This criterion would apply to marine habitat areas upon which ecologically limited species (e.g., threatened, endangered, rare, depleted, endemic, or peripheral species) are dependent during all or part of their lives.

(2) This criterion would apply to marine areas containing species which contribute in a significant way to the maintenance of a specified ecosystem found in the region or subregion, such as the Channel Islands National Marine Sanctuary which supports one of the largest and most varied assemblages of marine mammals and seabirds in the world.

(3) The waters off Point Lobos, California support a unique assemblage of kelp, sea urchin, abalone, and sea otters.

(4) Submarine canyons support unusual biological communities of soft corals, crustaceans, and fish known as "pueblo villages."

(5) This criterion would also apply to wide sandy bottom areas which are characterized by low productivity, but unique species composition, such as certain areas off central Texas.

E. *Species maintenance.* The area under consideration is important to life history activities, including special feeding, courtship, breeding, birthing/nursery, resting/wintering, and migration areas.

Examples: (1) The waters off the Point Reyes-Farallon Islands provide deep and shallow water feeding areas for a wide variety of marine organisms, including seabirds, marine mammals, and marine fisheries. The Farallon Islands support the largest seabird rookeries in the contiguous United States and are used, along with the mainland, by California sea lions, harbor seals, and elephant seals for hauling out and pupping purposes. Whales, including several endangered species, and porpoises pass through the sanctuary on annual migrations.

(2) The waters around certain Hawaiian Islands are important wintering, birthing/nursery, and perhaps courtship/breeding areas for endangered humpback whales.

(3) Spiny lobster migration routes off Florida are important for the "off shelf" movement of this species.

(4) The mouth of the Mississippi River is an important brown shrimp overwintering ground.

F. *Ecosystem Structure/Habitat Features.* The area under consideration is characterized by special chemical, physical, and/or geological habitat features.

Examples: (1) The Florida Middle Grounds on the Gulf of Mexico continental shelf represent an unusual geological formation—a drowned Pleistocene reef—which supports rich and diverse reef communities.

(2) Transition zones occur where two different marine systems converge—such as at coastal/marine system interfaces, shelf/slope interfaces, soft bottom/hard bottom ecotones, or cold water/warm water current convergence zone. There areas of mixing often have unique physical and ecological characteristics, high production, and species diversity/ population densities which are often greater than in areas flanking them. For example, a transition zone is formed near Cape Hatteras where cold northern waters of the Labrador Current mix with warm water eddies of Gulf Stream/Florida Current and as a result, northern and southern species mix and co-exist with species endemic to the area. (Note: This example also meets Criterion I.C.)

(3) Easternmost coastal areas of Maine—with unique bay-heads and rocky coasts, varied substrates derived from glacial materials, extensive sub-fjord character, and numerous offshore islands—are matched by few areas in the world in habitat types and species diversity.

II. Human-Use Values

A. *Fishery Resources of Recreational Importance.* The area under consideration contains fish and shellfish species, species groups (e.g., snapper-grouper complex), or fishery habitats which are important to the recreational fishing industry/community and for which conservation and management are in the public interest.

Example: The Florida Middle Grounds rank high in satistical surveys of demersal and pelagic fish catch and effort, recreational sector participation, and socioeconomic contribution.

B. *Fishery Resources of Commercial Importance.* The area under consideration contains fish and shellfish species, species groups (e.g., snapper-grouper complex), or fishery habitats which are important to the

commercial fishing industry and for which conservation and management are in the public interest.

Example: The waters of the Point Reyes-Farallon Islands National Marine Sanctuary provide substantial fishing opportunities, including commercial fisheries for bottom fishing, crab, salmon, albacore, and pelagic anchovy, herring, and other species.

C. *Ecological/Aesthetic Resources of Importance For Recreational Activities Other Than Fishing.* The area under consideration contains exceptional natural resources and features which, because of their importance to nature watching and other nonconsumptive recreational activities, enhance human appreciation, undertanding, and enjoyment of nature.

Examples: (1) Rocky shorelines, shallow nearshore waters, and intertidal pools in the Channel Islands and Point Reyes-Farallon Islands National Marine Sanctuaries have rich and varied plant and animal life which attract many persons interested in photography and nature study.

(2) The prominent topography around the Channel Islands and Point Reyes-Farallon Islands National Marine Sanctuaries provides outstanding ocean vistas.

(3) The spectacular spur-and-groove coral reef formation in the Looe Key National Marine Sanctuary attracts SCUBA and snorkeling enthusiasts from all over the world.

(4) The waters off Maui, Hawaii are popular for humpback whale watching.

D. *Research Opportunity.* The area under consideration provides exceptional opportunities for research in marine science and resource management.

Examples: (1) The Gray's Reef National Marine Sanctuary serves as a natural laboratory or control area for research in live bottom ecology.

(2) The Key Largo National Marine Sanctuary is amenable to onsite research activities for many reasons, including the diversity of resources available, the past history of scientific research and education in the area, the compatibility with similar research efforts in adjacent John Pennekamp State Park and Biscayne National Park, and the proximity of the site to user groups. In addition, the Carysfort Reef Lighthouse provides a unique research base from which to launch studies concerning the sanctuary environment.

(3) The Channel Islands National Marine Sanctuary offers a special opportunity to coordinate research with the Channel Islands National Park. Such coordination will contribute to a better scientific understanding of the marine environment and to more effective management by answering questions such as those related to fisheries, marine mammals, seabirds and those related to development and use of marine resources.

E. *Interpretive Opportunity.* The area under consideration provides an excellent opportunity to interpret the meanings and relationships of special marine resources in order to enhance general understanding, appreciation, and wise use of the marine environment.

Examples: (1) Through a variety of interpretive media, including aquaria displays, narrated slide shows and glassbottom boat tours, a visitor to the Key Largo National Marine Sanctuary is exposed to a variety of marine and coastal ecosystems, including open ocean, fringing coral reefs, patch reefs, mangroves, open bay, and barrier islands.

(2) The Channel Islands National Marine Sanctuary provides an exceptional opportunity to interpret marine and insular ecosystem features through the use of various interpretive "hands on" techniques that go beyond traditional educational tools, such as brochures and pamphlets.

F. *Historical, Archaeological or Paleontological.* The area under consideration contains (or is likely to contain) submerged remnants of past life that are of special historical, cultural or paleontological value.

Examples: (1) This criterion would apply to marine areas where known or possible shipwrecks, armaments, or other maritime relics occur and where protection is desirable to conserve or restore aesthetic values and to advance the goal of the United States antiquities laws to protect historical resources.

(2) This criterion would apply to marine areas containing, or suspected of containing, remnants of historic human occupation by Indians, Eskimos, early Americans, or other peoples.

(3) This criterion would apply to marine areas containing fossils and geological formations whose study would reveal clues to the earth's geologic history, the characteristics of ancient environments and the relationship of ancient plants and animals to the earth's evolutionary history.

Additional Factors in Site Identification

III. Potential Activity Impacts

Many marine areas are subject to human use, some of which bring adverse pressures to bear on the natural resources. The initial indentification of potential marine sanctuary areas includes a summary of existing and potential human activities in these areas as well as a preliminary assessment of environmental impacts. Since the pressures may arise from various activities, the present or potential ecological significance of each activity, as well as the cumulative impact of several activities, must be analyzed so that appropriate management action can be designed and implemented. Definitive environmental impact analyses, however, are hampered by the fact that adequate field data on natural or "existing" conditions are often lacking, thus making assessments of "human-induced" versus "natural" conditions difficult. Many judgments are, therefore, based on projections and can be subjective, i.e., the evaluation depends largely upon the experience and special interest of the reviewer.

Regional resource evaluation teams will preliminarily assess activity impacts based on a review of scientific literature (e.g., baseline studies and environmental impact studies) and discussions with persons knowledgeable in the field. The types of activities which might be considered for potential impacts include: (1) vessel traffic; (2) aircraft overflights; (3) commercial and recreational fishing; (4) other recreational activities such as SCUBA, snorkeling, spearfishing, and specimen collecting; (5) ocean dumping and waste disposal (including litter); (6) scientific research and educational demonstrations; (7) dredging and dredge disposal; (8) disturbing marine mammals and seabirds; (9) anchoring; (10) salvage operations; and (11) oil and gas recovery and associated activities. This is not meant as an exhaustive listing, but rather to illustrate the range and types of activities which may be evaluated for potential impacts on resources within a site identified for future marine sanctuary consideration.

IV. Management Concerns

A. *Relationship To Other Programs.* While some sanctuaries may be designated to protect resources not currently managed by other existing programs (e.g., the *U.S.S. MONITOR* on the continental shelf off North Carolina), most recommendations involve cooperation with some other Federal, State, or local agency or organization. The ability of existing regulatory mechanisms to protect the values of the area and the conribution of the Sanctuary Program to that existing management effort may be an important factor in selecting sanctuary candidates. Depending on the location, the resource, and the existing system, the Program could either complement the status quo by filling specific gaps or form a management umbrella over a fragmented system to help coordinate and strengthen diverse, but related efforts. At different sites, NOAA may work to complement other programs efforts such as estuarine sanctuaries, national parks, wildlife refuges, or state preserves, among others. There may be instances where NOAA's primary contribution to protection of special marine areas will be in the form of enhanced public awareness through interpretive and research programs.

B. *Management of a Conservation Unit.* Optimum size of a marine sanctuary is an issue to be considered in potential sanctuary sites. The size or extent of a marine sanctuary should be a cohesive conservation unit amenable to effective management given fiscal and staff constraints of the managing entities. A discussion of sanctuary size is included in the PDP.

C. *Accessibility.* Since national marine sanctuaries are to be readily available for public use, when use is compatible with the sanctuary's goals and objectives, consideration should be given to factors which limit or enhance public access to a particular site.

D. *Surveillance and Enforcement.* Another issue to be considered when evaluating a potential sanctuary site is the the degree to which the area lends itself to adequate endorcement and surveillance and the capabilities of responsible agents (e.g., U.S. Coast Guard, state law enforcement divisions, or the like). This depends on the location, its size, and the types of resources involved. Consideration is also given to: (1) degree of surveillence/enforcement presence needed in the area-light, medium, or heavy; (2) schedule—routine, prescribed, or case-by-case basis; and (3) logistics—vessels, aircraft,

manpower, equipment, and budgetary requirements.

E. *Economic Considerations.* The designation of any national marine sanctuary could have economic effects at both local and national levels. Prior to the development of a management plan for a particular site which describes permitted and restricted activities, it is difficult to calculate the economic impact of sanctuary designation. It is even more difficult to determine the economic value of the sanctuary to society as a whole based on such things as public use, research and interpretive value. Sanctuary designation often enhances economic value by ensuring long-term protection for commercially significant resources, such as commercial or recreational fish stocks, vital habitats, and resources which generate tourism. Conversely, a marine sanctuary may also have negative economic impacts if management regulations restrict activities that generate income. However, in these cases, the economic value is usually not irretrievably lost since the resources remain protected for the long term and could be used if necessary. In cases where certain economic values are reduced or foregone, this impact must be weighed against the long-term benefits to society. Analysis of a potiential site for marine sanctuary status will take socioeconomic impacts into consideration.

B. SITE EVALUATION MATRIX

Appendix 1.A. outlines the criteria for identifying potential marine sanctuary sites. Four categories of criteria are presented; namely, natural resource values, human use values, potential activity impacts, and management concerns. The criteria address characteristics which are of particular significance to the national marine sanctuary program.

After a site is examined to determine which criteria are met, the next step involves an evaluation of the relative value of each criterion. This is accomplished using the guidelines provided below. Sites are evaluated in terms of the individual value of each criterion met (e.g., low, moderate, or high value) and in relation to other sites with complimentary characteristics. The following rating system is recommended:

Low Value (L)—Low quality; not significant but still a viable concern; of minor contribution to national system; of minor importance; other equally good representatives are available; or duplicates, in significant measure, another recommended area or designated sanctuary.

Moderate Value (M)—Moderately good quality; significant but not the most important concern; help to support species, but not critical; helps to support the regional ecology, but only in a small measure or in a general way; a few other good representatives are available; or moderate contribution to the national system.

Moderate Value (H)—Very high value; high quality; a major reason for sanctuary consideration; extremely important to regionally significant species; of great importance in terms of ecological features and processes; regional ecology would likely be significantly altered if the values were not protected; no significant duplication of other recommended areas; absolutely unique; one of a kind; best available regional representative; or excellent contribution to the national system.

Unknown Value (X)—Value or consequences unknown; more study needed to determine value or consequence; factor does not apply; or factor is not an issue, does not need to be considered.

Sites which consistently have relatively low values receive an overall "low priority" assessment and are eliminated. In contrast, sites which consistently have relatively high values receive a "high priority" assessment and are recommended for further consideration.

I. NATURAL RESOURCE VALUES

A. Subregional Representation

L—Other equally good or better sites available; not a good representative of the subregion.

M—Few other sites available; good representative of the subregion.

H—Best available site; only one or two sites in the subregion; best representative of subregional characteristics.

B. Community Representation

L—Poor representation of the community types found within the specified habitat type or within the biogeographic region or subregion; low percentage of communities on site; low percent cover of communities on site.

M—Good representation of the community types found within the specified habitat type or within the biogeographic region or subregion; limited number of communities on site; good range of common communities present; moderate percent cover of communities on site.

H—Excellent representation of the community types found within the specified habitat area or within the biogeographic region or subregion; good or very good range of habitats and communities on site; localized, relict, or special communities present.

C. Biological Productivity

L—Contribution to local production minor; low productivity as defined by the classical definition of productivity.

M—Contribution to local production moderate; trophic relationships are typical or common for the region or subregion.

H—Contribution to local production extremely important; local ecology would likely be significant altered if natural (normal) production levels change; highly exemplary, special or unusual tropic relationships.

D. Biotic Character/Species Representation

L—Characteristic species are common in the region/subregion; few, if any: (1) ecologically limited species (e.g., threatened, endangered, rare, depleted, endemic or peripheral species); (2) ecologically important species; or (3) special species combinations or biological assemblages; low percentage of regionally or locally available species; other equally good or better sites available.

M—The area is only of moderate importance to populations of ecologically limited species or ecologically important species; few, if any, special species combinations or assemblages; percentage of regionally or locally available species is moderate; some other similar sites available.

H—Very important to species which are of high ecologic value or ecologically limited in regional, national or international distribution or existence (e.g. endemic, threatened, endangered, rare, depleted); contains special species combinations or biological assemblages; outstanding diversity for a particular habitat or community type; best available site; only one or two sites in the region or subregion.

E. Species Maintenance

L—Of some importance to supporting life history activities of regional/subregional species; no local dependence upon this area; many other equally important sites available.

M—Important to supporting life history activities of regional/subregional species, but not critical; some other equally important sites available.

H—Extremely important to supporting life history activities of regional/subregional species; only one or two other sites available.

F. Ecosystem Structure/Habitat Features

L—Habitat features are common in the region/subregion, but are not outstanding representatives; no significant contribution to regional/subregional ecosystem structure; no special chemical, physical or geological habitat features.

M—Habitat features are common in the region/subregion; some special features are available; few other sites available; moderate contribution to the regional/subregional structure.

H—Unique, different or special habitat features; only one or two other sites available; significant contribution to regional/subregional structure; structual features have strong influence on ecological processes in the area.

II. HUMAN USE VALUES

A. Fishery Resources of Recreational Importance

L—Low recreational importance; many other fishery opportunities available.

M—Moderate recreational importance; some other fishery opportunities available.

H—High recreational importance; only one or two other fishery opportunities available.

B. Fishery Resources of Commercial Importance

L—Low commercial importance; many other fishery opportunities available.

M—Moderate commercial importance; some other fishery opportunities available.

H—High commercial importance; only one or two other fishery opportunities available.

C. Ecological/Aesthetic Resources of Importance for Recreational Activities Other Than Fishing

L—Low value; minimum opportunty for recreation; many other sites available.
M—Moderate value, good opportunity for recreation; few other sites available.
H—High value; excellent opportunity for recreation; rare in the region; only one or two sites available.

D. Research Opportunity

L—Very limited research opportunities; the site has already received considerable research attention (i.e., "researched to death"); not suitable for study; many other sites available.
M—Good research opportunities; good for use at most levels of research, formal and informal; few other sites available.
H—Excellent research opportunities; outstanding for use at all levels of research, formal and informal; can withstand some pressure from these activities; only one or few other sites available.

E. Interpretive Opportunity

L—Low or minimal interpretive value; opportunities for interpretation are limited; has already received considerable interpretive attention; resource features are common in the region; many other sites available.
M—Moderate or good interpretive value; opportunities for interpretation fairly good; visually attractive features; resource features are fairly limited in the region; few other sites available.
H—Excellent interpretive value; opportunities for interpretation excellent or unusual; visually attractive features; resource features are special in the region or subregion; only one or two other sites available; good potential for interpretive center and/or displays; the enhancement of public awareness through this resource is paramount.

F. Historical, Cultural or Paleontological Importance

L—Little or no historical, cultural or paleontological importance; many other sites available.
M—Moderate or good historical, cultural or paleontological importance; few other sites available.
H—Very special historical, cultural or paleontological value; only one or two other sites available.

III. POTENTIAL ACTIVITY IMPACTS

Existing and potential activities within a particular area are listed by Resource Evaluation Teams on the Site Evaluation Matrix. The potential impact of each activity is evaluated using the following recommended scheme:

L—This activity is not highly significant, but still a viable issue; little or no impact at current activity levels; very little potential for harm by increase of this activity; if the activity is remote, there is an adequate buffer to protect the area; no known or proposed future development which could affect resource or human use value; no current or potential user conflict.
M—This activity is significant, but not the most important issue; some impact on resources of current activity levels, but the system is resilient with little permanent damage or other long-lasting effect; some possible negative impact if activity level increases; if the activity is remote, there is a fairly good buffer zone to protect the area; some possible future development likely which could affect resource or human use values; some current or potential user conflicts which threaten resource or human use value.
H—Potential for impact at current activity levels is high or is already major issue; resources are suspected to be very sensitive to environmental change, not resilient; resource would likely be significantly altered if values are not protected; the area is in immediate need of protection; negative impact likely if activity levels increase or continue at present level; current or potential user conflicts could significantly threaten resource or human use values.
X—Environmental consequences unknown. More study is needed.

IV. MANAGEMENT CONCERNS

A. Relationship to Other Programs

L—Other equally good or better programs in effect.
M—Few complementary programs in place, but none that offer the same comprehensive management opportunities or public benefits.
H—No other programs available or in place; marine sanctuary program is the best available program; offers unique or special management opportunities or public benefits; fills existing regulatory or non-regulatory management gaps; coordinates management, research and education efforts.

B. Management of a Conservation Unit

L—Does not represent a conservation unit; contains only fragments of the ecosystem of concern; protection of a portion of the system does not help or only minimally helps the overall system; not a manageable unit; excessive size; some boundary problems foreseen.
M—Represents a good portion of the ecosystem in question; represents fairly good conservation unit; protection of this area would benefit the ecosystem, but only in a small measure or in a general way; fairly manageable unit; moderate size; few, if any, boundary problems.
H—Represents a complete and ecologically sound conservation unit; protection of this area would benefit the ecosystem in a significant way; manageable unit; not of excessive size; no boundary problems foreseen.

C. Accessibility

L—Inaccessible or accessible with considerable difficulty; situated in an extremely remote area; no human interest in visiting the site.
M—Fairly accessible; if remote, access is good, but often with some difficulty (e.g., weather or sea conditions variable); only limited human interest in visiting the site.
H—Easily accessible, with no major difficulty; considerable human interest in visiting the site; not adversely impacted visitation; inaccessibility of the site is desirable because increased visitation is likely and/or could severely threaten resource or human use values without some management structure.

D. Surveillance and Enforcement

L—Open, long, or insecure boundary; remote, not amenable to surveillance and enforcement efforts; requires considerable commitment of manpower, equipment and budget, no on-going or potential activities that would require an increase in surveillance and enforcement efforts.
M—Moderate boundary, fairly secure; accessible; requires moderate commitment of manpower, equipment and funds; some on-going or potential activities in the area which would require an increase in current surveillance and enforcement efforts.
H—Reasonable boundary, secure; accessible; amenable to surveillance and enforcement efforts; minimal commitment of manpower, equipment and funds; major activity(ies) in the area which require an increase in surveillance and enforcement efforts.

E. Economic Considerations

L—High mangement costs likely; designation or restriction of certain activities would result in negative economic impact; public benefit does not outweigh economic values which may be reduced or foregone by designation.
M—Moderate mangement costs likely; designation or restriction of certain activites would result in some short-term negative economic impact, but public benefit outweighs economic values which may be reduced or foregone; resources are protected for the long term.
H—Low managment costs; designation or restriction of certain activities would result in very minor if any negative economic impact; benefit to society greatly outweighs any reduction of economic value; designation enhances economic value.

Overall Site Evaluation By Resource Evaluation Teams. Even though a value rating scheme is used, the overall assessment of a particular site is based on a subjective evaluation. This is preferred over adding-up a total score for each site—a procedure which tends to mask significant features, gives poor discrimination among sites, and leads to faulty assumptions about the value of a particular site. Instead, evaluation scheme present are meant to be used only as a sorting mechanism; i.e., to compare complementary sites and to eliminate those sites which are inappropriate. As mentioned previously, sites which consistently have relatively low values receive an overall "low priority" assessment and are eliminated. In contrast, sites which consistently have relatively high values receive an overall "high priority" assessment and are recommended for further consideration.

The Regional Resource Evaluation Teams consider each category of criteria separately so that any one category does not override the others and thus affect the overall evaluation. For example, the rationale for low

priority judgment might be based on the following observations: low natural resource values; low human use value; low protection interest; or management problems likely. In contrast, high priority sites might be characterized as having: outstanding natural resource value; high human use value; special features requiring higher level of protection; or no management problems foreseen.

A narrative is written by the Regional Resource Evaluation Teams to support the evaluation. The narrative provides the rationale for the particular priority ranking and identifies sources of information.

At this point, public on priority sites is sought and based on this comment, a list of three to five sites per region along with the written narrative is submitted to NOAA. NOAA makes the final decision as to which sites are to be placed on the SEL.

Later, when NOAA considers a particular site on the SEL for active candidate status, its selection will depend not only on the evaluation performed by the resource evaluation teams, but also upon specific policy considerations and the political climate, as described in the PDP.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 184 and 186

[Docket No. 82N-0120]

Substances Generally Recognized as Safe

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations on substances that the agency has affirmed as generally recognized as safe (GRAS). This proposal was prompted by the agency's experience during its comprehensive safety review of GRAS ingredients. The agency is proposing to amend its regulations to define more clearly the meaning of "current good manufacturing practice" for GRAS ingredients, to eliminate the requirement that a GRAS affirmation regulation contain explicit details of the conditions of use that are affirmed as GRAS, and to make editorial changes.

DATE: Comments by November 8, 1982.

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

FOR FURTHER INFORMATION CONTACT: Mary C. Custer, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-9463.

SUPPLEMENTARY INFORMATION: FDA is conducting a comprehensive safety review of direct and indirect human food ingredients classified as GRAS or subject to a prior sanction. In the **Federal Register** of September 23, 1974 (39 FR 34194), FDA published proposed regulations that set forth the procedures to be used during this review. The agency issued the final procedural regulations in the **Federal Register** of December 7, 1976 (41 FR 53600). FDA is proposing to amend § 184.1(b), (b)(1), and (c) and § 186.1(b), (b)(1), (c), and (d) of these procedural regulations.

In § 184.1(b)(1), FDA explains the meaning of regulations that affirm a substance as GRAS with no limitation other than current good manufacturing practice. The regulation states that FDA will report in this type of GRAS affirmation regulation the conditions of use that provided the basis for FDA's decision to affirm the substance as GRAS. It also states that the ingredient shall be regarded as GRAS so long as its conditions of use are not significantly different from those reported in the GRAS affirmation regulation. Section 186.1(b)(1) contains identical provisions for substances in food-contact surfaces that FDA affirms are GRAS.

In implementing §§ 184.1(b)(1) and 186.1(b)(1), FDA has usually set forth in GRAS affirmation regulations the current good manufacturing practice conditions of use that were reported to the agency and evaluated during the safety review of the substance. These conditions of use have generally included the technical effects for which the ingredient is used, the food categories in which the ingredient is used, and, for each food category, the maximum level at which the ingredient is used. FDA decided to report these conditions of use in GRAS affirmation regulations because it was concerned that the proliferation of food uses for GRAS ingredients that had taken place between 1958 and 1972 would continue and would result in new uses for these ingredients that the agency had not considered when it affirmed the ingredients as GRAS. The agency felt that it consequently was important to make prominent in GRAS affirmation regulations the data upon which the affirmation determinations were based.

The agency discussed its intent to incorporate conditions of use in GRAS affirmation regulations, and its reasons for so doing, in the preambles to the **Federal Register** documents published on July 26, 1973 (38 FR 20044), September 23, 1974 (39 FR 34173 and 34194), and December 7, 1976 (41 FR 53600). In the preamble to the September 23, 1974 proposal, the agency specifically stated that regulations that affirmed substances as GRAS with no limitations other than current good manufacturing practice would specify the conditions of use that were reported in the 1971 National Academy of Sciences/National Research Council (NAS/NRC) survey of food manufacturers (39 FR 34195). However, after 7 years' experience in the GRAS review program, several factors have convinced the agency to reevaluate this practice.

The agency's determination to incorporate detailed conditions of use in GRAS affirmation regulations has elicited public comment since the early stages of the GRAS review program. In response to the proposed procedural regulations for the GRAS review, FDA received numerous comments expressing concern about the inclusion of conditions of use. The agency addressed these comments in the preamble to the final regulation published in the **Federal Register** of December 7, 1976 (41 FR 53601). FDA explained that its intent in including conditions of use in GRAS affirmation regulations was not to establish rigid restrictions on the use of GRAS substances but to set forth the conditions of use that the agency had reviewed and was affirming as GRAS. The agency also explained that it would not object to deviations from these conditions, so long as the conditions of use were not significantly different from those reported in the regulation.

Despite the agency's efforts to explain the purpose of the conditions of use, FDA has continued to receive comments about them from industry in response to individual GRAS affirmation proposals. These comments assert that the conditions of use are confusing, and that they are being interpreted by a significant segment of the food industry as specific limitations. These comments claim that as a result, the inclusion of the conditions of use in the regulations inhibits the use of GRAS ingredients in new food products that have been developed since the 1971 NAS/NRC survey.

The agency has continued to give these comments consideration. In addition, FDA has become aware through its experience that listing detailed conditions of use is not always possible or practical. For instance, FDA has published GRAS affirmation regulations for garlic and dill (December 7, 1976; 41 FR 53616 and 53614, respectively) and clove (January 19, 1979; 44 FR 3962) that specify the

technical effects for these ingredients but that do not specify food categories or levels of use. In the preambles to these regulations, FDA explained that it was not necessary to set forth food categories and use levels because these ingredients have only limited uses, and because there is a wide margin of safety associated with their use.

The agency is also aware that including detailed conditions of use in a regulation could lead to confusion when the use of the ingredient in food is complicated by other factors. For instance, under current good manufacturing practice, propyl gallate, alone or in combination with other antioxidants, is added to food at a level not to exceed 0.02 percent of the fat or oil content. Listing food categories for this ingredient is inappropriate, however, because the use of propyl gallate is determined by whether a specific food product contains fat or oil and not by the food category. Therefore, the GRAS affirmation regulation for propyl gallate (September 11, 1979; 44 FR 52825) specifies a technical effect and a maximum reported level of use but no food categories.

As a result of the comments it has received relating to conditions of use and the effects that they have on the development of new food uses of GRAS ingredients and of the other specific problems indicated above, FDA has reevaluated its decision to incorporate specific conditions of use in all GRAS affirmation regulations. The agency now believes that a description of the current good manufacturing practice conditions of use in a GRAS affirmation regulation is necessary only when such a description is needed to ensure the continued safe use of the ingredient. Thus, a GRAS affirmation regulation for a substance will contain a description of one or more of its conditions of use when that substance has a limited use in food, and the agency's conclusion regarding its safety and GRAS status was based on that limited use. On the other hand, when a substance is used extensively in food, and the agency has evaluated its safety in light of this extensive use, the GRAS affirmation regulation will usually contain a much more abbreviated description of current good manufacturing practice conditions of use of the substance.

The agency believes that its determination whether to include a description of one or more of the current good manufacturing practice conditions of use in a GRAS affirmation regulation should be based on consideration of the following factors: (1) The amount (total poundage) and the extent of the use of the ingredient in food; (2) the magnitude of the safety factor that exists for the ingredient; and (3) whether use of the ingredient may be self-limiting for food use.

FDA believes that this approach will continue to protect the public health, while expediting the agency's comprehensive safety review of GRAS ingredients and minimizing industry's concern over the inclusion of specific current good manufacturing practice conditions of use in some GRAS regulations. Therefore, the agency is proposing to amend §§ 184.1(b)(1) and 186.1(b)(1) to indicate clearly that FDA will specify one or more of the current good manufacturing practice conditions of use in regulations for substances affirmed as GRAS with no limitations other than current good manufacturing practice only when the agency determines that it is appropriate to do so.

To clarify further its regulations, the agency also believes that a general definition of current good manufacturing practice should be incorporated into §§ 184.1(b) and 186.1(b). Both § 184.1(b) and § 186.1(b) currently state that any use levels in GRAS affirmation regulations represent maximum use levels under current good manufacturing practice. FDA proposes to amend those regulations to make clear that GRAS ingredients are not only to be used at the level not to exceed that reasonably required to accomplish their intended effect, but also that GRAS ingredients are to be of appropriate purity, and that GRAS ingredients that are directly added to food must be prepared and handled in an appropriate manner.

The agency intends to review at a future date the conditions of use that it has included in the GRAS affirmation regulations it has adopted since the beginning of the GRAS review to determine whether it is necessary to continue to describe one or more of these conditions of use in the regulations. In the meantime, FDA will begin issuing proposed GRAS affirmation regulations that are consistent with the policy described in this proposal.

In addition, the agency is proposing to make editorial changes in § 184.1(b) and (c) and § 186.1(b), (c), and (d) to change the reference to "section" to read "Part".

The agency has determined under 21 CFR 25.24(d)(6) (proposed December 11, 1979; 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. This is a proposed procedural regulation which in and of itself will have no impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

FDA, in accordance with the Regulatory Flexibility Act, has considered the effect that this proposal would have on small entities including small businesses and has determined that the effect of this proposal is to simplify the regulations for GRAS substances manufactured and used by both large and small businesses. Therefore, FDA certifies in accordance with section 605(b) of the Regulatory Flexibility Act that no significant economic impact on a substantial number of small entities will derive from this action.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this proposal, and the agency has determined that the final rule, if promulgated, would not be a major rule as defined by the Order. A copy of the threshold assessment supporting this determination is on file with the Dockets Management Branch, Food and Drug Administration.

List of Subjects

21 CFR Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients.

21 CFR Part 186

Food ingredients, Generally recognized as safe (GRAS) food ingredients, Indirect food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 stat. 1055, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner of food and Drugs (21 CFR 5.10), it is proposed that Parts 184 and 186 be amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. In Part 184, § 184.1 is amended by revising the introductory text of paragraph (b) and revising paragraphs (b)(1) and (c), to read as follows:

§ 184.1 Substances added directly to human food affirmed as generally recognized as safe (GRAS).

* * * * *

(b) Any ingredient affirmed as GRAS in this Part shall be used in accordance with current good manufacturing practice. For the purpose of this Part, current good manufacturing practice

includes the requirements that a direct human food ingredient be of appropriate food grade; that it be prepared and handled as a food ingredient; and that the quantity of the ingredient added to food does not exceed the amount reasonably required to accomplish the intended physical, nutritional, or other technical effect in food.

(1) If the ingredient is affirmed as GRAS with no limitations on its conditions of use other than current good manufactuiring practice, it shall be regarded as GRAS if its conditions of use are consistent with the requirements of paragraphs (b), (c), and (d) of this section. When the Food and Drug Administration determines that it is appropriate, the agency will describe one or more current good manufacturing practice conditions of use in the regulation that affirms the GRAS status of the ingredient. For example, when the safety of an ingredient has been evaluated on the basis of limited conditions of use, the agency will describe in the regulation that affirms the GRAS status of the ingredient, one or more of these limited conditions of use, which may include the category of food(s), the technical effect(s) or functional use(s) of the ingredient, and the level(s) of use. If the ingredient is used under conditions that are significantly different from those described in the regulation, that use of the ingredient may not be GRAS. In such a case, a manufacturer may not rely on the regulation as authorizing that use but shall independently establish that that use is GRAS or shall use the ingredient in accordance with a food additive regulation.

* * * * *

(c) The listing of a food ingredient in this Part does not authorize the use of such substance in a manner that may lead to deception of the consumer or to any other violation of the act.

* * * * *

PART 186—INDIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

2. In Part 186, § 186.1 is amended by revising the introductory text of paragraph (b) and revising paragraphs (b)(1), (c), and (d), to read as follows:

§ 186.1 Substances in food-contact surfaces affirmed as generally recognized as safe (GRAS).

* * * * *

(b) The regulations in this Part do not authorize direct addition of any food ingredient to a food. They authorize only the use of these ingredients as indirect ingredients of food, through migration from their immediate wrapper, container, or other food-contact surface. Any ingredient affirmed as GRAS in this part shall be used in accordance with current good manufacturing practice. For the purpose of this part, current good manufacturing practice includes the requirements that an indirect human food ingredient be of a purity suitable for its intended use, and that it be used at a level no higher than reasonably required to achieve its intended technical effect in the food-contact article.

(1) If the ingredient is affirmed as GRAS with no limitations on its conditions of use other than current good manufacturing practice, it shall be regarded as GRAS if its conditions of use are consistent with the requirements of paragraphs (b), (c), and (d) of this section. When the Food and Drug Administration determines that it is appropriate, the agency will describe one or more current good manufacturing practice conditions of use in the regulation that affirms the GRAS status of the indirect ingredient. For example, when the safety of an ingredient has been evaluated on the basis of limited conditions of use, the agency will describe in the regulation that affirms the GRAS status of the indirect ingredient, one or more of these limited conditions of use, which may include the category of food-contact surface(s), the technical effect(s) or functional use(s) of the indirect ingredient, and the level(s) of use. If the ingredient is used under conditions that are significantly different from those described in the regulation, such use of a substance may not be GRAS. In such a case, a manufacturer may not rely on the regulation as authorizing that use but shall independently establish that that use is GRAS or shall use the ingredient in accordance with a food additive regulation.

* * * * *

(c) The listing of a food ingredient in this Part does not authorize the use of such substance for the purpose of adding the ingredient to the food through extraction from the food-contact surface.

(d) The listing of a food ingredient in this Part does not authorize the use of such substance in a manner that may lead to deception to the consumer or to any other violation of the act.

* * * * *

Interested persons may, on or before November 8, 1982, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 11, 1982.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

[FR Doc. 82-24421 Filed 9-3-82; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 700, 701, 715, 717, 736, 760, 762, 769, 770, 771, 772, 773, 775, 776, 778, 779, 780, 782, 783, 784, 785, 786, 787, 788, 815, 816, 817, 818, 819, 822, 823, 824, 826, 827, 843, and 850

Permanent Regulatory Program: Notice To Reopen the Public Comment Periods for Draft Supplemental Environmental Impact Statement and Certain Proposed Rules

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of reopening of public comment periods.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) has published several proposed rules for public comment which would amend OSM's permanent regulatory program. OSM has prepared a draft supplemental environmental impact statement (EIS) on some of these rules. The comment periods on the draft EIS and on the proposed rules analyzed therein closed on August 25, 1982. OSM is now reopening the comment period on the draft EIS and those proposed rules covered by the EIS.

DATES: The comment periods on the draft supplemental EIS and the proposed rules listed in this notice will close at 5:00 pm e.d.t. on September 10, 1982. For additional information see Supplemental Information.

FOR FURTHER INFORMATION CONTACT: Jerry R. Ennis, Office of Surface Mining, U.S. Department of the Interior, 1951 Constitution Avenue, NW., Washington, DC. 20240, 202-343-7881.

SUPPLEMENTARY INFORMATION: As part of its regulatory reform effort, OSM has proposed the rules identified below which are considered in a draft supplement to the Final Environmental Impact Statement on the Permanent Regulatory Program (OSM-EIS-1,

January 1979). The comment periods on all of these rules and the draft EIS closed on August 25, 1982. See notice at 47 FR 30266 (July 13, 1982).

Since the publication of the July 13, 1982, **Federal Register** notice, the United States House of Representatives Committee on Interior and Insular Affairs has scheduled oversight hearings for September 9 and 10, 1982. At these hearings in which OSM will participate, it is expected that OSM's proposed rules and draft EIS will be discussed. OSM intends to insert the oral comments received at those hearings into the administrative record for the relevant rulemakings and the EIS. In addition, partly as a result of public meetings held during the last few days of the scheduled public comment period, OSM now believes it would be useful to allow the public the opportunity to add to, modify, or respond to analyses and concerns contained in comments already submitted. Thus, OSM has decided to reopen the comment period for the rules for which the comment period closed on August 25, 1982, and for the draft supplemental EIS.

The public comment periods for both the draft supplemental EIS and the associated proposed rules will close at 5:00 pm. e.d.t. on September 10, 1982. Comments received after that time will not necessarily be considered by OSM or incorporated in the Administrative Record.

The comment period for the following proposed rules or, with respect to the Sedimentation Pond and the Inspection and Enforcement rules, specified portions thereof will close on September 10, 1982:

Rule	Federal Register citation	Date published
Sedimentation Ponds	46 FR 34784	July 2, 1981.
Inspection and Enforcement.	46 FR 58464	Dec. 1, 1981.
Topsoil	47 FR 10742	Mar. 11, 1982.
Experimental Practices	47 FR 12082	Mar. 19, 1982.
Auger Mining	47 FR 12088	Mar. 19, 1982.
Revegetation	47 FR 12596	Mar. 23, 1982.
Blaster Certification	47 FR 12779	Mar. 24, 1982.
Fish and Wildlife	47 FR 13466	Mar. 30, 1982.
Postmining Land Use and Vanances from Approximate Original contour.	47 FR 16152	Apr. 14, 1982.
Roads	47 FR 16592	Apr. 16, 1982.
Subsidence and Concurrent Surface and Underground Mining.	47 FR 16604	Apr. 16, 1982.
Prime Farmlands	47 FR 19075	May 3, 1982.
Coal Exploration	47 FR 21442	May 18, 1982.
Excess Spoil Fills	47 FR 24954	June 8, 1982.
Lands Unsuitable	47 FR 25278	June 10, 1982.
Alluvial Valley Floors	47 FR 25486	June 11, 1982.
Coal Processing Waste	47 FR 26598	June 18, 1982.
Impoundments	47 FR 26754	June 21, 1982.
Backfilling and Grading	47 FR 26760	June 21, 1982.
Support Facilities/Coal Processing Plants.	47 FR 27688	June 25, 1982.
Permitting	47 FR 27694	June 25, 1982.
Hydrology	47 FR 27712	June 25, 1982.
Remining	47 FR 27734	June 25, 1982.

Sedimentation Ponds

The following portions of the proposed sedimention rule are comprised of the EPA effluent limitation guidelines and are not being considered in the EIS: 30 CFR 715.17(a), 717.17(a), 816.42 and 817.42. The comment period on these portions of the Sedimentation Pond rule was closed on July 23, 1982, and will not be reopened. The comment period for the following portions of the proposed Sedimentation Pond rule will close on September 10, 1982: 30 CFR 715.17(e), 717.17(e), 816.46 and 817.46.

Inspection and Enforcement

The comment period for proposed 30 CFR 843.12(a)(2) will close on September 10, 1982. The other portions of the inspection and enforcement rules were published in final form on August 16, 1982 (47 FR 25620).

Dated: September 1, 1982.

J. Steven Griles,

Deputy Director, Office of Surface Mining, Reclamation and Enforcement.

[FR Doc. 82-24531 Filed 9-3-82; 8:45 am]

BILLING CODE 4310-05-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[A-3-FR 2168-1; EPA Docket No. AW009WV]

State of West Virginia Proposed Revision of the West Virginia State Implementation Plan

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: On July 6, 1982, the State of West Virginia submitted a proposed revision to its State Implementation Plan to incorporate in alternate emission reduction plan or "bubble". West Virginia has requested the plan be approved by EPA for the Weirton Steel Division plant of the national Steel corporation in Weirton, West Virginia. This plan consists of a State Consent Order which applies to fugitive process emissions from the Blast Furnace Cast Houses, the Basic Oxygen Furnace Shop Roof Monitor, the Sinter Plant Cooler, and the Blooming Mill Machine Scarfing Operation. In lieu of installing emission controls for these operations, the Company has agreed to implement a program to control particulate matter emissions from roads and parking lots at the plant.

For such a proposal, EPA requires a dispersion modeling analysis to demonstrate air quality equivalence. EPA has conducted a modeling analysis which shows annual air quality equivalence, but has had difficulty in conducting short term modeling for this situation, i.e. a complex source in complex terrain where particulate deposition is of critical concern. EPA is exploring techniques that will allow a short term ambient equivalence determination to be made and believes that such short term analysis will confirm the ambient equivalence as shown for the annual average. In addition, to determine the air quality effectiveness of the proposed emissions trade, EPA is requiring extensive ambient air quality monitoring. The Agency believes the proposal outlined above is reasonable considering the aforementioned complex issues involved in short term air quality equivalency demonstrations. EPA solicits comments on the reasonableness of this proposal.

DATE: Comments must be submitted on or before October 7, 1982.

ADDRESSES: Copies of the proposed SIP revision and the accompanying support documents are available for inspection during normal business hours at the following offices:

U.S. Environmental Protection Agency, Air Programs and Energy Branch, Curtis Building, 6th & Walnut Streets, Philadelphia, PA 19106, Attn. Patricia Sheridan

West Virginia Air Pollution Control Commission, 1558 Washington Street, East, Charleston, West Virginia 25311, Attn. Mr. Carl G. Beard

All comments on this proposed revision submitted on or before October 7, 1982 will be considered and should be directed to: James E. Sydnor, Chief, West Virginia, Virginia Section (3AW13), U.S. Environmental Protection Agency, Region III, 6th and Walnut Streets, Philadelphia, PA 19106.

FOR FURTHER INFORMATION CONTACT: Edward A. Vollberg (3AW13), U.S. Environmental Protection Agency, Region III, 6th and Walnut Streets, Philadelphia, PA 19106, Telephone: (215) 597-8990.

SUPPLEMENTARY INFORMATION: West Virginia has proposed an alternate emission control program (bubble) for the Weirton Division Steel Mill of the National Steel Corporation. The bubble, is in the form of a State Consent Order,

and has been designed in accordance with EPA's Emission Trading Policy Statement, an interim guidance document published on April 7, 1982 (47 FR 15076). Any written comments received by EPA, will be considered by EPA in making a final determination on the approvability of the plan.

The bubble plan proposes to control in-plant road and parking lot fugitive dust emissions in lieu of process fugitive emissions at the blast furnace cast houses, the sinter plant cooler, the blooming mill machine scarfer, and secondary process fugitive emissions at the basic oxygen furnace. The emission limits which would require the control of fugitive emissions from the blast furnace cast houses, the basic oxygen furnace and sinter plant are contained in a Consent Decree between National Steel and the United States of America (Civil Action No. 81–00005–W (H)), entered on July 17, 1981, were adopted by the West Virginia Air Pollution Control Commission (the Commission) on August 11, 1982, and represent reasonably available control technology (RACT). The fugitive emission control requirements for the blooming mill scarfer were also adopted by the Commission on August 11, 1982 and represent RACT. These emission limits require that the current emissions of 2,120 tons/ year of particulate matter from these process sources not exceed 301 tons/year for a net difference of 1819 tons/year.

The proposed bubble plan would replace this 1819 tons/year of required emissions reductions with 2,659 tons/ year of emissions reductions through control of the non-process fugitive dust emissions from plant roads and parking lots. These road dust emissions currently total 3,191 tons/year of particulate matter. The Order establishes a control program containing specific, enforceable measures which will reduce these emissions to a level of 532 tons/year of particulate matter. The bubble will therefore result in reduction of 840 tons/year over current required levels.

This additional reduction of 840 tons/ year is required by this SIP revision as part of this bubble and is not available for future emissions trades. As a result of this bubble plan, the Company has provided information which indicates a savings in pollution control costs of approximately $30 million due to implementing controls required by the bubble.

The approved SIP for the Wierton area demonstrates attainment of the TSP standards (45 FR 5402 and 47 FR 36449); also, the current total particulate emission limitations for the four process operations represent RACT. According to the Emissions Trading Policy Statement (47 FR 15076) the alternative emission limitations must be at least as effective as the SIP limitations or RACT in terms of ambient impact.

EPA has examined the impact of the proposed bubble on levels of total suspended particulates (TSP) using diffusion modeling. EPA utilized a model acceptable in this situation for comparing annual average concentrations of TSP and applied it conservatively to estimate the change in ambient impacts resulting from the bubble proposal. EPA found an improvement in annual average TSP levels at each receptor site, as compared to the current emission limits under the Consent Decree.

EPA has had difficulty in conducting short term modeling for this situation, i.e. a complex source in complex terrain where particulate deposition is of critical concern. EPA is exploring techniques that will allow a short term ambient equivalence determination to be made and believes that such short term analysis will confirm the ambient equivalence as shown for the annual average. In addition, to determine the air quality effectiveness of the proposed emissions trade, EPA is requiring extensive ambient air quality monitoring including the collection of on-site meteorological data.

The Order is for a period of three years; however, if the monitoring program or other information available to EPA indicates that the program is not being effective, EPA can call for a plan revision under the authority of Section 110(a)(2)(H) of the Clean Air Act.

The Order contains a provision whereby the State and the Company will request a revision of the Federal Consent Decree to reflect the bubble. Such an action may not be undertaken until judicial review of EPA's approval of the bubble has been completed or foreclosed.

EPA has reviewed the bubble proposal and has concluded that it satisfies the requirements of the interim guidance, Emission Trading Policy Statement (47 FR 15076, April 7, 1982). Therefore, EPA is today proposing to approve the Consent Order for the bubble plan as a SIP revision.

The public is invited to submit, to the address above, comments on whether the proposed bubble plan for the Weirton Steel plant should be approved as a revision to the West Virginia State Implementation Plan.

The Administrator's decision to approve or disapprove the proposed revision will be based on the comments received and on a determination of whether the amendments meet the requirements of Section 110(a)(2) of the Clean Air Act and 40 CFR Part 51, Requirements for Preparation, Adoption, and Submittal of State Implementation Plans.

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

Under 5 U.S.C. 605(b), the Administrator has certified that SIP approvals do not have a significant economic impact on a substantial number of small entities. (See 46 FR 8709.)

List of Subjects in 40 CFR Part 52

Air pollution control, Ozone, Sulfur oxides, Nitrogen dioxide, Lead, Particulate matter, Carbon monoxide, Hydrocarbons, Intergovernmental relation.

(42 U.S.C. 7401–7642)

Dated: July 6, 1982.

Peter N. Bibko,

Regional Administrator.

[FR Doc. 82–24466 Filed 9–3–82; 8:45 am]

BILLING CODE 6560–50–M

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40 CFR Part 52

[A–4–FRL 2190–; TN–001]

Approval and Promulgation of Implementation Plans; Tennessee; Proposed Plan Revisions

AGENCY: Environmental Protection Agency.

ACTION: Proposal rule.

SUMMARY: EPA proposes to approve State Implementation Plan (SIP) revisions submitted by the Tennessee Department of Public Health, pursuant to the requirements of Part D of Title I of the Clean Air Act (CAA) of 1977, for the Kingsport particulate nonattainment area. EPA is also proposing to approve a visible emission reading technique for nontraditional fugitive dust sources, and state-adopted standards of performance for storage vessels for petroleum liquids. The public is invited to submit written comments on these proposed actions.

DATE: To be considered, comments must be received on or before October 7, 1982.

ADDRESS: Written comments should be addressed to Raymond S. Gregory of EPA Region IV's Air Management Branch (see EPA Region IV address below). Copies of the material submitted by Tennessee may be examined during normal business hours at the following locations:

Air Management Branch, Environmental Protection Agency, Region IV, 345 Courtland Street N.E., Atlanta, Georgia 30365
Tennessee Air Pollution Control Division, 150 9th Avenue North, Nashville, Tennessee 37203.

FOR FURTHER INFORMATION CONTACT: Raymond S. Gregory of EPA Region IV's Air Management Branch, 345 Courtland Street, NE, Atlanta, Georgia 30365, telephone 404/881-3286 (FTS 257-3286).

SUPPLEMENTARY INFORMATION: In the March 3, 1978 **Federal Register** (43 FR 8962 at 9035); the September 11, 1978 **Federal Register** (43 FR 40412 at 40432); and the August 27, 1979 **Federal Register** (44 FR 50098), a number of areas within the State of Tennessee were designated as not attaining certain national ambient air quality standards (NAAQS). A portion of Kingsport was designated as nonattainment for the primary and secondary NAAQS for particulate matter. Implementation plan revisions for attainment of the particulate matter NAAQS were conditionally approved for Kingsport on November 17, 1980 (45 FR 75660 at 75661), and final approval was given on May 27, 1982 (47 FR 23160 at 23162).

As part of the original approval, the State was required to submit permits without expiration dates. As the subject permits have periodically expired, the State has reissued them without expiration dates. On May 10, 1982, the State submitted certain reissued permits. With that submittal, permits for some additional minor fugitive dust sources and certain permits with minor changes not affecting emission amounts were included. There will be a net air quality benefit from these changes.

Included in the May 10, 1982, submittal was a technique for reading visible emissions from nontraditional fugitive dust sources. The opacity determined using this method will be based on an average of 8 consecutive observations recorded at 15-second intervals. This method is to be used for reading the opacity of emissions from roads and parking areas in the Kingsport particulate nonattainment area.

The State submitted on May 5, 1982, a revision which is entitled "Standards of Performance for Storage Vessels for Petroleum Liquids Constructed after May 18, 1978." This rule (1200–3–16–.09a) is substantially the same as EPA's New Source Performance Standard of the same title (40 CFR Part 60 Subpart Ka) except for two items. The first item of concern is in the section on testing and procedures. It includes a requirement for testing of secondary seal gaps. The regulation states, "Determine the gap areas and maximum gap widths between the primary seal and the tank wall, and the secondary seal and the tank wall according to the following frequency and furnish the Technical Secretary with a written report of the results within 60 days of performance of gap measurements * * *" However, the State failed to include a schedule ("frequency") for testing the secondary seals. For the primary seals, Tennessee's regulation states, "gap measurements shall be performed within 60 days of the initial fill with petroleum liquid and at least once every year thereafter." This frequency should have been specified for the secondary seals also. EPA is proposing to approve ths standard with the understanding that the State will require the secondary seals to be tested on the same frequency as the primary seals.

The second item concerns the prior notice given to the State before the gap measurement is made to afford the State an opportunity to have an observer present. EPA's standard requires 30 days prior notice. The State's standard does not specify a minimum time period of prior notice. EPA is proposing to approve this standard with the understanding that the State will require a minimum time period for prior notice of 30 days before the gap measurement is to be made.

Action

EPA proposes to approve revisions to the Tennessee State Implementation Plan concerning source permits for the Kingsport particulate nonattainment area, a visible emission reading technique for nontraditional fugitive dust sources, and standards of performance for storage vessels for petroleum liquids constructed after May 18, 1978. The last proposal is made with the understanding that the State will require the secondary seal gaps to be measured on the same frequency as the primary seal gaps, and that the State will require sources to give 30 days prior notice of seal gap measurements.

As previously stated, written comments must be received on or before October 7, 1982. A thirty-day comment period is being used because the SIP submission and the issues involved are not so complex as to warrant a longer comment period. At the close of the comment period, EPA will review all comments and publish a notice of final rulemaking.

Under 5 U.S.C. Section 605(b), the Administrator has certified that SIP approvals do not have a significant economic impact on a substantial number of small entities. (See 46 FR 8709.)

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

List of Subjects in 40 CFR Part 52

Air pollution control, Ozone, Sulfur oxides, Nitrogen dioxide, Lead, Particulate matter, Carbon monoxide, Hydrocarbons.

(Sec. 110, 172, Clean Air Act, as amended (42 U.S.C. 7410 and 7502))

Dated: August 2, 1982.

Charles R. Jeter.

Regional Administrator.

[FR Doc. 82-24493 Filed 9-3-82; 8:45 am]
BILLING CODE 6560-50-M

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40 CFR Part 60

[AD-FRL 2085-3]

Standards of Performance for New Stationary Sources, Appendix A; Revisions to Method 3, Appendix A of 40 CFR Part 60

January 22, 1982.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule and notice of public hearing.

SUMMARY: The purpose of this action is to propose revisions to Method 3 (gas analysis for carbon dioxide, oxygen, excess air, and dry molecular weight) of Appendix A of 40 CFR Part 60 that add quality assurance procedures for the test data. These revisions would require source testers to analyze for both CO_2 and O_2 when determining the emission rate correction factor or excess air for combustion sources in order that the resulting data can be assessed for agreement using the F_o fuel factor. In addition, the revisions would require an audit of the Orsat equipment using ambient air. The current regulation includes only limited quality assurance requirements and, as a result of this proposed regulation, the quality of compliance data will improve.

A public hearing will be held, if requested, to provide interested persons an opportunity for oral presentation of data, views, or arguments concerning the proposed revisions.

DATES:

Comments. Comments must be received on or before November 8, 1982.

Public Hearing. A public hearing will be held, if requested. Persons wishing to request a public hearing must contact EPA by November 8, 1982. If a hearing is

requested, an announcement of the date and place will appear in a separate Federal Register notice.

ADDRESSES:

Comments. Comments should be submitted (in duplicate if possible) to: Central Docket Section (A–130), Attention: Docket Number A–82–05, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460.

Public Hearing. Persons wishing to present oral testimony should notify Mrs. Naomi Durkee, Emission Standards and Engineering Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541–5578.

Docket. Docket No. A–82–05, containing materials relevant to this rulemaking, is available for public inspection and copying between 8:00 a.m. and 4:00 p.m., Monday through Friday, at EPA's Central Docket Section, West Tower Lobby, Gallery 1, Waterside Mall, 401 M Street, S.W., Washington, D.C. 20460. A reasonable fee may be changed for copying.

FOR FURTHER INFORMATION CONTACT:

Mr. Roger Shigehara, Emission Measurement Branch (MD–19), Emission Standards and Engineering Division, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541–2237.

SUPPLEMENTARY INFORMATION: The proposed method revisions will require the source tester to: (1) Analyze both CO_2 and O_2 with the Orsat analyzer for each compliance sample, (2) assure that the results agree within the limits specified for the fuel type, F_o factor procedure, and (3) analyze a sample of ambient air with each set of compliance samples.

These revisions would apply to all sources subject to standards of performance specifying the use of Method 3 for the measurement of O_2 and CO_2 concentrations in the emissions from combustion sources, including standards already promulgated. This rulemaking would not impose any additional emission measurement requirements on any facilities. Rather, the rulemaking would simply revise a test method associated with emission measurement requirements that would apply irrespective of this rulemaking.

Miscellaneous

Under Executive Order 12291, EPA must judge whether a regulation is "major" and, therefore, subject to the requirement of a regulatory impact analysis. This regulation is not major because it will not have an annual effect on the economy of $100 million or more; it will not result in a major increase in costs or prices; and there will be no significant effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The regulation was submitted to the Office of Management and Budget for review as required by Executive Order 12291.

Pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that the attached rule will not have a significant economic impact on a substantial number of small entities.

(Sec. 111, 114, and 301(a) of the Clean Air Act, as amended (42 U.S.C. 7411, 7414, and 76(a))

List of Subjects in 40 CFR Part 60

Air pollution control, Aluminum, Ammonium sulfate plants, Cement industry, Coal, Copper, Electric power plants, Glass and glass products, Grains, Intergovernmental relations, Iron, Lead, Metals, Motor vehicles, Nitric acid plants, Paper and paper products industry, Petroleum.

Dated: August 24, 1982.

J. Daniel,

Acting Administrator.

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

It is proposed that Appendix A of 40 CFR Part 60 be amended as follows:

1. By revising Method 3 as follows:

Method 3—Gas Analysis For Carbon Dioxide, Oxgyen, Excess Air, and Dry Molecular Weight

* * * * *

4. *Emission Rate Correction Factor or Excess Air Determination*

* * * * *

Delete the sentence: "Each of the three procedures below shall be used only when specified in the applicable subpart of the standards." Replace it with: "Each of the three procedures below plus the quality assurance procedures in Section 4.4 shall be used when specified in the applicable subpart of the regulation."

* * * * *

In Sections 4.1.5 and 4.2.7, delete the sentence: "Although in most cases only CO_2 or O_2 is required, it is recommended that both CO_2 and O_2 be measured, and that Citation 5 in the Bibilography be used to validate the analytical data."

* * * * *

4.4 Quality Assurance Procedures

4.4.1 Data Validation. Although in most instances, only CO_2 or O_2 measurement is required, measure both CO_2 and O_2 when using the Orsat. Using the following procedure, verify that the fuel factor, F_o, is within ±5 of the established value (i.e., either the average value found in the table below or the value calculated from ultimate analyses results of representative fuel samples following the procedures in 40 CFR Part 60, Appendix A, Method 19).

Determine the F_o factor using the following:

$$F_o = \frac{20.9 - \%O_{2d}}{\%CO_{2d}}$$

Where:

$\%O_{2d}$ = Measured oxgyen concentration; percent, dry.

$\%CO_{2d}$ = Measured carbon dioxide concentration; percent, dry.

20.9 = Percent oxygen concentration in ambient air. Compare the F_o factor determined above with the appropriate value from the following table:

Fuel type	F_o
Coal:	
Anthracite	1.070
Bituminous	1.140
Lignite	1.076
Oil	1.346
Gas:	
Natural	1.749
Propane	1.510
Butane	1.479
Wood	1.050
Wood bark	1.056

4.4.2 Equipment/Analyzer Check. At the completion of each test series (e.g., set of three test runs), analyze a sample of the ambient air with the Orsat. Report the results and verify that the O_2 value is 20.9 ± 0.3 percent.

4.4.3 If either of the above criterion is not met, repeat the sampling and analysis and the quality assurance check. Report all the results for all test runs.

[FR Doc. 82-24494 Filed 9-3-82; 8:45 am]

BILLING CODE 6560-50-M

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40 CFR Part 60

[AD-FRL-2085-2]

Standards of Performance for New Stationary Sources; Appendix A; Revisions to Methods 4 and 5

January 28, 1982.

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule and notice of public hearing.

SUMMARY: The purpose of this action is to propose revisions to Methods 4 (determination of moisture content in stack gases) and 5 (determination of particulate emissions from stationary sources) of Appendix A of 40 CFR Part 60 that add quality assurance procedures for the test data. These revisions would require source testers to prepare a calibration curve of meter volume flow rate versus an orifice pressure factor during the calibration of

the volume metering system and use this curve in performing a file check of the calibration. Criteria for acceptance are provided. The current regulation involves only limited quality assurance requirements and, as a result of this proposed regulation, the quality of compliance data will improve.

A public hearing will be held, if requested, to provide interested persons an opportunity for oral presentation of data, views, or arguments concerning the proposed revisions.

DATES: *Comments.* Comments must be received on or before November 8, 1982.

Public Hearing. A public hearing will be held, if requested. Persons wising to request a public hearing must contact EPA by November 8, 1982. If a hearing is requested, an announcement of the date and place will appear in a separate **Federal Register** notice.

ADDRESSES: *Comments.* Comments should be submitted (in duplicate if possible) to: Central Docket Section (A–130), Attention: Docket Number A–82–04, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460.

Public Hearing. Persons wishing to present oral testimony should notify Mrs. Naomi Durkee, Emission Standards and Engineering Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541–5578.

Docket. Docket No. A–82–04, containing materials relevant to this rulemaking, is available for public inspection and copying between 8:00 a.m. and 4:00 p.m., Monday through Friday, at EPA's Central Docket Section, West Tower Lobby, Gallery 1, Waterside Mall, 401 M Street, SW., Washington, D.C. 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Mr. Roger Shigehara, Emission Measurement Branch (MD–19), Emission Standards and Engineering Division, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541–2237.

SUPPLEMENTARY INFORMATION: The proposed method revisions will require the tester to: (1) Prepare a calibration curve for the dry gas meter and corresponding orifice, (2) perform a field check of the dry gas volume meter versus the orifice factor, (3) assure that the results are within the limits specified by the method.

These revisions add quality assurance procedures to Methods 4 and 5 that will help verify the quality of the measurements made with the methods. The procedures are appropriate as little additional effort is required to gain valuable quality assurance data while also providing the tester with quality control guidelines.

These revisions would apply to all sources subject to standards of performance specifying the use of Method 4 for moisture determination or Method 5 for particulate emission measurement, including standards that have already been promulgated. This rulemaking would not impose any additional emission measurement requirements on any facilities. Rather, the rulemaking would simply revise a test method associated with emission measurement requirements that would apply irrespective of this rulemaking.

Miscellaneous

Under Executive Order 12291, EPA must judge whether a regulation is "major" and , therefore, subject to the requirement of a regulatory impact analysis. This regulation is not major because it will not have an annual effect on the economy of $100 million or more; it will not result in a major increase in costs or prices; and there will be no significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The regulation was submitted to to the Office of Management and Budget for review as required by Executive Order 12291.

Pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that the attached rule will not have a significant economic impact on a substantial number of small entities.

(Sec. 111, 114, and 301(a) of the Clean Air Act, amended (42 U.S.C. 7411, 7414, and 7601(a)))

List of Subjects in 40 CFR Part 60

Air pollution control, Aluminum, Ammonium sulfate plants, Cement industry, Coal, Copper, Electric power plants, Glass and glass products, Grains, Intergovernmental relations, Iron, Lead, Metals, Motor vehicles, Nitric acid plants, Paper and paper products industry, Petroleum.

Dated: August 24, 1982.

John Daniel,

Acting Administrator.

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

It is proposed that Appendix A of 40 CFR Part 60 be amended as follows:

1. By revising Method 4 and Method 5 as follows:

Method 4—Determination of Moisture Content in Stack Gases

* * * * *

4. *Calibrations*

* * * * *

4.2 Quality Assurance Procedures. For the reference method, follow the procedures in Method 5, Section 4.4 in determining the acceptability of the volume calibration values on the field test site.

* * * * *

Method 5—Determination of Particulate Emissions From Stationary Sources

* * * * *

4. *Procedure*

* * * * *

4.4 Quality Assurance Procedures. These quality assurance procedures check the calibration values obtained for the volume metering system under field conditions. The check shall be conducted prior to the start of the first emission test run of a series of runs conducted for determination of compliance with an applicable emission standard. The results shall be reported with the post-test calibration check (Section 5.3).

4.4 Orifice Factor Determination. Calibrate the dry gas meter and orifice according to the procedures in Section 5.3, recording the dry gas meter volume, run time, meter inlet and outlet temperatures, orifice pressure, wet test meter volume, and the ambient conditions. With the meter calibration coefficient and the other calibration data, calculate the dry gas meter volume flow rate at each of the orifice pressures tested:

$$Q_i = (Y)(0.3855)(Vol_i)\left[\frac{P_b - \frac{\Delta H_i}{13.6}}{T_m + 273}\right]\frac{1}{\Theta}$$

where:

Q_i = Volume flow rate for run i, l/min (ft^3/min).

Y = Dry gas meter calibration coefficient, dimensionless.

0.3855 = Standard temperature and pressure correction, °K/mmHg (or 17.64 °R/in. Hg).

Vol_i = Dry gas meter volume for run i, l (ft^3).

P_b = Barometric pressure, mm Hg (in. Hg).

ΔH_i = Average orifice pressure during run i, (in. H_2O).

Θ = Duration of run i, min.

Calculate the orifice factor, OF, for each run i:

$$OF = \sqrt{\left(\frac{T_o}{P_b}\right)\Delta H_i}$$

where:

T_o = Average gas meter exhaust temperature, °K (°R).

4.4.2 Correlation Line. Determine a best-fit, linear regression equation (e.g. least-

squares determination) for the flow-rate values and the corresponding orifice factors so that the form of the equation is:

$Q = a + b(OF)$

where:

a and b = Empirical constants.

Record and identify this equation for the meter being calibrated using the meter box number or other permanent identification.

4.4.3 Field Check. In the field and just prior to the initiation of the sampling, check the volume meter calibration using the following procedure: Operate the meter box at an orifice pressure approximately equal to the meter $\Delta H_@$ for about 10 minutes recording the operation time, initial and final dry gas meter readings, initial and final inlet and outlet meter temperatures, and barometric pressure. Maintain a constant orifice pressure reading throughout the run at or near the meter $\Delta H_@$.

At the completion of the run, determine the average meter flow rate using the recorded data as defined in Section 4.4.1. Calculate the orifice factor using the recorded data as defined in Section 4.4.1. Determine the predicted flow rate using the linear regression equation developed in Section 4.4.2 and the measured orifice factor.

Compare the predicted flow rate with the measured flow rate. The meter coefficient is determined to be acceptable if the measured flow rate agrees with the predicted flow to within ±1.5 percent of the measured value. If this criterion is not met, the meter shall be recalibrated prior to use as described in Section 5.3.

4.4.4 Alternative Procedure. A calibrated critical orifice, calibrated against a wet test meter or spirometer and designed to be inserted at the inlet of the sampling meter box may be used as an alternative. The calibration procedure and the quality assurance check procedure should be submitted to the Administrator for approval prior to use.

* * * * *

[FR Doc. 82-24495 Filed 9-3-82; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[BC Docket No. 82-358; RM-4057]

FM Broadcast Station in Anchorage and Wasilla, Alaska; Order Extending Time To File Comments and Reply Comments

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; extension of time for filing comments and reply comments.

SUMMARY: Action taken herein extends the time filing comments and reply comments in the proceeding involving the assignment of Channel 289 to Wasilla, Alaska, and the substitution of Channel 285A for Channel 288A at Anchorage, Alaska. Northern Television, Inc.

DATES: Comments must be filed on or before August 20, 1982, and reply comments on or before September 4, 1982.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Montrose H. Tyree, Broadcast Bureau, (202) 632-7792.

SUPPLEMENTARY INFORMATION:

List of Subjects in 47 CFR Part 73

Radio broadcasting.

In the matter of Amendment of § 73.202(b), Table of Assignments, FM Broadcast Stations. (Anchorage and Wasilla, Alaska), BC Docket No. 82-358 RM-4057.

Order Extending Time For Filing Comments and Reply Comments

Adopted: August 18, 1982.

Released: August 26, 1982.

By the Chief, Policy and Rules Division.

1. On June 28, 1982, the Commission adopted a Notice of Proposed Rule Making, 47 FR 31013, published July 16, 1982, in response to a petition filed by Snow Peak Corporation, which proposes to assign Channel 289 to Wasilla, Alaska, and substitute Channel 285A for Channel 288A at Anchorage, Alaska. Comments and reply comments are presently due August 16 and August 31, 1982, respectively.

2. Counsel for Northern Television, Inc., on August 13, 1982, submitted a request to extend the time for filing initial comments to August 20, 1982, stating that the additional time is needed to prepare and submit comments. Counsel states that Snow Peak Corporation has consented to the requested extension and that another commenting party, Alaska Village Mission, has also consented.

3. Section 1.47 of the Commission's Rules states that extension requests must be filed seven days in advance of the deadline date. However, since no party has objected to the extension and we wish to have all pertinent information in order to resolve this proceeding, we are granting the extension. We have also extended the reply comment date to give at least 15 days.

4. Accordingly, it is Ordered, That the dates for filing comments and reply comments are extended to and including August 20, 1982, and September 7, 1982, respectively.

5. This action is pursuant to authority contained in sections 4(i), 5(d)(1), and 303(r) of the Communications Act of 1934, as amended, and sections 0.204(b) and 0.281 of the Commission's rules.

Federal Communications Commission.

Roderick K. Porter,

Chief, Policy and Rules Division, Broadcast Bureau.

[FR Doc. 82-24492 Filed 9-3-82; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 76

[Docket No. 18891; FCC 82-322]

Amendment of the Commission's Rules Relative to Diversification of Control of Community Antenna Television Systems; and Inquiry With Respect Thereto To Formulate Regulatory Policy and Rulemaking and/or Legislative Proposals

AGENCY: Federal Communications Commission.

ACTION: Proposed rule withdrawn (Report and Order).

SUMMARY: By a *Notice of Proposed Rulemaking and Inquiry in Docket 18891*, 23 FCC 2d 833 (1970), the Commission sought comments on a proposal to limit multiple ownership of cable television systems. After considering the comments received in this proceeeding as well as other evidence which became available in the twelve years since issuance of the *Notice*, the Commission concluded that, given the persistently unconcentrated nature of the industry, no rules restricting multiple ownership of cable television systems are presently justified. Accordingly, the Commission adopted a *Report and Order in Docket 18891* terminating the proceeding insofar as it related to the issue of multiple ownership restrictions, without the adoption of rules.

FOR FURTHER INFORMATION CONTACT: Robert H. Ratcliffe, Cable Television Bureau, Federal Communications Commission, Washington, D.C. 20554, (202) 632-6468.

In the matter of: Amendment of Part 76, Subpart J of the Commission's rules and regulations relative to diversification of control of community antenna television systems; and inquiry with respect thereto to formulate regulatory policy and rulemaking and/or legislative proposals; Docket No. 18891.

Report and Order

Adopted: July 15, 1982.

Released: August 27, 1982.

By the Commission: Commissioner Washburn dissenting and issuing a statement; Commissioners Dawson and Rivera concurring and issuing statements.

1. *The Notice of Proposed Rulemaking and Inquiry* in this proceeding (23 FCC 2d 833) (1970)) was adopted by the Commission over ten years ago. It proposed, among other things, to limit either the number of cable systems or the number of cable subscribers that could be controlled by any single cable television system multiple owner. Although a number of alternative rules were proposed, the one receiving the most attention would have limited a single owner to systems serving no more than 2,000,000 subscribers. This proposal followed up on a more general discussion of the question of multiple ownership in the Commission's *Notice of Proposed Rulemaking and Notice of Inquiry in Docket 18397*, 15 FCC 2d 417, (1968). The rationale for these proposals, although not set forth in any great detail, appears to have been a general desire to promote diversification of control of the media of mass communications.

2. Comments responsive to this proposal were filed with the Commission in 1970. Some twenty-four commenting parties addressed the issue of multiple ownership. Given the length of time since these comments were filed, many are based on circumstances that have now significantly changed. We will, therefore, not summarize in detail all of the points raised.

3. Of the commenting parties, eight, including Professor Stephen R. Barnett, the United States Department of Justice (DOJ), the National Citizens Committee for Broadcasting (NCCB), the Corporation for Public Broadcasting (CPB), Best Efforts for Soul in Television (BEST), and three broadcasting parties (Junction City Broadcasting, Montana network *et al.*, and Hirsch Broadcasting Company) were in some measure supportive of the need for multiple ownership restrictions in the cable industry. The broadcast parties, to the extent they are supportive of the need for limits, appear to believe that such limits, by reducing the aggregate financial base of any cable firm, can be used as a means of assuring that local television broadcast stations are not faced with unacceptable levels of cable competition.

4. The comments from BEST were premised on the desirability of local ownership and urge an alternative rule that would require a majority of the stock of each cable system be owned by persons registered to vote in the cable community. NCCB based its argument about the need for limits on the concern that if the industry came to be dominated by a single firm "such a commanding position would give a single owner the opportunity to use his purchasing power to favor the equipment of particular manufacturers and the products of particular producers * * *. [This] might tend to prejudice the development of superior technologies and diverse program sources." Although CPB recognized the importance of cable owners being "at least large enough to achieve [the] financial stability and flexibility required to undertake experimentation and development in new uses and technology," both CPB and Barnett urged that size limits are desirable to promote competition and diversity.

5. The Department of Justice raised concerns similar to those of NCCB concerning the relationship between concentration in the cable market and competition among cable equipment suppliers and urged that "some eventual limitation on multiple ownership of CATV systems" is needed. It argued against limits based on subscriber counts or the number of markets that can be served, however, on the grounds that such limits would discourage expansion of existing systems and that overly restrictive limitations would impair the ability of system operators to act as potential competitors. Moreover, it was said that excessive fractionalization of the market through regulation could undermine the ability of large systems to, directly or indirectly, sponsor CATV network programming. The Department's more recent comments, filed in response to a Commission study of cable ownership issues (see paragraph 8 below), do not suggest that such regulation is needed at this time.

6. The other comments filed, principally by cable television system operators, all opposed the adoption of rules on various grounds. First, it was argued that the adoption of rules was premature at the time (1970) either because the nature of the industry and its regulation was not known or simply because the industry was not concentrated enough to warrant regulatory concern. With respect to the question of the unknown nature of the industry, Cable Information Systems, Inc. (a multiple cable system operator) argued, for example, that the principal function of the industry would be the provision of channels for hire and thus concerns about a concentration of control over media voices were inappropriate. Second, the commentors urged that parallels with multiple ownership limits in the broadcast area were inappropriate because individual broadcasters or broadcast group owners were permitted to serve far more than the 2,000,000 subscriber limit proposed for the cable industry. Third, it was urged that significant multiple ownership might well be desirable in order for firms in the cable industry to be more credible competitors with firms in the telephone and broadcast industries which had far larger financial bases. Large size might also be necessary for cable firms to sustain program production and technical research efforts.[1]

7. Although these comments were summarized by the staff and discussed with the Commission, no action was taken at that time. In the succeeding years the general patterns of growth in the cable industry were followed in some detail. These patterns, expressed both in terms of company subscribership as a percentage of total industry subscribership and as a percentage of the aggregate subscribership of the 50 largest cable companies, are presented in Appendix A hereto. for purposes of this study, we have used industry concentration ratios based on subscribership because these data are readily available and broadly indicative of trends within the cable industry.[2] We have had occasion in the past, however, to note our belief that "the peculiar characteristics of the present cable market render inappropriate a conventional analysis of the CATV market. * * * The competition among CATV firms is for new franchises, but this is competition for new subscribers, not for those subscribers represented in conventional measures of market share and concentration." *Miami Valley Broadcasting*, 47 R.R. 2d 445, 471–2 (1980), *vacated*, FCC 80–745 (released Dec. 22, 1980). Beyond this, it is probably inappropriate to consider cable entirely separate from the broader video entertainment markets in which cable participates. Placed in a broader market context, the degree of apparent concentration reflected in Appendix A would be significantly reduced. During this period, the Commission also ruled on a series of merger proposals involving firms in the cable television industry. In each instance the Commission reviewed the proposal in the context of the overall development of the industry, including the general issue of concentration, and in each

[1] Some of the commenting parties also disputed the Commission's authority to adopt multiple ownership regulation in light of the Commission's "ancillary to broadcasting" jurisdiction over the cable industry. In light of our decision herein we have not found it necessary to address this issue.

[2] *See* Staff Report, *FCC Policy on Cable Ownership* (cited in para. 8, below) at Chapter 5, for a discussion of the limitations of concentration ratios as indicators of market power.

instance the merger was found to be in the public interest and approved.[3]

8. In 1980 a study of trends in cable television system ownership was undertaken for the Commission's Network Inquiry Special Staff and released for public comment. *See* Y. M. Braunstein, *Recent Trends in Cable Television Related to the Prospects for New Television Networks*, Appendix to *Preliminary Report on Prospects For Additional Networks* (January 1980). More recently the issue has been studied by the Commission's Office of Plans and Policy as part of a more comprehensive study of cable television ownership policies. *See* K. Gordon, J. Levy, and R. Preece, *FCC Policy on Cable Ownership* (Staff Report, FCC Office of Plans and Policy), November 1981 [hereinafter Staff Study]. The Staff Study notes, as did the Network Inquiry Special Staff Report, that horizontal concentration achieved through multiple system ownership could pose a threat to diversity if it reached significant levels. But, the Study states, after extensive review of current data, that industry concentration is, in fact, neither high now nor likely to become so in the foreseeable future. Moreover, the study points out that substantial benefits may be derived from multiple system ownership and that, given the absence of a real threat from over-concentration, cable owners and subscribers should be permitted to realize these organizational benefits.[4] The Study concludes:

> Since separate cable systems do not compete directly, MSO's have no direct effect on local markets. Workable competition there depends on the existence of alternative local transmission media. At the national level, MSO's compete for franchises and for programming. If a few MSO's were to gain control of most video outlets in the country, their share of total media outlets might be unacceptably high. The data presented in the chapter suggest that this point has not nearly been reached; concentration is low, other media are available, and there are many credible potential entrants into the cable business. Against this background, it seems likely that MSO growth (short of growth to a very high market share) is based on organizational efficiencies and hence is desirable.
>
> If the situation were to change drastically in the future, the antitrust laws could be used to insure that MSO concentration does not adversely affect performance in the franchising and programming markets. Furthermore, the Commission could reconsider the question of MSO limitations at a later date. The availability of these options, the current low level of MSO concentration, and the potential efficiencies of multiple system ownership discussed above, taken together lead to the conclusion that no restrictions on MSO's are currently desirable.[5]

9. These studies, our own reviews of the industry in the merger context, and Appendix A hereto all suggest that while the amount of concentration in the cable television industry is increasing it is still not a concentrated industry and that, in general, there is no reason to suspect that any trend exists which is decreasing the vigor of competition between cable television operators in the franchising process or that the industry has reached or is likely to reach a point in the near future where concentration in it endangers the diversity of viewpoints received by the public.[6]

10. Under the Commission's rules common ownership of more than seven television stations is prohibited. 47 CFR 73.636(a)(2). It is sometimes suggested that multiple ownership limitations for the cable industry are needed or desirable to parallel these broadcast industry ownership rules. We do not believe, however, that the analogy justifies the adoption of regulatory constraints at this time. Although television stations do not have "subscribers," using net weekly circulation as a proxy, the largest cable system owner has only about thirteen percent of the circulation of the largest television multiple owner. If ranked by circulation, the largest cable firm would rank approximately 30th on a combined list of cable and broadcast multiple outlet firms.[7] Because cable systems frequently are not directly involved in the production of programming, the cable industry's leading firms would appear even farther down any list of "opinion molders."[8]

11. Accordingly, in light of these findings, the growth in the cable television and video markets that has occurred since this proceeding was commenced, and consistent with the conclusions of the two studies undertaken for the Commission (paragraph 8), we are terminating this proceeding, without the adoption of rules, insofar as it relates to the issue of cable television multiple ownership.

This action is taken pursuant to authority contained in Sections 1, 2, 3, 4(i) and (j), 301, 303, 307, 309, and 403 of the Communications Act of 1934, as amended.

Accordingly, it is ordered, That the proceeding in Docket 18891 relating to cable television multiple ownership is terminated.

Federal Communications Commission.

William J. Tricarico,

Secretary.

Appendix A

Concentration of Control in the Cable Television Industry

The attached chart contains statistics relating to concentration of ownership in the cable television industry from 1969 through 1982. Data published by *Television Digest* in December of each year were used in the preparation of this chart, except for 1969 which are February data and 1982 which are April data. For each year the subscribers to each of the ten largest cable television system owners are shown as a percent of total industry subscribers and as a percent of subscribers to all systems of the 50 largest system owners. [Starting at the upper left, the chart may be read as follows: in 1969 H & B was the largest cable television system owner in terms of subscribers, its subscribers comprising 10.6% of subscribers to the 50 largest companies and 6.3% of all subscribers.]

Also shown are the same data totaled for the 4, 8, 25, and 50 largest system owners. At the right side of the chart, subscriber data for each firm are shown

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[3] The firms in question were holders of radio station licenses (generally in the point-to-point microwave radio services) so that Commission consent to the transfers of control involved was required by Section 310(d) of the Communications Act. The Commission approved the merger of H & B and Teleprompter in *Teleprompter Transmission of Kansas, Inc.*, 25 FCC 2d 469 (1970); the merger of Warner and Cypress in *Warner Communications, Inc.*, 37 FCC 2d 260 (1972); the merger of Athena and Tele-Communications, Inc., in *Athena Communications Corp.*, 47 FCC 2d 535 (1974); the merger of Time, Inc., and ATC in *American TV & Communications Corporation*, 70 FCC 2d 2175 (1978); Cox and G.E. in *Miami Valley Broadcasting*, 47 RR 2d 445 (1980) (vacated); and Westinghouse and Teleprompter in *Teleprompter Corporation*, 87 FCC 2d 531 (1981), *aff'd on recon.*, 89 FCC 2d 417 (1982), *appeal pending*.

[4] *See* Staff Study at pp. 99–104.

[5] *Id.* at p. 106. The Commission has adopted a *Notice of Proposed Rulemaking in CT Docket 82–434*, FCC 82–323 (released August 27, 1982), concerning cable-network cross-ownership rules. In that proceeding an effort will be made to develop some measures of concentration of more general applicability. That process should provide an additional mechanism for tracking developments in this area and triggering further action where warranted.

[6] In reaching this conclusion we have also considered public comments filed in connection with the Staff Study, the most recent document treating the multiple ownership issue. None of the commenters provided evidence to suggest that the Study's recommendation against the adoption of multiple ownership restrictions is ill-founded.

[7] The data used here concerning group broadcasters is from a 1979 study prepared for the National Association of Broadcasters by Herbert H. Howard entitled "Television Station Group Ownership: 1979."

[8] Even the nationally distributed cable networks, it should be noted, are having some difficulties accumulating audience sufficient to be reflected in the data available from the national audience rating firms.

as a percentage of total television households in 1982. At the bottom of the chart, the "Gini coefficient" for the fifty largest firms is provided. The Gini coefficient is one commonly used measure of industry concentration. It is a measure of how close a given distribution is to absolute equality or inequality. A Gini coefficient of zero indicates perfect equality of firm shares; a coefficient of 1.0 reveals total inequality (with the leading firm producing the entire output).

A similar measure of concentration, of some current interest in the antitrust field, is the Herfindahl (or Herfindahl-Hirschman) index. The Herfindahl index is calculated by summing the squares of the market shares of all firms in an industry. It is a measure of concentration that takes account of the entire firm size distribution. Its value falls with increasing numbers of firms but rises as the degree of inequality among them increases. When an industry is occupied by one firm, the index attains its maximum value of one. Although the Herfindahl index for each year is not included on the attached chart, they are: for 1967, 366; for 1974, 559; and for 1982, 507. [While ideally this index is based on all industry firms, the results here are based on the fifty largest cable firms only. Nonetheless, we believe the results are meaningful and would not be substantially different if calculated on an all-industry basis.]

For some more general discussion of concentration ratios, see F. M. Scherer, *Industrial Market Structure and Economic Performance* (Chicago: Rand McNally, 1980) pages 56–64.

Company Name Abbreviation Code and Ownership Notes

Abbreviation, Name, and Ownership Notes

ATC—American TV and Communications Corp.: in 1972 acquired systems of Time-Life Cable other than Manhattan Cable TV. Now wholly owned by Time, Inc. *See American TV & Communications Corp.*, 70 FCC 2d 2175 (1978).

CBS—Columbia Broadcasting System: In 1971 the cable systems of CBS were spun off to the stockholder of CBS to form Viacom International, Inc. *See Iacopi v. FCC*, 451 F 2d 1142 (1971).

C–G—Cablecom-General: Acquired by Capital Cities Cable from RKO General in 1981. *See Cablecon-General, Inc.*, FCC 81–265 (released June 11, 1981)

CPI—Communications Properties, Inc.: Acquired by Times Mirror Co. in 1979.

CTC—Community Tele-Communications Inc.: Became TCI in 1972.

Cox—Cox Cable Communications Inc.

Cypress—Cypress Communications Corp.: merged with TVC in 1971 to form Warner Cable Communications. *See Warner Communications Inc.*, 37 FCC 2d 260 (1972).

GenCoE—GenCoE.: became LVO Cable, Inc. which became United.

H & B—H & B American Corp.: merged with Teleprompter and Reeves Telecom Corp. in 1971 to form TPT. *See Teleprompter Transmission of Kansas, Inc.*, 25 FCC 2d 469 (1970).

HarriS—HarriScope Cable Corp.: merged into Cypress in 1970.

Jerrold—Jerrold Corp.: systems sold to National Trans-Video in 1971 to form Sammons Communications Inc.

Midwest—Midwest Video Corp.

Newhouse—Newhouse Bcstg.

Rog's–UA—Rogers UA Cablesystems Inc.: Formerly UA-Columbia Cablevision Inc.

Sammons—Sammons Communications Inc.: acquired systems of National Trans-Video and Jerrold in 1971.

Ser. El.—Service Electric Cable TV Inc.

Storer—Storer Cable TV Inc.

TCI—Tele-Communications Inc.: formerly CTC. 1979 data includes subscribers to Athena which is 42% owned by TCI. With respect to this relationship, *See Athena Communications Corp.*, 47 FCC 2d 535 (1974).

T–L—Time-Life Cable Communications: bulk of systems sold to ATC in 1972; merged with ATC in 1978.

T–M—Times Mirror Co.: acquired CPI in 1979.

TPT—Teleprompter Corp.: merged with H & B and Reeves Telecom Corp. in 1970. *See Teleprompter Transmission of Kansas, Inc.*, 25 FCC 2d 469 (1970). Acquired by Westinghouse Broadcasting in 1981. *See Teleprompter Corp.*, 87 FCC 2d 531 (1981), *aff'd on recon.*, 89 FCC 2d 417 (1982), *appeal pending.*

TVC—TV Communications Corp.: merged with Cypress in 1971 to form Warner.

UA-Col.—UA-Columbia Cablevision Inc.

United—United Cable TV Corp.: formerly LVO Cable Inc.

Viacom—Viacom International Inc.: formerly part of CBS.

Warner—Warner Amex Communications Corp.

Westgh—Group W Cable. Westinghouse Broadcasting and Cable Inc. acquired Teleprompter Corp. in 1982.

BILLING CODE 6712-01-M

CONCENTRATION OF OWNERSHIP IN THE CABLE TELEVISION INDUSTRY
(Subscribers to largest companies as a percent of total industry and top-50 company subscribers)

Rank	1969	1970	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981	1982	1982 SUB TVHSLDS
1	H & S	H & S	TPT	TPT	TPT	TPT	TPT	TPT	TPT	TPT	TPT	TPT	ATC	TCI	
	10.6 *	9.7	15.8	15.0	15.0	16.0	15.3	14.0	13.0	12.6	11.6	10.5	10.8	11.1	
	6.3 **	5.8	10.4	09.9	10.2	10.7	10.4	9.3	8.5	8.5	8.4	7.7	8.5	8.7	2.5
2	TPT	COX	COX	WARNER	WARNER	WARNER	TCI	TCI	ATC	ATC	ATC	ATC	TPT	ATC	
	5.2	6.5	6.4	8.2	7.8	7.8	7.6	7.2	7.6	8.1	9.2	9.5	9.9	10.4	
	3.4	3.9	4.2	5.4	5.3	5.2	5.2	4.8	5.0	5.5	6.7	7.0	7.9	8.2	2.3
3	ATC	ATC	ATC	TCI	TCI	TCI	WARNER	ATC	TCI	WARNER	TCI	TCI	TCI	WESTCH	
	5.4	5.9	5.4	6.8	7.4	7.7	7.4	7.2	6.8	6.5	7.3	8.1	9.0	9.4	
	3.2	3.5	3.6	4.5	5.1	5.1	5.0	4.8	4.5	4.4	5.3	5.9	7.2	7.3	2.0
4	JERROLD	TPT	CYPRESS	ATC	ATC	ATC	ATC	WARNER	WARNER	TCI	WARNER	COX	COX	COX	
	5.0	5.6	4.1	6.0	6.5	6.8	7.0	7.2	6.8	6.2	6.2	6.9	6.8	6.4	
	2.9	3.4	2.7	4.0	4.4	4.6	4.7	4.8	4.4	4.2	4.5	5.1	5.4	5.1	1.4
Top 4	26.9	23.9	31.8	35.9	36.7	38.3	37.3	35.6	34.1	33.4	34.3	35.0	36.5	37.3	
	15.8	16.6	20.9	23.9	24.9	25.6	25.2	23.7	22.4	22.5	24.9	25.7	29.0	29.3	8.2
5	COX	CBS	VIACOM	COX	COX	COX	COX	COX	COX	COX	COX	WARNER	WARNER	STORER	
	4.8	5.6	3.8	5.5	5.2	5.2	5.3	5.4	5.6	6.1	6.2	5.7	5.2	5.2	
	2.8	3.3	2.5	3.7	3.5	3.5	3.6	3.6	3.7	4.1	4.5	4.2	4.1	4.0	1.1
6	CBS	JERROLD	CTC	VIACOM	VIACOM	VIACOM	VIACOM	VIACOM	VIACOM	VIACOM	T-M	T-M	STORER	WARNER	
	4.0	5.0	3.8	4.0	4.5	4.6	4.1	4.0	4.0	3.9	4.3	4.3	5.0	5.0	
	2.4	3.0	2.5	2.7	3.1	3.1	2.8	2.6	2.6	2.6	3.1	3.1	4.0	4.0	1.1
7	C-G	Harris	C-G	SAMMONS	SAMMONS	SAMMONS	SAMMONS	SAMMONS	SAMMONS	SAMMONS	VIACOM	STORER	T-M	T-M	
	3.7	4.1	3.7	4.0	4.4	3.6	3.8	3.8	3.6	3.5	3.9	4.2	4.1	3.7	
	2.1	2.4	2.4	2.7	3.0	2.4	2.6	2.5	2.4	2.4	2.8	3.1	3.2	2.9	0.8
8	NT-V	C-G	T-L	C-G	C-G	CPI	CPI	CPI	CPI	CPI	SAMMONS	VIACOM	VIACOM	NEWHOUSE	
	3.5	3.5	3.2	3.9	3.5	3.5	3.5	3.3	3.5	3.3	3.4	3.6	3.2	3.4	
	2.0	2.1	2.1	2.6	2.4	2.3	2.4	2.2	2.3	2.3	2.5	2.7	2.6	2.6	0.7
Top 8	42.9	42.8	46.3	53.4	54.3	55.1	54.0	52.1	50.9	50.2	52.1	52.8	54.0	54.6	
	25.1	27.4	30.4	35.4	36.9	36.9	36.5	34.6	33.4	33.8	37.8	38.8	42.9	42.8	11.9
9	GENCOE	MIDWEST	TVC	CPI	CPI	C-G	UNITED	UA-COL	UA-COL	UA-COL	STORER	SAMMONS	UA-COL	VIACOM	
	3.3	3.3	2.8	3.8	3.3	3.0	2.7	2.7	2.7	2.7	3.1	3.1	3.0	2.9	
	1.9	2.0	1.9	2.6	2.2	2.0	1.8	1.8	1.8	1.8	2.2	2.3	2.3	2.3	0.6
10	TVC	CTC	NT-V	SER. EL.	UA-COL	UA-COL	C-G	UNITED	UNITED	STORER	UA-COL	UA-COL	UNITED	ROG'S-UA	
	3.2	3.3	2.8	2.4	2.8	2.7	2.6	2.3	2.4	2.6	2.8	3.0	2.8	2.8	
	1.9	2.0	1.8	1.6	1.9	1.8	1.8	1.6	1.6	1.8	2.1	2.2	2.2	2.3	0.6
Top 25	78.0	77.7	79.6	83.2	84.3	83.8	82.7	81.8	80.9	80.8	83.0	82.8	83.0	83.8	
	45.8	49.7	52.3	55.2	57.3	56.2	56.0	54.2	53.1	54.5	60.3	60.9	65.9	65.8	18.2
Top 50	----	----	----	----	----	----	----	----	----	----	----	----	----	----	
	58.7	64.1	65.8	66.4	68.0	67.1	67.8	66.3	65.6	67.4	72.7	73.5	79.4	78.5	21.7
GINI CO-EF.	.44	.41	.45	.52	.53	.56	.52	.50	.48	.48	.49	.51	.52	.53	

Source: Individual company subscriber counts obtained directly from company officials by Television Digest, Inc.

* Upper line: Subscribers as a percent of subscribers to 50 largest companies.
** Lower line: Subscribers as a percent of total industry subscribers.

BILLING CODE 6712-01-C

Concurring Statement of Commissioner Mimi Weyforth Dawson re Multiple Ownership Rules for the Cable Television Industry

With this decision the Commission has declined to adopt a limit either on the number of cable systems or the number of cable subscribers that could be controlled by any single cable television system multiple owner. The stated rationale for the decision is that the cable industry has not reached, nor is likely to reach in the near future, a level of concentration that endangers the diversity of viewpoints received by the public. This conclusion is supported by concentration ratios in the cable industry over the past fourteen years.

While I fully support the decision not to impose a limit on cable ownership at this time, I nevertheless have two concerns. First, I'm afraid we have analyzed concentration ratios for only a small portion of the relevant market. It seems to me that the relevant market in this context is the nationwide video distribution market. This being the case, the concentration ratios reported in the item, although small to begin with, are nonetheless inappropriately inflated. Second, I'm also concerned that we have not specified any index by which to judge whether concentration in the nationwide video distribution market has reached unacceptable levels. I am hopeful, however, that this issue will be fully ventilated in the record of the network/cable cross-ownership item.

For the above stated reasons, I concur.

Dissenting Statement of Commissioner Abbott Washburn re Limitations on Multiple Ownership of Cable TV Systems

July 15, 1982.

As I have said in earlier Commission actions,[1] I am saddened and concerned by the placing of the organs of information, news and opinion in this country in fewer and fewer hands. This is an unhealthy trend for a democracy. Absentee ownership of daily newspapers by chains, for example, is rapidly increasing at the expense of independent local publishers of the William Allen White tradition.[2] Today's vote extends that unfortunate trend to the cable television industry. By refusing to set a limitation on the size of the cable holdings of any single multiple system operator, the majority has made it possible for one MSO to own and control several thousand systems. The small, locally-owned systems one-by-one are already disappearing, and this will accelerate that process. The Commission's inaction allows one MSO to control which broadcasting stations and which pay-TV services reach the public, via cable, in thousands of communities. This concentration of control of media outlets, in my opinion, is not in the public interest. In addition, it diminishes the potential for minority ownership of cable systems.

Large corporate conglomerates, of course, are free to purchase the MSO combines, in which case the decision-makers on programming would be persons totally unfamiliar with media communications. Nor is there any rule or law to prevent those individuals from being nationals of foreign countries.[3]

The Order quotes language to the effect that if undue concentration develops, "the Commission could reconsider the question of MSO limitations at a later date." But it would then be extremely difficult to disentangle the ownership interests which had been acquired.

While it may be in line with the popular current of deregulation and *laissezfaire*, today's action goes in the wrong direction. I greatly fear that in the long run the Commission will look back and regret its failure to take responsible action.

Concurring Statement of Commissioner Henry M. Rivera re Termination of Docket 18891

By accepted measures, the cable industry is neither excessively concentrated nor appears likely to become so. In these circumstances, refraining from imposing aggregate onwership limits on cable operations at this time is not inherently troubling. While I would have preferred deferring final action in this proceeding until the completion of a comprehensive analysis of the attributes of the entire video market and appropriate structural limitations nationwide, I am hopeful that we will ultimately conduct such a study and at that time consider anew the wisdom of ownership or other structural proscriptions if necessary.[1]

I would also point out that contrary to the implication of the quoted portion of the *Staff Study, see Report and Order* para. 8, FCC media ownership policies have never been, nor should they ever be, driven by a desire to facilitate a market structure which, short of domination by "few firms," will yield maximum organizational efficiencies. Efficiency is not the touchstone of the Commission's ownership regulations. Rather, those policies have long been guided by the view that "diversification of mass media ownership serves the public interest by promoting diversity of program and service viewpoints, as well as preventing undue concentrations of power."[2] To the extent the inquiry launched in the Commission's cable/network proposal reflects the spirit of this bulwark regulatory philosophy, I endorse it.

[FR Doc. 82-24489 Filed 9-3-82; 8:45 am]
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47 CFR Part 76

[CT Docket No. 82-434; FCC 82-323]

Amendment of the Commission's Rules Relative to Elimination of the Prohibition on Common Ownership of Cable Television Systems and National Television Networks

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission proposes to delete Section 76.501(a)(1) of its rules to permit cross-ownership between national television networks and cable television systems. After considerable experience with the present rule prohibiting such cross-ownership, including two extensive staff studies of the issue, the Commission has reached the preliminary conclusion that this restriction is unnecessary. Elimination of the rule will allow the marketplace to operate more freely, enhance competition and permit realization of the potential in terms of reduced costs which network/cable cross-ownership could bring.

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[1] *In Re Applications of Combined Communications Corporation*, 45 RR 2d 1387, 1402 (1979) (Washburn Dissenting).

[2] Fortunately the Commission's multiple ownership rules prohibit the acquisition of more than seven AM stations, seven FM stations and seven television stations by one entity.

[3] Section 310 of the Communications Act wisely restricts the FCC from issuing licenses for broadcasting services to aliens. This does not apply to cable-TV.

[1] Of particular concern from the vantage point of ideological diversity is the dilemma posed by vesting ownership and control of multiple channels in a single entity. Despite the *Report and Order's* assertion that because cable operators may not always be directly involved in program production their influence as "opinion molders" is reduced, the fact is that "ownership carries with it the power to select, to edit, and to choose the methods, manner and emphasis of presentation, all of which are critical aspects of the public interest." *See Second Report and Order* in Docket 18110, 50 FCC 2d 1046 1050 (1975) (emphasis added).

[2] *FCC* v. *National Citizens Committee for Broadcasting*, 436 U.S. 775, 780 (1980).

DATES: Comments must be received on or before November 29, 1982 and Reply Comments must be received on or before January 14, 1983.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Robert H. Ratcliffe, Cable Television Bureau, Federal Communications Commission, Washington, D.C. 20554, (202) 632–6468.

SUPPLEMENTARY INFORMATION:

List of Subjects in 47 CFR Part 76

Cable television.

In the matter of amendment of Part 76, Subpart J, § 76.501 of the Commission's rules and regulations relative to elimination of the prohibition on common ownership of cable television systems and national television networks; CT Docket No. 82–434.

Notice of Proposed Rulemaking

Adopted: July 15, 1982.

Released: August 27, 1982.

By the Commission: Commissioner Washburn concurring in the result; Commissioner Dawson issuing a separate statement; Commissioner Rivera concurring and issuing a statement.

Introduction

1. Notice is hereby given of the proposed deletion of § 76.501(a)(1) of the Commission's Rules which prohibits the common ownership of cable television systems and national television networks.[1]

2. Rules prohibiting ownership of cable television systems by the major national television networks were adopted in 1970.[2] Although the document enacting them contains only a brief mention of their basis and no detailed analysis of their consequences, it is apparent that the rules were grounded on the same general policy considerations as those prohibiting the common ownership of local television stations and cable systems serving the same area. As the Commission later explained:

> Our adoption of these provisions—designed to foster diversification of control of the channels of mass communications—was guided by two principal goals, both of which have long been established as basic legislative policies. One of these goals is increased competition in the economic marketplace; the other is increased competition in the marketplace of ideas.[3]

The Commission also expressed concern that

> the networks already have a predominant position nationwide through their affiliated stations in all markets, their control over network programming presented in prime time, and their share of the national television audience.[4]

Other rules adopted at the same time, including the "Prime Time Access Rule," and the "Financial Interest" and "Syndication" rules were also intended to restrict the operations of the national television networks in order to encourage the development of alternative sources of television programming.

3. After some years of experience with these rules, however, doubts began to arise as to their appropriateness. Thus, in 1977, the Commission issued its *Notice of Inquiry in Docket 21049* [5] and began the process of reviewing all of its network regulations. Later, a special, multi-disciplinary staff was assembled to study the issues involved, and a *Further Notice of Inquiry in Docket 21049* issued.[6] In the *Further Notice* the Commission expressed concern that its earlier position, that is, that network dominance would severly hamper broadcast licensee program discretion, might no longer be justified in light of recent technological, legal and economic developments. As a result of the *Further Notice,* various reports and studies were released by the special staff for public comment. In October 1980, the staff's voluminous final report, entitled "New Television Networks: Entry, Jurisdiction, Ownership and Regulation" was issued.[7] One of the matters considered in this report was the rule limiting common ownership of cable television systems and the broadcast television networks.

4. The network staff concluded that the presence of limitations on entry into and ownership of the new technologies by the existing television broadcast networks did not aid in the accomplishment of the Commission's stated goals.[8] To the contrary, the staff suggested that there were certain advantages to cross-ownership which were not considered by the Commission when the network ban was originally adopted:

> In promulgating an absolute ban on broadcast network ownership of cable franchises, the Commission has failed to appreciate that such a rule prohibits the networks from engaging in some integration into cable system operations that would have no adverse effect on competition in any market, but that could enhance efficiency and lower the price and increase the quality of cable service to advertisers and viewers. Rather than adopting the facile approach of prohibiting broadcast network expansion into cable system operations, the Commission should, as suggested above, employ rigorous horizontal analysis to identify a threshold of ownership concentration among the nation's cable systems below which the dangers of market power and cable network foreclosure are slight and then permit any firm to acquire cable franchises as long as its acquisitions do not push the firm's cable system aggregate ownership above that threshold.[9]

Ultimately, the authors of this report found it "difficult to see how this rule could serve any purpose but to restrain competition and diversity in the operation of cable systems." [10]

5. A further review of the issues raised by the cable ownership rules was then undertaken by the Commission's Office of Plans and Policy (OPP). The Commission had become concerned that the rules limiting cable system and telephone cross-ownership might no longer be soundly based. It requested that the telephone issue be reviewed by OPP. At the same time, the Commission requested a more general study of ownership issues relating to the cable television industry.[11] By Public Notice of November 17, 1981, the OPP report on these issues was released for public comment.[12]

6. The Study begins by describing the evolution of cable television from a limited, off-the-air retransmission service to the multichannel, diverse

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[1] Presently 47 CFR 76.501(a)(1): originally adopted as 47 CFR 74.1131.

§ 76.501 Cross-Ownership.

(a) No cable television system (including all parties under common control) shall carry the signal of any television broadcast station if such system directly or indirectly owns, operates, controls, or has an interest in:

(1) a national television (such as ABC, CBS, or NBC);

[2] * * *

[3] 39 FCC 2d at 391. Other than general reference to concerns about programming diversity and network manipulation of the market and cross-reference to the same standards applied in broadcast/cable cross-ownership, the network ownership rule was not independently discussed. *See also* discussion in *Columbia Pictures Industries, et al,* 30 FCC 2d 9 at para. 15 (1971), *aff'd sub nom., Iacopi v. FCC,* 451 F.2d 1142.

[4] 23 FCC 2d 816, para. 15.

[5] *See Report and Order in Docket 12782,* 23 FCC 2d 382 (1970). *See also* 62 FCC 2d 548 (1977).

[6] 69 FCC 2d 1524 (1978).

[7] Final Report, FCC Network Inquiry Special Staff (October 1980).

[8] *Id.* at page III–158 *et seq.*

[9] *Id.* at page III–163.

[10] *Id.* at page III–158.

[11] *See FCC Initiates Staff Study to Reassess Cable TV/Telephone Company Cross-Ownership Ban,* (CC Docket NO. 78–219), released October 22, 1980. The Commission instructed the staff to examine issues involving cable/telco cross-ownership, separations policies (preventing cable system owners from programming some or all of the channels of their systems), cable system multiple ownership, cable system/broadcast station cross-ownership, and cable system/television network cross-ownership.

[12] K. Gordon, J. Levy and R. Preece, *FCC Policy on Cable Ownership* (Staff Report, FCC Office of Plans and Policy), November 1981 [hereinafter Staff Study or Study].

video and non-video service which state-of-the-art cable systems provide today. It then develops a framework for analysis of the cable industry by defining the relevant economic markets for cable television service and examining the competitive forces at work in these markets.[13] In general, the Study finds that the local video marketplace in which cable operates is workably competitive, since in the great majority of markets there are many non-cable video program sources available to consumers; that the level of this competition is likely to increase in the future; and that, given these competitive circumstances, as well as the intervention of increasingly sophisticated franchise authorities, cable operators have substantial incentives to maximize the services provided by their systems in order to maximize their profits. The Study also finds that competition among cable operators in the franchise market is quite intense and that the existence of more than 30 cable networks, with their growth continuing, attests to the highly competitive nature of cable networking endeavors. In view of these findings, the Study concludes that the original rationales advanced by the Commission for adopting the network/cable cross-ownership prohibition—the threat to program diversity (it was feared that the networks' interest in maximizing the audience for their broadcast network fare would prompt them to limit diversity of programming on cross-owned systems) and the likelihood that broadcast network ownership would hinder the development of new cable networks (thus limiting competition at the national level)—are simply not supported by the realities of current conditions.[14] As a result, the Study reasons that the network/cable cross-ownership rule may well be unnecessarily sacrificing the substantial benefits, in terms of increased efficiency and lower costs, which vertical integration among networks and cable television systems could provide. Finally, the Study examines the first amendment implications of existing Commission cross-ownership policy. In this context, the Study concludes that the net effect of the network/cable cross-ownership rule may well be negative since it results in lost efficiencies, and thus in increases in the cost of access to channels of communication, yet it provides no countervailing benefit in terms of assuring program diversity. In sum, the Study recommends rescission of the network/cable cross-ownership rule, advocating a policy of free entry into the cable television industry as the best means of encouraging the development of a rapidly growing, technologically dynamic service capable of meeting consumers' needs and of vindicating the Commission's long held interest in maximizing the opportunities for free expression.

7. In the main, broadcasters who commented on the Study support its conclusions regarding network and broadcaster cross-ownership. These commenters, including the National Association of Broadcasters (NAB) and the broadcast networks, request a rulemaking be initiated immediately to effectuate the Study's suggested results. NAB and the American Broadcasting Company (ABC) note that the Study's recommendation to eliminate the cable cross-ownership rules is consistent not only with the Network Inquiry Special Staff's final report, but also with research available to the Commission in other rulemaking proceedings.[15] National Broadcasting Company, Inc. (NBC), making the same argument, reviews the history of cable industry development as well as the research available to the Commission and argues that cable ownership rules are "unnecessary and counterproductive." Furthermore, NBC contends, these structural regulations are "anachronisms at a time when the telecommunications marketplace is characterized by a number of voices."

8. Commenters in the cable industry, on the other hand, generally oppose OPP's recommendations. The National Cable Television Association (NCTA) argues that the Staff Study does not provide an adequate vehicle for the comprehensive reevaluation of the cross-ownership rules. NCTA urges that the marketplace, as it exists under the present regulatory scheme, is effective. NCTA suggests that the OPP study too matter-of-factly accepts the proposition that deregulation is a superior alternative, and does not adequately address the more fundamental issue of whether there may be adverse consequences involved in adopting a policy of deregulation. NCTA urges that the Commission issue a Notice of Inquiry to address the more fundamental issues involved prior to the initiation of any specific rulemaking proceeding to delete the rules. Other strong opposition to OPP's recommendations comes from a group of 52 cable companies in comments jointly filed. These commenters argue that OPP's economic analysis must not be confused with a finding that cross-ownership would serve the public interest. The commenters contend that (1) the costs of maintaining the rule are minimal, while any possible small gain in diversity is worth pursuing. There are, they claim, important first amendment concerns which are not adequately addressed by the Staff Study; (2) the Study's economic analysis deviates from traditionally accepted principles of economic theory and as such is inadequate; (3) terms which are fundamental to the Study's economic premise, such as "substitutability" and "workably competitive" are never properly defined; and finally, (4) the study ignores the realities of the industry.

9. Comments were also received from the United States Department of Justice (DOJ). DOJ agreed with the conclusions of the report with respect to the network issue and supported the recommendation that the network ban be eliminated. This is particularly significant because it reflects a change in the traditional DOJ posture as a firm supporter of regulations in this area.

> The Department generally agrees with the *Staff Report's* conclusion that network/cable crossownership prohibitions should be reevaluated. However, our basis for reaching that conclusion is not that a vertical relationship poses no potential for economic harm, as suggested by the *Report*. We conclude that the possibility of economic harm, although extant, may be too remote to justify imposition of a broad prophylactic rule (citations omitted).

10. At approximately the same time as the OPP study was completed a study entitled "Telecommunications in Transition: The Status of Competition in the Telecommunications Industry" was released by the Subcommittee on Telecommunications, Consumer Protection and Finance of the Committee on Energy and Commerce.[16] This report, prepared by the majority staff of the Subcommittee, while not specifically addressing the cable/network crossownership issue, does contain information relating to media ownership regulation in general. Although the study was less optimistic than the OPP study as to whether the

[13] *See generally* Staff Study, Chapters 2 and 3.

[14] Specific treatment of the network/cable cross-ownership issue is found in Chapter 6 of the Study.

[15] *See* study conducted by James C. Miller, and appended to Petition for Rulemaking filed by Marsh Media, Ltd. for deletion of Section 76.501, (RM-3810, file November 24, 1980). *See also* comments of Chronicle Broadcasting Company filed in response to *Further Notice of Proposed Rulemaking* in Docket 20423, 81 FCC 2d 150 (1980). It should be noted, however, that these studies are generally directed at the issue of local broadcast station, and not network, cross-ownership.

[16] Committee Print 97-V, 97th Congress, 1st Session, released November 3, 1981.

video markets in which cable participates are workably competitive, it clearly reflects the increasing number of outlets in these markets over the past decade.

11. In addition to the studies mentioned above, the Commission has also had the opportunity to consider issues relating to the network/cable cross-ownership rule in a more limited context. By petition for special relief, CBS, Inc., requested that the Commission waive its cross-ownership rules to permit CBS to own cable television systems whose aggregate number of subscribers does not exceed the lesser of one-half of one per cent of the total number of U.S. cable subscribers, or 90,000 subscribers. In addressing this petition, the Commission refused to consider arguments challenging the basis for the rules since to do so would have been inappropriate in a waiver proceeding.[17] Nevertheless, the decision does serve to exemplify some of the specific benefits which vertical integration can engender and to concretely illustrate, as a result, that network/cable cross-ownership restrictions are not cost free.

Discussion

12. Given the studies suggesting rather forcefully that the network/cable cross-ownership prohibition is not soundly based and the acknowledged changes in the video marketplace that have occurred over the last twelve years and will occur within the forseeable future, it appears highly desirable that this rule now be carefully re-examined. It is important that the abstract notions on which the rule was based be tested against present market realities and in particular that careful consideration be given to the costs it imposes and to the dynamics of the competitive processes that are involved. Our preliminary review in this regard yields the conclusion that this rule no longer serves the public interest and should therefore be eliminated. The basis of this evaluation will be set forth to assist the parties in commenting on this rule elimination proposal.

13. As previously noted, the Commission did not systematically analyze the nature of network cross-owners' possible behavior before adopting the network/cable cross-ownership rule. It appears, however, that the rule reflected three basic beliefs: (1) the networks' interest in maximizing the audience for their television broadcast programming would prompt them to restrict the amount and diversity of competing programming supplied by their cable television systems; (2) the networks, by refusing to carry the programming of rival networks, would hinder the development of new cable networks, thus limiting network competition at the national level; and (3) cable ownership would increase the already dominant position of the networks as suppliers of television to the viewing public, thereby limiting the diversity of voices in the video marketplace. Any countervailing costs to the public from the imposition of these restraints in terms of lost efficiency apparently were not regarded as significant.

14. With respect to the first of these concerns, our analysis so far indicates that economic incentives for this type of output-limiting behavior do not exist at this stage in the development of the cable television industry. The OPP Study suggests that there might be some incentive for local station cross-owners to offer "a slightly narrower range of video options at slightly higher prices" because of costs associated with lost broadcast revenues which new cable services would impose on such cross-owners.[18] An independent operator would not be so motivated. For several reasons, however, the Study concludes that neither local station nor network cross-owners are likely to follow this course:

> Any cable system owner must be responsive to the demands of subscribers in order to make profits. Furthermore, most cable systems are in competition with other video delivery systems and are subject to the requirements imposed by the franchising authority. Finally, the advent of pay programming (which was in its infancy when the rule was adopted) makes it possible for programmers to profit from catering to the intensely felt preferences of small groups. In this regime maximizing audience size is not the only way to succeed.[19]

It is important to note that the competitive and local governmental forces cited by the Study, as well as the cable industry itself, have undergone substantial changes since 1970, when the network ownership ban was adopted. Cable service, for example, is now provided to some 23 million subscribers,[20] while in 1970 only about 4.5 million households were served.[21] The evident demand for cable service illustrated by this nearly six-fold increase in industry subscribership has attracted a large number of highly competitive firms to the cable business. This, in turn, has resulted in increasingly intense competition in the franchise market. Moreover, the proliferation of cable service and the years of experience since 1970 have provided more and more local franchising authorities with a growing sophistication in dealing with cable television issues. The dramatic rise in cable subscribership, as well as various regulatory and technical developments, has been paralleled by a corresponding rise in the number of cable networks supplying programming to the industry. Indeed, there are now more than 30 such netweorks,[22] with no indication that their growth is abating. And, as noted in the above citation, pay cable networking was only just beginning in 1970, while today its programming reaches over half of all cable subscribers.[23]

15. Changes in the competitive nature of local video markets since the ownership ban was adopted are similarly notable. In 1970, there were neither STV nor MDS services available as alternative delivery systems to cable television.[24] Indeed, the first non-experimental STV facility did not commence operation until 1977 and rules providing for the MDS service were not even adopted until 1974. By contrast, there are now 27 operational STV stations[25] serving a market potential of nearly 33 million television households.[26] Active MDS stations supplying subscription entertainment programming currently number 73 and serve areas comprised of more than 16 million households.[27] Conventional

[17] *CBS, Inc.*, FCC 89-391, 87 FCC 2d 587 (1981).

[18] Staff Study at p. 70.

[19] Staff Study at pp. 107-108.

[20] *Cablevision* (May 10, 1982) at p. 436 places the actual figure, as of March 31, 1982, at 22,821,167. A.C. Nielsen Co. studies place the total as high as 27,362,000. See *Multichannel News*, June 4, 1982 at 1.

[21] *Television Factbook* (1982-82 ed.) at p. 83-a.

[22] *See* Staff Study at pp. 117-120.

[23] *Cablevision*, *supra* n.20. The exact percentage of basic subscribers receiving pay cable service, as of March 31, 1982, is said to be 52.81. At least in part, the rapid growth of pay cable can be attributed to the deletion, in 1977, of the program content restrictions originally imposed by the commission on this service. *See Home Box Office v. FCC*, 567 F.2d 9 (D.C. Cir. 1977), *cert denied*, 435 U.S. 829 (1977).

[24] For a summary of both the regulatory and operational history of STV, *see Further Notice of Proposed Rule Making in Docket 21502*, FCC 81-449.88 FCC 2d 213 (1981) and *Third Report and Order in Docket 21502*, FCC 82-281, —— FCC 2d —— (adopted June 17, 1982). As to MDS developments, *see Report and Order in Docket 19493*, FCC 74-34, 45 FCC 2d 616 (1974) and *Notice of Inquiry, Proposed Rulemaking and Order in Gen. Docket No. 80-112*, FCC 80-136, 45 Fed. Reg. 29323 (1980).

[25] *Third Report and Order in Docket 21502*, FCC 82-281, —— FCC 2d (adopted June 17, 1982).

[26] "Pay TV Subscriber History," *The Kagan Census of Cable and Pay TV* (as of December 1981), Paul Kagan Associates, Inc., June 1982. The most recent subscriber count available for STV stations (based on 25 stations as of December 31, 1981) puts total subscribership at 1,319,459.

[27] "Census of MDS Pay TV as of 12/31/81", *Multicast* (March 22, 1982) at pp. 6-7 [citing Paul Kagan Associates, Inc.]. The current subscribership of these MDS stations is calculated to be 544,713.

television broadcasting has also grown some 23 percent in terms of the number of operating stations since 1970.[28]

16. It seems likely, moreover, that the number and quality of video delivery system competitors for cable television systems will increase in the near future, thereby further intensifying the pressure on cable operators to effectively compete by providing the optimum mixture of services possible. There are, for example, 19 additional STV stations now authorized and applications are pending for authorization of 25 more, while 419 applications are pending for authorization of new MDS stations. Also, recent Commission actions have lifted many of the restrictions once applicable to STV, including the "one to a market" rule,[29] and, more recently, the "complement of four" limitation as well as the conventional broadcasting and STV ascertainment obligations.[30] Additionally, the Commission has recently approved a low power television service (LPTV)[31] as well as a new, satellite-delivered, multiple channel direct broadcast service,[32] both of which should appreciably increase the number of television broadcast competitors in the video marketplace. And, proposals now before the Commission raise the possibility of a substantially expanded, multiple channel MDS service in single communities.[33]

17. There are additional considerations specifically relevant to network cross-owners which lessen the probability of output-limiting behavior still further. First, network cross-owners' presumed conflict between broadcast-delivered and cable-delivered programming is even more remote than that of local station cross-owners. This is a function of the fact that network-supplied programming constitutes only a portion of the broadcast service provided by any local, network-affiliated station and of the fact that networks have no direct ownership interest in the local affiliates with which their cable systems would coexist.[34] Second, any adverse impact on network program viewing which might occur in a given television market is severely diluted from the network cross-owner's viewpoint by the relatively small size of the contribution to total network return which any single market station makes. Thus, unless networks were to achieve a position of dominant multiple system ownership in the cable television industry, there seems little chance that audience diversion consequences in cross-owned markets would be sufficient to prompt intentional anti-competitive actions by network cable owners. The likelihood of networks achieving such a position of dominance seems very low, given the historically unconcentrated nature of the industry.[35]

18. The second concern on which the rules appear to be based—predatory exclusion of rival networks from cable carriage for the purpose of limiting entry into the national cable networking market—rests on the highly questionable assumption that networks could achieve a substantial degree of horizontal integration in the cable industry. Absent control of a significant share of the existing cable outlets for networked programming, network cross-owners would simply be unable to foreclose the national market for such programming and could not therefore have any appreciable adverse effect on existing or prospective cable networking endeavors. Since our own review of the cable industry reveals a persistent lack of concentration,[36] there seems little likelihood that permitting network ownership of cable systems would suddenly reverse this situation and thereby enable network cross-owners to hinder the development of alternative cable networks. In any event, regulatory limits on multiple ownership, regardless of the character of the owner, or use of existing antitrust restraints, should a trend toward over-concentration appear, would seem far more appropriate means of addressing this concern than the narrow prohibition of network cross-ownership now in force.[37]

19. The multiple channel nature of cable television operations also militates against network cross-owners developing an exclusionary attitude toward alternative cable networks. With modern cable systems reaching capacities of more than 100 channels, the dominating concern in the industry is not the means of delivering programming, as in television broadcasting where exclusive network affiliation agreements are the rule, but obtaining sufficient programming to fill existing capacity. Network cross-owners would, therefore, have a substantial incentive to deal with the entire range of available program suppliers, including other cable networks. Indeed, the validity of this contention is strikingly supported by experience with cable network owners of cable television systems. These networks, such as HBO and Showtime, are not subject to regulatory restraints on ownership of cable systems and many have acquired a considerable number of systems. They stand in a closely similar relationship to their cable systems as would a television network cross-owner, yet they have shown little reluctance to carry diverse programming, including distant signals and even directly competitive alternative cable networks.[38] We believe this is indicative of the fact that a profit motive encourages system owners to provide the diverse programming that consumers desire and which the channel capacity of cable technology permits despite supposed conflicts which may be ascribed to particular types of owners.

20. The multiplicity of established cable networks, often operated by very substantial firms, acts as yet another barrier to any attempt which network cross-owners might make to dominate the cable networking business. Indeed, given the well developed and supported nature of existing cable network operations, it is much more likely that the entry of national television networks into cable networking would produce

[28] In 1970, there were a total of 862 television broadcast stations in operation. *Television Factbook* (1981–82 ed.) at p. 75–a. As of March 31, 1982, there were 1,059 such stations. FCC News Release dated April 26, 1982 (Mimeo No. 3666).

[29] *See First Report and Order in Docket 21502*, FCC 79–535, 44 FR 60091 (1979).

[30] *See Third Report and Order in Docket 21502*, *supra* at n. 25.

[31] *Report and order in BC Docket No. 78–253*, FCC 82–107, 47 FR 21468 (1982).

[32] *Report and Order in Gen. Docket No. 80–603*, FCC 82–285,——FCC 2d (adopted June 23, 1982).

[33] *Notice of Inquiry, Proposed Rulemaking and Order in Gen. Docket No. 80–112, supra* n. 24.

[34] In those markets where the networks own the local affiliate they are constrained from owning a cable television system by the local station/network cross-ownership rule.

[35] *See* para. 18 and n. 38, *infra*.

[36] The specifics of this review are contained in the *Report and Order in Docket 18891*, FCC 2d, FCC 82–322 (1982), adopted today, wherein we decline to restrict multiple cable system ownership. The review shows, among other things, that despite the more than 30 year history of cable television and its explosive growth in recent years, the largest multiple system operator in the country still serves less than nine percent of total industry subscribers. *See* Staff Study, Chapter 5, cited in the *Report and Order in Docket 18891, supra*, for a detailed treatment of the multiple ownership issue as well as an explanation of the limitations of concentration ratios as indicators of market power.

[37] Indeed, in terms of preventing excessive horizontal concentration and the foreclosure possibilities which such concentration permits, the network/cable cross-ownership prohibition is at once both overinclusive and underinclusive. It functions, for example, to bar the ownership of a single cable television system by a national television network even though this clearly raises no concentration issue, yet it imposes no ownership limits on cable network owners such as HBO or Showtime.

[38] *See, e.g.*, Paul Kagan Associates, Inc., *The Pay TV Newsletter* (June 27, 1980) at p. 3, and *Multichannel News* (June 1, 1981) at p. 6.

increased competition in this area rather than a threat of dominance.

21. The third rationale for the network rules was the belief that cable ownership would only further concentrate the control over television program sources exercised by the national television networks and that this would lead to a reduction in the diversity of programming available to the viewing public. We believe, however, that this concern may also no longer support a continuation of the rules. First, it is now apparent that the video markets here involved are becoming increasingly competitive and that the public, including particularly cable consumers, are now being provided with access to a greatly increased quantity of video programming. Secondly, because there may be operating efficiencies associated with common ownership, it is not clear that the rules here in question ultimately promote consumer welfare or indeed provide the public with greater programming diversity than they would receive in the absence of the rules. The importance of this issue, not only to this proceeding but to questions of media ownership more generally, however, suggests the need to develop systematic, rational methods for defining the relevant markets that are involved and assessing concentration in them.[39] We outline the relevant issues here in order to elicit public comment and assistance with respect to appropriate definitions and standards.

22. A valid market definition includes both product and geographic components. The Staff Study stresses the substitution possibilities among the various video media and the Wirth Committee report (see note 16 *supra*) speaks in terms of a video market. We urge comment on such a product market definition and on whether for some purposes (*e.g.* the provision of news and information) media such as radio and newspapers are relevant. Geographic markets can be local, regional, or national. It appears that the consumer of "media services" acts in a local market, choosing among various different local distribution media. On the other hand, a program producer seeking distribution outlets frequently faces a national market. Here the number and size distribution of owners of video outlets nationwide is important.

23. We request comment on both the product and geographic components of the market definition and on specific techniques for measuring concentration. The process of measuring concentration is a difficult and sometimes ambiguous one.[40] Hence we do not expect to arrive at a single "magic" number but may wish to employ several measures and/or a zone within which proposed combinations might be scrutinized rather than a strict "cutoff" point.

24. Our public interest mandate requires us to consider not only the economic welfare of the public but also "necessarily invites reference to the First Amendment goal of achieving the widest possible dissemination of information from diverse and antagonistic sources." [41] We invite comment on whether promotion of this goal makes desirable a lower level of concentration than economic considerations alone would suggest. This issue turns on whether maximum dispersion of *ownership* of media outlets is necessary for the widest dissemination of information from diverse *sources*. While it is true that all rules limiting cross-ownership, if they do not completely frustrate the creation of new outlets, tend to increase the total number of owners, such rules do not necessarily guarantee greater diversity of program content or advance the welfare of individual viewers. Whether that occurs depends, *inter alia*, on the costs which the ownership rules impose. These costs, which were not examined in depth when the rule was adopted, may be quite high. We are particularly concerned that the significant efficiencies which might result from vertical intergration between a network and a cable television system are being forgone as a result of the cross-ownership prohibition.

25. Vertical integration exists when transactions between buyers and sellers occur within a single firm. Thus, the combination of a television network, which packages programming, and a cable television system, which distributes it, is vertical. Traditionally, it was feared that in a vertically integrated cable market the owner of the cable system would favor its affiliated program supplier to the detriment of the diversity of programming which might otgherwise be available to system subscribers. Our foregoing analysis, however, indicates that the strongly competitive nature of the cable networking and local video marketplaces make such behavior highly unlikely. Efficient vertical integration, on the other hand, is said to provide several benefits, including an improvement in consumer welfare by reducing the costs and risks associated with market transactions. Such risk reduction may, in fact, be essential to a given transaction when the service to be provided is complex and future market conditions are difficult to forecast. Vertical integration may also facilitate the flow of information between stages of production, cut marketing and distribution costs, and create economies of scale since overhead costs may be spread vertically as well as horizontally. Additionally, management talents may be used more intensively and efficiently in the larger, integrated organization.[42]

26. In sum, it is clear that there have been many changes in the years since the Commission first adopted the network/cable cross-ownership rules and that these changes have greatly minimized the concerns initially motivating these ownership restraints. In 1970, the amount of television broadcast programming available for cable television carriage was severely limited by Commission rules and the amount of nonbroadcast programming was even more sharply limited. By contrast, today there are numerous diverse and well established sources of satellite distributed programming for cable television use as well as a considerably less restricted environment for the carriage of broadcast programming. Moreover, the rapid growth of the cable television industry in recent years has been accompanied by a dramatic increase in the level of competition among prospective system operators at the franchising stage of system development while concurrent changes in the video marketplace in general have intensified competitive pressures on all system operators. Both of these factors work to ensure that system owners will provide the program diversity which their subscribers demand and which increasingly competent local franchising authorities often require. Given these developments, as well as what we now perceive to be the questionable nature of some of the assumptions which initially underpinned the network ownership prohibition, we believe that the network/cable cross-ownership

[39] Network Inquiry Special Staff urged that we "examine methods for identifying undue concentration of markets." *Recommendations of the Network Inquire Special Staff to the Federal Communications Commission* (December 1980) at 7.

[40] See F.M. Scherer, *Industrial Market Structure and Economic Performance* (Chicago: Rand-McNally, 1980) at 56–64 for a discussion of the strengths and weaknesses of the various concentration measures. Also useful in this regard is the discussion of the Herfindahl index used by the Department of Justice in its *Merger Guidelines* issued June 14, 1982. See also the associated *Statement of Federal Trade Commission Concerning Horizontal Mergers.*

[41] *FCC* v. *National Citizens Committee for Broadcasting* 436 U.S. 775 (1978).

[42] *See* Staff Study at pp. 109–110. *See also CBS, Inc., supra* at n.17.

rules should be eliminated to permit the transfer of technical and marketing knowledge across traditional media lines and to permit market forces to bring out whatever efficiencies are associated with common ownership between the two industries.

Accordingly, in view of the foregoing, we propose, and seek full comment regarding, elimination of the present prohibition on national television network ownership of cable television systems contained in Section 76.501(a)(1) of the Commission's Rules.

Authority for the proposed Rulemaking instituted herein is contained in Sections 1, 2, 3, 4 (i) and (j), 301, 303, 307, 308, 309, and 403 of the Communications Act of 1934, as amended.

All interested parties are invited to file written comments on or before November 29, 1982, and reply comments on or before January 14, 1983. All relevant and timely filed comments will be considered by the Commission before final action is taken in this proceeding. In reaching its decision, the Commission may take into consideration information and ideas not contained in the comments, provided that such information or a writing indicating the nature and source of such information is placed in the public file, and provided that the fact of the Commission's reliance on such information is noted in the Report and Order.

For purposes of this non-restricted notice and comment rulemaking proceeding, members of the public are advised that *ex parte* contracts are permitted from the time the Commission adopts a notice of proposed rulemaking until the time a public notice is issued stating that a substantive disposition of the matter is to be considered at a forthcoming meeting or until a final order disposing of the matter is adopted by the Commission, whichever is earlier. In general, an *ex parte* presentation is any written or oral communication (other than formal written comments/pleadings and formal oral arguments) between a person outside the Commission and a Commissioner or a member of the Commission's staff which addresses the merits of the proceeding. Any person who submits a written *ex parte* presentation must serve a copy of that presentation on the Commission's Secretary for inclusion in the public file. Any person who makes an oral *ex parte* presentation addressing matters not fully covered in any previously-filed written comments for the proceeding must prepare a written summary of that presentation; on the day of oral presentation, that written summary must be served on the Commission's Secretary for inclusion in the public file, with a copy to the Commission official receiving the oral presentation. Each *ex parte* presentation described above must state on its face that the Secretary has been served, and must also state by docket number the proceeding to which it relates. *See generally*, 1.1231 of the Commission's rules, 47 CFR 1.1231.

As required by Section 603 of the Regulatory Flexibility Act, the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) of the expected impact of these proposed policies and rules on small entities. The IRFA is set forth herein as attachment A. Written public comments are requested on the IRFA. These comments must be filed in accordance with the same filing deadlines as comments on the rest of the Notice, but they must have a separate and distinct heading designating them as responses to the Regulatory Flexibility Analysis. The Secretary shall cause a copy of this Notice, including the IRFA, to be sent to the Chief Counsel for Advocacy of the Small Business Administration in accordance with Section 603(a) of the Regulatory Flexibility Act.

In accordance with the provisions of § 1.419 of the Commission's Rules and Regulations, an original and 5 copies of all comments, reply comments, pleadings, briefs or other documents shall be furnished to the Commission. Participants filing the required copies who also wish each Commissioner to have a personal copy of the comments may file an additional 6 copies. Members of the general public who wish to express their interest by participating informally in the rulemaking proceeding may do so by submitting one copy of the comments, without regard to form, provided only that the docket number is specified in the heading. Responses will be available for public inspection during regular business hours in the Commission's Docket Reference Room at its Headquarters, 1919 "M" Street, N.W., Washington, D.C. 20554. Further information on the procedures to be followed or the status of this proceeding may be obtained by contacting Robert H. Ratcliffe, Cable Television Bureau, Federal Communications Commission, (202) 632-6468.

(Secs. 4, 303, 48 stat., as amended, 1066, 1082; 47 U.S.C. 154, 303)

Federal Communications Commission.

William J. Tricarico,

Secretary.

Separate Statement of Commissioner Mimi Weyforth Dawson re: Network/Cable Cross-Ownership Rules

I believe a hard look at the Commission's network/cable cross-ownership rules is long overdue. The rules apparently were adopted without explicit notice nor the luxury of a cost-benefit analysis. Since that time the rules have received extensive review and criticism from the Network Inquiry Special Staff and the Office of Plans and Policy.

While I endorse Commission review of the network/cable cross-ownership rules, I am concerned that we couch the ensuing analysis in the proper framework. To pursue any meaningful market analysis with respect to our ownership policies, we must define not only the part of commerce under consideration but also the geographic area in which the relevant firms compete.[1]

With respect to the geographic market boundary, it appears that a study of our network/cable cross-ownership rules should focus on the potential for excessive concentration in a nationwide market. This being the case, I am troubled at the prospect of studying the network/cable cross-ownership rules in isolation from other rules, such as multiple ownership restrictions, that also affect nationwide concentration. As I will develop more fully later, I would like the commenting parties to focus on the extent of concentration in communications properties that any one entity, or entities, may accumulate before public interest concerns are raised. I do not believe that anyone will quarrel with the notion that undue concentration of control in the nationwide geographic market disserves the public interest and should be prohibited.

The second part of the analysis requires identification of the appropriate line of commerce. Traditional antitrust and economic analysis dictates that we consider all services that are reasonably interchangeable in the eyes of the beholder.[2] In this regard, the OPP report and responds thereto make a persuasive case that the relevant market is the video distribution market. Such a market would seem to include such

[1] See *United States* v. *E. I. du Pont de Nemours & Co.*, 351 U.S. 377 (1956); and *Tampa Electric Co.* v. *Nashville Coal Co., et al.*, 365 U.S. 320 (1961).

[2] See, *e.g.*, *U.S.* v. *E. I. du Pont de Nemours & Co.*, *supra*, and F.M. Scherer *Industrial Market Structure and Economic Performance* (1980).

services as over-the-air television, subscription TV, multipoint distribution service, low power television, direct broadcast satellites, cable television and satellite-fed master antenna systems. I believe it is critical for commenting parties to address the appropriate contours of the video distribution market, including the submarkets, if any, that should be identified for regulatory purposes.[3]

The next logical question for consideration is what constitutes undue concentration in the nationwide video distribution market. To determine this, we first need a measure of concentration. While I recognize the number of possible statistical approaches to deriving this measure is large, I nevertheless will proffer a suggestion at this point to enable commenting parties to provide more focussed comment. Quite simply, I propose that concentration be measured in terms of net weekly circulation [4] for services provided without any direct charge and in terms of subscribers for those services with a direct fee. Each communication entity would be credited with a unit of ownership for each home that it reaches with a distinct video distribution mechanism.[5] For example, if one entity provided both cable television service and direct broadcast satellite service to one specific household, it would be counted as having two units of ownership. Of course, all units of ownership would be accumulated over all video distribution services—nationwide—for each entity. That entity's concentration ratio would then be derived by dividing its total number of ownership units by the total number attributable to all communications entities.[6]

To determine the level at which concentration in the nationwide market is too high, the Commission could rely on the Herfindahl index used by the Department of Justice for mergers. For example, any acquisition of properties or licenses that would increase concentration beyond generally accepted levels would require intensive Commission scrutiny before approval. On the other hand, the Commission may adopt streamlined processes for considering ownership issues in the context of license and merger applications when the concentration index for the relevant market is within a zone of reasonableness. However, I would like commenting parties to discuss whether any downward adjustment to the Justice Department's standard is appropriate here in light of external benefits that may flow to society from diversely owned video outlets. Such external benefits may arise because of the effect that television has in shaping the attitudes and values of citizens, in making the electorate more informed and responsible, and in contributing to greater understanding and respect among racial and ethnic groups. Of course, such concerns parallel those voiced by the Supreme Court in stating that "the public interest standard necessarily invites reference to the First Amendment goal of achieving the widest possible dissemination of information from diverse and antagonistic sources."[7]

I offer these suggestions merely as an inducement to the development of a robust record for the Commission to consider when analyzing its video ownership policies as they relate to the nationwide geographic market. I'm sure that the commenting parties will have various recommendations concerning the appropriate measure or measures of concentration and the level at which concentration becomes detrimental to the public interest. I look forward to studying these recommendations. However, at this point in time, I believe that such an approach of adopting a "safety net" is essential to ensure a procompetitive transition to a deregulatory marketplace.

Concurring Statement of Commissioner Henry M. Rivera

Re: Notice of Proposed Rulemaking to Repeal Cable-Network Cross Ownership Ban.

The ownership issues posed by this Notice and by the Report and Order terminating Docket 18891 would have been more productively examined in a holistic, analytically complete framework considering Commission policies affecting ownership and control of all video services. I sincerely hope that the piecemeal inquiry begun herein does not portend the creation of a new, disjointed regulatory scheme in this area.[1]

Reconfiguring the Commission's media ownership rules is a major step that should only take place with the benefit of a comprehensive set of comments. A vastly simplified proposal, unveiled in a narrow mosaic of the larger video picture, is likely to produce ill-considered, myopic analyses by the public and the Commission. While reactions to the proposal in paragraphs 21–24 will provide a start, a more refined further proceeding should issue before the Commission alters its present regulatory regime in the ownership area. In my view, the sounder approach to the critical issues of media diversity and competition would have been to launch a carefully structured, broadly based proceeding fleshing out in surer strokes alternative approaches to meeting the concerns that undergird the Commission's ownership rules.

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[3] See, *e.g., Brown Shoe Co.* v. *United States*, 370 U.S. 294 (1962).

[4] Net weekly circulation is a measure of effective reach. Specifically, it is the number of households that watched a particular station for at least five minutes a week in the survey period.

[5] Such an approach points to the need to have a clearly defined and meaningful guide for attribution purposes.

[6] I believe such an approach also is adaptable to measuring concentration in local video distribution markets for purposes of analyzing the desirablity of such rules as the duopoly restrictions.

[7] *FCC* v. *National Citizens Committee for Broadcasting*, 436 U.S. 775 (1978).

[1] It appears wasteful, for instance, to issue a Notice proposing to allow the major networks to become cable operators before conduting a general inquiry into indicia of permissible media concentration. It might be, for example, that the control exercised by these entities by their national video distribution network and through their owned stations is so pervasive that they should not be allowed to enter the cable ownership market at all.

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 23

Proposed Additions to Appendices to the Convention on International Trade in Endangered Species of Wild Fauna and Flora

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of potential United States proposals.

SUMMARY: The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) regulates international trade in certain animal and plant species, which are listed in appendices to CITES. The United States, as a Party to CITES, may propose amendments to the appendices for consideration by the other Parties.

The Service invites comments and information from the public on species that have been identified as candidates for U.S. proposals to amend Appendix I or II. This is in addition to an earlier request for information concerning possible changes in the status of certain North American species that are already listed.

DATE: The Service will consider all information received by September 15, 1982, regarding proposals to list species mentioned in this notice.

ADDRESS: Please send correspondence concerning this notice to the Office of the Scientific Authority, U.S. Fish and Wildlife Service, Washington, D.C. 20240. Materials received will be available for public inspection from 7:45 a.m. to 4:15 p.m., Monday through Friday, in room 536, 1717 H Street, N.W., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Dr. Richard L. Jachowski, Office of the Scientific Authority, U.S. Fish and Wildlife Service, Washington, D.C. 20240, telephone (202) 653–5948.

SUPPLEMENTARY INFORMATION:

Background

CITES regulates import, export, reexport, and introduction from the sea of certain animal and plant species. Species for which trade is controlled are included in three appendices. Appendix I includes species threatened with extinction that are or may be affected by trade. Appendix II includes species that although not necessarily threatened with extinction may become so unless trade in them is strictly controlled. It also lists species that must be subject to regulation in order that trade in other currently or potentially threatened species may be brought under effective control. Such listings may be required because of difficulty in distinguishing specimens of currently or potentially threatened species from other species at ports of entry. Appendix III includes species that any Party nation identifies as being subject to regulation within its jurisdiction for purposes of preventing or restricting exploitation, and for which it needs cooperation of other Parties in controlling trade.

Any Party nation may propose amendments to Appendices I and II for consideration at meetings of the Conference of the Parties. The text of any proposal must be communicated to the CITES Secretariat at least 150 days before the meeting. The Secretariat must then consult the other Parties and interested intergovernmental bodies, and communicate their responses to all Parties not later than 30 days before the meeting. Amendments are adopted by a two-thirds majority of the Parties present and voting.

On February 16, 1982, the Service requested information that might lead it to develop proposed amendments or to recommend that other Parties develop proposed amendments for consideration at the fourth meeting of the Parties (47 FR 6772). The meeting is planned for the second half of April 1983 at Gaborone, Botswana.

Information Received for Animals

In response to the February 16 notice, the Service received extensive information from Mr. Bill Clark of the Hai-bar Arava wildlife reserve in Israel, who recommended including the African wild ass (*Equus asinus africanus*) in Appendix I. This subspecies is represented by perhaps 3,000 individuals, most of them in Ethiopia. The Director of the Wildlife Conservation Organization of the Ethiopian Government has informed the Service of his support for this proposal.

Dr. Alan H. Shoemaker of the Riverbanks Zoological Park suggested transferring the Central American river otter (*Lutra annectens*) from Appendix II to Appendix I, but mentioned that he could not provide supporting data. The Service presently lacks information showing a need for this change and will not include it in its final proposals unless sufficient information is received in response to this notice.

TRAFFIC (U.S.A.), an organization that monitors the international trade in wild animals and plants, submitted information in support of proposals to transfer the following species or subspecies from Appendix II to I: the yacare caiman (*Caiman crocodilus yacare*), the red-fronted macaw (*Ara rubrogenys*), the caninde macaw (*Ara caninde*), the Indian pangolin (*Manis crassicaudata*), the Malayan pangolin (*Manis javanica*), and the Chinese pangolin (*Manis pentadactyla*). TRAFFIC (U.S.A.) also submitted evidence in support of a proposal to include the collared peccary or javelina (*Tayassu tajacu*) and the white-lipped peccary (*T. albirostris*) in Appendix II. With the possible exception of the two macaw species, further information on population status is needed to determine if these proposals are appropriate.

Dr. George Archibald of the International Crane Foundation suggested including the wattled crane (*Bugeranus carunculatus*) in Appendix I, on the grounds that it is acutely endangered and in trade. The Service is seeking information to substantiate the need for this listing.

Dr. Wayne King, Director of the Florida State Museum, recommended that the black softshell turtle of Mexico (*Trionyz ater*) be removed from Appendix I because it is reported to have been genetically swamped by *Trionyx spiniferus emoryi*. According to H. Smith and R. Smith (1980), in their Synopis of the Herpetofauna of Mexico, the listed species is no longer genetically or morphologically distinct. The Service is seeking scientific evidence to determine if this has occurred.

Summary of Potential U.S. Proposals Outside of the 10-Year Review

August 13, 1982

For the purpose of seeking further information, the Service now considers the following animals to be candidates for U.S. proposals to amend Appendix I or II:

Mammals:
- *Manis crassicaudata* (Indian pangolin)—App. I
- *M. javanica* (Malayan pangolin)—App. I
- *M. pentadactyla* (Chinese pangolin)—App. I
- *Tayassu albirostris* (White-lipped peccary)—App. II
- *T. tajacu* (Collared peccary or javelina)—App. II
- *Equs asinus africanus* (African wild ass)—App. I

Birds:
- *Ara caninde* (Caninde macaw)—App. I
- *A. rubrogenys* (Red-fronted macaw)—App. I
- *Bugeranus carunculatus* (wattled crane)—App. I

Reptiles:
- *Caiman crocodilus yacare* (Yacare)—App. I
- *Trionyx ater* (Cuatro Cienegas softshell turtle)—Delist

Information Received for Plants

Numerous comments were received from various State and Federal agencies and from private organizations and individuals in response to the Services' February 16, 1982, notice of potential plant additions to the CITES appendices. The volume of information received on plants is too great to adequately summarize in the current notice, but is available for public inspection during regular working hours. Because of the extensive response received by the Service on plants, and because a complete summarization of this data and full explanation of the basis for the Service's negotiating positions would injuriously delay the formulation of these positions, the Director has suspended the requirements of 50 CFR 23.33 with respect to this notice in order to prevent interference with the timely or appropriate development of negotiating positions. See 50 CFR 23.38(a).

The following agencies, organizations, and individuals submitted information and comments to the Service on CITES plant candidates:

Federal:
FWS Regional Office in Portland (Region 1), Albuquerque (Region 2), Atlanta (Region 4), and Denver (Region 6).
U.S. Forest Service Rocky Mountain, Pacific Southwest and Southwest Regional Offices.
State:
Arizona Natural Heritage Program
Florida Game and Fresh Water Fish Commission
Georgia Department of Natural Resources
Indiana Department of Natural Resources
Missouri Department of Conservation
North Carolina Department of Agriculture
Ohio Department of Natural Resources
Pennsylvania Department of Environmental Resources
South Carolina Wildlife and Marine Resources Department
Private:
Dr. Faith Campbell, Natural Resources Defense Council
Dr. Thomas Gibson, University of Arizona
Dr. Linda McMahan, TRAFFIC (U.S.A.)
Dr. William Meijer, University of Kentucky

As a result of the comments of information received, the Service now considers the following species to be viable candidates for possible addition to the CITES appendices. States where these species are known to occur are enclosed in parentheses following the species' names. The Service requests additional information on these species, particularly detailed population data and trade statistics.

Plants:
Family Berberidaceae (Barberry family)
Mahonia (-Berberis) nevinii (Nevin's barberry)—App. I (CA)
M. Sonnei (Truckee barberry)—App. I (CA)
Family Crassulaceae (Orpine family)
Dudleya (AZ, CA, NV, OR, Mex.)—all species added to Appendix II except the following California species, which might be added to App. I:
D. cymosa ssp. *marcescens* (Santa Monica Mtns. dudleya) (CA)
D. densiflora (San Gabriel Mtn. dudleya) (CA)
D. parva (Conejo dudleya) (CA)
D. stolonifera (Laguna Beach dudleya) (CA)
D. traskiae (Santa Barbara Island dudleya) (CA)
Family Diapensiaceae (Diapensia family)
Shortia galacifolia (Oconee-bells)—App. II (GA, NC, SC)
Family Droseraceae (Sundew family)
Dionaea muscipula (Venus flytrap)—App. II (NC, SC)
Family Ericaceae (Heath family)
Kalmia cuneata (White wicky)—App. II (NC, SC)
Rhododendron chapmannii (Chapman's rhododendron)—App. I (AL, FL, GA?)
R. prunifolium (Plumleaf azalea)—App. I (AL, GA)
Family Fouquieriaceae (Candlewood family)
Fouquieria columnaris (*-Idria columnaris*) (Boojum tree)—App. II (Mex.)
F. fasciculata (Abrol de Barril)—App. I (Mex.)
F. Purpusii—App. I (Mex.)
Family Liliaceae (Lily family)
Agave arizonica (New River agave)—App. I (AZ)
A. parviflora (Santa Cruz striped agave)—App. I (AZ, Mex.)
A. victoria-reginae (Queen Victoria agave)—App. II (Mex.)
Lilium grayi (Gray's or Roan lily)—App. I (NC, TN, VA)
L. iridollae (Pot-of-gold or Panhandle lily)—App. I (AL, FL)
L. occidentale (Western lily)—App. I (CA, OR)
L. parryi (Lemon lily)—App. II (AZ, CA)
L. Pitkinense (Pitkin Marsh lily)—App.; I (CA)
Nolina interrata (Dehesa bear-grass)—App. I (CA, Mex.)
Family Portulacaceae (Purslane family)
Lewisia cantelowii (Cantelow's lewisia)—App. II (CA)
L. cotyledon—(Lewisia)—App. II (CA, OR)
L. maguirei (Maguire's lewisia)—App. II (NV)
L. megarhiza (Lewisia)—App. II (Guatemala, Mex.)
L. serrata (Saw-toothed lewisia)—App. II (CA)
L. tweedyi (Tweedy's lewisia)—App. II (WA)

Future Actions

The Service plans to publish a further **Federal Register** notice in October 1982, announcing its decisions on the species proposals discussed above, prior to submitting U.S. proposals to the CITES Secretariat for consideration at the Fourth Meeting of the Conference of the Parties. For species which occur outside the U.S., the countries of origin will be contacted and consulted before a decision is made on submittal of a proposal by the U.S.

Persons having current information about these species are invited to contact the Service's Office of the Scientific Authority at the above address. The Service also requests information on environmental impacts of such proposed actions and their potential economic effects on State and local governments, persons, businesses, and organizations.

This notice was prepared by Dr. Richard L. Jachowski and Mr. Joseph J. Dowhan, Office of the Scientific Authority.

List of Subjects in 50 CFR Part 23

Endangered and threatened wildlife, Exports, Fish, Imports, Plants (agriculture), Treaties.

Dated: August 31, 1982.

Craig Potter,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 82-24485 Filed 9-3-82; 8:45 am]
BILLING CODE 4310-01-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 654

Gulf of Mexico Fishery Management Council; Stone Crab Fishery; Public Hearing

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of Public Hearing.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will hold a public hearing for the purpose of gathering information on possible long-term solutions to gear conflicts in Federal waters off Citrus County, Florida. This hearing has particular reference to extension of control over shrimping and stone crabbing to the Federal waters to complement similar management of these fisheries as provided for under Florida law. The Council seeks views on possible amendment of its stone crab fishery management plan (FMP) which may be necessary for orderly conduct of these fisheries in Federal waters to reduce the possibility of conflict between stone crab and other fishermen in the area.

DATES: Written comments on the proposed management measures or alternatives from members of the public may be submitted no later than October 20, 1982. Individuals, agencies, or organizations wishing to comment on this matter may do so at a public

hearing to be held as follows: September 29, 1982, Crystal River, Florida.

The hearing will start at 7:00 p.m. and adjourn at 10:00 p.m. The hearing will be tape recorded and the tapes will be filed as an official transcript of the proceedings. A written summary will be prepared on the hearing.

ADDRESS: Send comments to: Wayne E. Swingle, Executive Director, Gulf of Mexico Fishery Management Council, Lincoln Center, Suite 881, Tampa, Florida 33609, (813) 228–2815.

Hearing location: September 29, 1982, Plantation Inn and Golf Resort, Kings Bay Road, Crystal River, Florida.

FOR FURTHER INFORMATION CONTACT: Wayne E. Swingle, Executive Director, Gulf of Mexico Fishery Management Council, Lincoln Center, Suite 881, 5401 Kennedy Boulevard, Tampa, Florida 33609, (813) 228–2815.

SUPPLEMENTARY INFORMATION: The fact finding hearing will deal with the need to amend the FMP as a result of cumulative losses of traps by stone crab fishermen in the Gulf of Mexico, and the possiblilty of conflict between shrimp and stone crab fishermen in Federal waters adjacent to an area managed by the State of Florida (Chapter 81–199 of the Florida Code).

This State statute provides for fishing zones for shrimping and stone crabbing that change over the course of the stone crab season and that can be modified by State regulation based on the recommendation of the Citrus County Shrimping and Crabbing Advisory Committee. This Committee is duly constituted by the statute and represents both shrimping and crabbing interests.

The fishing zones established by State statutes extend out to the limit of the State's fishery jurisdiction (nine nautical miles). The State boundary of the territorial sea transects the outer zone originally proposed by the Committee, leaving a small portion in the fishery conservation zone (FCZ). The Committee has petitioned the Gulf Council to modify its FMP to establish this small portion as an area where stone crab fishing is prohibited in the FCZ for the period of March 16th to May 20th each year. Further, the Committee has recommended the establishment of a Fixed Gear Zone seaward of the State fishing zone for a distance of six nautical miles. Other shrimping and stone crabbing would be allowed in the zone, but special regulations prohibiting willful molestation and destruction of traps would apply. The Council is holding the fact-finding hearing to seek public input on these proposed measures and alternatives, and to determine if amendment of the FMP is appropriate.

List of Subjects in 50 CFR Part 654

Fish, Fisheries, Fishing, Reporting requirements.

(16 U.S.C. 1801, et seq.)

Dated: August 31, 1982.

E. Craig Felber,

Chief, Management Services Staff, National Marine Fisheries Service.

[FR Doc. 82-24541 Filed 9-3-82; 8:45 am]

BILLING CODE 3510-22-M

Notices

Federal Register
Vol. 47, No. 173
Tuesday, September 7, 1982

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

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Review of United States Sugar Import Quota System

AGENCY: Office of the Secretary, USDA.

ACTION: Notice.

SUMMARY: This notice reviews the U.S. sugar import quota system established by Presidential Proclamation 4941 of May 5, 1982. (47 FR 19661).

FOR FURTHER INFORMATION CONTACT: James Truran, Telephone 202 447-2916.

SUPPLEMENTARY INFORMATION: In accordance with paragraph (f) of Headnote 3, subpart A, part 10, schedule 1 of the Tariff Schedules of the United States (TSUS), The Secretary of Agriculture has consulted with the U.S. Trade Representative, the Department of State, and the Department of the Treasury concerning the operation of the sugar import quota system established under the authority of Headnotes 2 and 3 of subpart A of part 10 of schedule 1 of the TSUS, the International Sugar Agreement, 1977, Implementation Act, and Section 201 of the Trade Expansion Act of 1962. After reveiwing the operation of the sugar import quota system the Secretary of Agriculture has determined that the system should be continued in effect in order to give due consideration to the interests in the United States sugar market of domestic producers and materially affected contracting parties to the General Agreement on Tariffs and Trade. The rationale for this decision is based on the following analysis.

World Sugar Situation

World production of centrifugal sugar (raw value) for 1981/82 (September/August) is currently estimated at a record 97.9 million tons of which cane and beet sugar account for 61.3 million and 36.6 million tons, respectively. The record output of both cane and beet sugar is largely due to higher production in major sugarcane producing countries as well as higher beet sugar production in the European Economic Community (EEC). The outlook for 1982/83 world beet sugar production is 35.1 million tons, down only 4 percent from record 1981/82 output owing largely to reduced plantings in the United States and the EEC. Prospects for the major cane sugar producers for 1982/83 appear good. USDA's first estimate of world 1982/83 cane and beet sugar production will be issued November 10, 1982.

World consumption of sugar for 1981/82 is currently estimated at around 91 million tons resulting in a world surplus of sugar of about 7 million tons. Due to the price inelastic nature of sugar demand, sugar consumption is likely to change little in 1982/83 despite low world prices. Current estimates are for consumption to increase marginally to around 92 to 93 million tons due largely to population growth.

World sugar prices during 1981/82 have been weak, falling below 8 cents per pound over the last several months—the lowest price levels since mid-1978. A principal explanatory factor in sugar price movements is the level of sugar stocks relative to sugar consumption. Statistically, this relationship is highly and inversely correlated to world raw sugar prices. Surplus sugar production in 1981/82, added to existing stocks, have pushed total stock levels, as a percent of consumption, to over 30 percent—the highest level since 1978. The stock to consumption ratio is expected to change little during 1982/83 given current production and consumption prospects. Also adding to the downward pressure on prices has been the continued existence of subsidized EEC sugar on the world market. The EEC does not belong to the International Sugar Organization (ISO), a situation which has complicated the ISO's attempt to stabilize world sugar prices within the agreed price range of the International Sugar Agreement. As the world sugar market is a "residual market" (sugar traded freely in world markets is only a residual of total world sugar production), the EEC surplus sugar has had a significant dampening affect on world prices.

U.S. Price Support Program

Title IX of the Agriculture and Food Act of 1981 provided for a price support program for sugar. A purchase program is in effect for sugar processed between December 22, 1981 and March 31, 1982. Under provisions of the program, the Commodity Credit Corporation (CCC) has entered into agreements to purchase this sugar at a national average price for raw sugar of 16.75 cents per pound. Effective October 1, 1982, a loan program will come into operation in which CCC will make non-recourse price support loans on 1982/83 sugar at not less than 17 cents per pound. At a minimum, this loan rate will increase to 17.50 cents for the 1983 crop, to 17.75 cents for the 1984 crop and to 18 cents for the 1985 crop.

Actions To Restrain Imports

Given the world sugar supply and price situation at the beginning of FY 1982 and the mandate of the 1981 Farm Act to support the price of domestic sugar at specified levels, it was obvious that imports, if not restrained, would displace domestic sugar and force it into the hands of the Commodity Credit Corporation. Such a result would have adversely affected the interests in the U.S. sugar market of domestic producers. To prevent this, import fees and import duties on sugar were increased in December 1981. Despite these increases and owing to a drop in the world price below 10 cents per pound, it was no longer possible to achieve, through fees and duties, reasonable market prices which gave due consideration to the interests in the U.S. sugar market of domestic producers of sugarcane and sugar beets. As a result, restrictive import quotas were imposed (effective May 11) until such time as the world market price strengthened sufficiently to permit a return to an effective system of fees and duties.

Quarterly quotas were established for the May 11 to June 30 period and July 1 to September 30 period at 220,000 and 420,000 short tons, respectively. A tentative quota for FY 1983 was set at 3.3 million short tons. Simultaneously, with the import quota proclamation issued on May 5, 1982, the President issued Proclamation 4940 which revised the Section 22 fee system by increasing the market stabilization price (MSP) for

the 1982 purchase agreement program from 19.08 to 19.88 cents per pound.

Conclusion

The fundamental imbalance between world sugar supplies and demand continues and is expected to persist over the next fiscal year. Large supplies and lack of effective discipline over subsidized exports from the EEC imply prices at levels that, lacking effective import restraints, would threaten the domestic sugar industry. The continued imposition of the import quota system is therefore necessary.

Notice

In accordance with paragraph (f) of Headnote 3 subpart A, part 10, schedule 1 of the Tariff Schedules of the United States, I have determined that the continued operation of paragraphs (b), (c), (d), and (e) of this Headnote 3 gives due consideration to the interests in the United States sugar market of domestic producers and materially affected contracting parties to the General Agreement on Tariffs and Trade, and that the operation of paragraph (g) of this headnote would not give due consideration to such interests.

Dated: September 1, 1982.

Richard E. Lyng,

Acting Secretary of Agriculture.

[FR Doc. 82-24496 Filed 9-1-82; 4:24 pm]

BILLING CODE 3410-01-M

DEPARTMENT OF COMMERCE

International Trade Administration

Brookhaven National Laboratory; Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued pursuant thereto (15 CFR Part 301 as amended by 47 FR 32517).

A copy of the record pertaining to this decision is available for public review between 8:30 AM and 5:00 PM in Room 2097, Statutory Import Programs Staff, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, D.C. 20230.

Docket No. 82-00178. Applicant: Brookhaven National Laboratory, Upton, New York 11973. Article: Monochromator Crystals. Manufacturer: Cristal Tec, France. Intended use of article: See Notice on page 21906 in the Federal Register of May 20, 1982.

Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign instrument, for such purposes as this instrument is intended to be used, is being manufactured in the United States. Reasons: The foreign instrument is a crystal monochromator capable of selecting neutrons of a single energy from neutrons with a smooth distribution of energies. The National Bureau of Standards advises in its memorandum dated August 5, 1982 that (1) the capability of the foreign instrument described above is 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.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign instrument, for such purposes as this instrument is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 82-24528 Filed 9-3-82; 8:45 am]

BILLING CODE 3510-25-M

Duke University; Notice of Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued pursuant thereto (15 CFR part 301 as amended by 47 FR 32517).

A copy of the record pertaining to this decision is available for public review between 8:30 AM and 5:00 PM in Room 2097, Statutory Import Programs Staff, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, D.C. 20230.

Docket No. 82-00151. Applicant: Duke University, Medical Center, Department of Physiology, Box 3709, Durham, NC 27710. Article: Multichannel Cytomic Analyzer. Manufacturer: Max-Planck-Institute for Biochemie, West Germany. Intended use of article: See Notice on page 20837 in the Federal Register of May 14, 1982.

Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign instrument, for such purposes as this instrument is intended to be used, is being manufactured in the United States. Reasons: The foreign instrument is identical with other equipment used in a joint research project. The work is at the state of the art level and exact duplication of technique is critical. The Department of Health and Human Services advises in its memorandum dated July 7, 1982 that (1) the capability of the foreign instrument described above is 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.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign instrument, for such purposes as this article is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 82-24525 Filed 9-3-82; 8:45 am]

BILLING CODE 3510-25-M

Georgetown University Medical Center; Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued pursuant thereto (15 CFR Part 301 as amended by 47 FR 32517).

A copy of the record pertaining to this decision is available for public review between 8:30 AM and 5:00 PM in Room 2097, Statutory Import Programs Staff, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, D.C. 20230.

Docket No. 82-00186. Applicant: Georgetown University Medical Center, 3800 Reservoir Road, NW., Washington, D.C. 20007. Article: Medical Irradiator with Accessories. Manufacturer: Isotopen-Technik, Dr. Sauerwein GmbH, West Germany. Intended use of article: See Notice on page 24166 in the Federal Register of June 3, 1982.

Comments: No comments have been received with respect to this application.

Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign instrument, for such purposes as this instrument is intended to be used, is being manufactured in the United States. Reasons: The foreign instrument provides programmable movement of a 5–10 curie radioactive source that is small enough to fit into needles for interstitial tissue insert. The Department of Health and Human Services advises in its memorandum dated July 20, 1982 that (1) the capability of the foreign instrument described above is 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.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign instrument, for such purposes as this instrument is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 82-24529 Filed 9-3-82; 8:45 am]

BILLING CODE 3510-25-M

Railcars From Canada; Postponement of Preliminary Countervailing Duty Determination

AGENCY: International Trade Administration, Commerce.

ACTION: Postponement of Preliminary Countervailing Duty Determination.

SUMMARY: The preliminary determination of railcars from Canada is being postponed, and we intend to issue it not later than November 22, 1982.

EFFECTIVE DATE: September 7, 1982.

FOR FURTHER INFORMATION CONTACT: Paul Nichols, Office of Investigations, Import Administration, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, D.C. 20230 (202) 377–1768.

SUPPLEMENTARY INFORMATION: On July 14, 1982, we announced the initiation of a countervailing duty investigation to determine whether the government of Canada is giving its producers, manufacturers, or exporters of railcars certain benefits that are bounties or grants within the meaning of the countervailing duty law. The notice stated that we would issue a preliminary determination by September 17, 1982.

As detailed in the notice of initiation of the countervailing duty investigation, the petition alleges two subsidy programs that the government of Canada provides to producers and exporters of railcars.

Section 703(c) of the Act provides that the Department of Commerce may postpone its preliminary determination if it concludes that the parties involved are cooperating in the investigation and determines that the case is extraordinarily complicated by reason of the complexity of the alleged subsidy practices and the novelty of the issues presented. We find these factors to exist in this case and that additional time is needed to make the preliminary determination. For these reasons we have determined that this case is extraordinarily complicated in accordance with section 703(c)(1)(B) of the Tariff Act of 1930, as amended ("the Act"), and we intend to issue a preliminary determination not later than November 22, 1982.

This notice is published pursuant to section 703(c)(2) of the Act.

Judith Hippler Bello,

Acting Deputy Assistant Secretary for Import Administration.

August 31, 1982.

[FR Doc. 82-24522 Filed 9-3-82; 8:45 am]

BILLING CODE 3510-25-M

St. Vincent Medical Center; Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897) and the regulations issued pursuant thereto (15 CFR Part 301 as amended by 47 FR 32517).

A copy of the record pertaining to this decision is available for public review between 8:30 AM and 5:00 PM in Room 2097, Statutory Import Programs Staff, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, D.C. 20230.

Docket No. 82–00079. Applicant: St. Vincent Medical Center, 2131 West Third Street, P.O. Box 57992, Foy Street Station, Los Angeles, CA 90057. Article: Stereotactic Head Set. Manufacturer: F. L. Fischer GMBL & Co., West Germany. Intended use of article: See Notice on page 6680 in the **Federal Register** of February 16, 1982.

Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign instrument, for such purposes as this instrument is intended to be used, is being manufactured in the United States. Reasons: The foreign instrument is a developed and proven stereotactic headframe, adapted for computer aided CT use. The Department of Health and Human Services advises in its memorandum dated May 6, 1982 that (1) the capability of the foreign instrument described above is 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.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign instrument, for such purposes as this instrument is intended to be used, which is being manufactured in the United States.

(Catalog of federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 82-24524 Filed 9-3-82; 8:45 am]

Billing Code 3510-25-M

Stanford University; Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897) and the regulations issued pursuant thereto (15 CFR Part 301 as amended by 47 FR 32517).

A copy of the record pertaining to this decision is available for public review between 8:30 AM and 5:00 PM in Room 2097, Statutory Import Programs Staff, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, D.C. 20230.

Docket No. 82–00164. Applicant: Stanford University, Procurement Department, AEL–109, Stanford, CA 94305. Article: Infrared Gas Analyzer. Manufacturer: Binos, West Germany. Intended use of article; See Notice on page 21905 in the **Federal Register** of May 20, 1982.

Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign instrument, for such purposes as this instrument is intended to be used, is

being manufactured in the United States. Reason: The foreign instrument provides portablity and stability of 50/60 Hertz ±5% at remote locations under diverse power conditions. The Department of Health and Human Services advises in its memorandum dated July 7, 1982 that (1) the capabilities of the foreign instrument described above 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.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign instrument, for such purposes as this instrument is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 82-24527 Filed 9-3-82; 8:45 am]

BILLING CODE 3510-25-M

University of Utah Medical Center; Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued pursuant thereto (15 CFR Part 301 as amended by 47 FR 32517).

A copy of the record pertaining to this decision is available for public review between 8:30 AM and 5:00 PM in Room 2097, Statutory Import Programs Staff, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, D.C. 20230.

Docket No. 82-00165. Applicant: University of Utah Medical Center, Department of Surgery, 50 No. Medical Drive, Salt Lake City, Utah 84132. Article: Neodymium YAG Surgical Laser. Manufacturer: M.B.B.-A.T., G.M.B.H., West Germany. Intended use of article: See Notice on page 21905 in the **Federal Register** of May 20, 1982.

Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign instrument, for such purposes as this instrument is intented to be used, is being manufactured in the United States. Reasons: The foreign instrument provides for use with a dedicated endoscope, portability and maneuverability. The Department of Health and Human Services advises in its memorandum dated July 7, 1982 that (1) the capabilities of the foreign instrument described above 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.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign instrument, for such purposes as this instrument is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 82-24526 Filed 9-3-82; 8:45 am]

BILLING CODE 3510-25-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Announcing Import Restraint Levels for Certain Cotton Textile Products Exported From the Republic of Indonesia

September 1, 1982.

On June 8, 1982, there was published in the **Federal Register** (47 FR 24766) a notice dated June 1, 1982, announcing that, on May 28, 1982, the United States Government, pursuant to the Arrangement Regarding International Trade in Textiles, had requested the Government of the Republic of Indonesia to enter into consultations concerning exports to the United States of woven cotton shirts in Category 340 and cotton trousers in Category 347/348, produced or manufactured in Indonesia.

During the period August 23-24, consultations were held between representatives of the two governments. No agreement was reached on a solution to this problem; however, the United States Government is continuing consultations with the Government of the Republic of Indonesia. In the meantime, under the terms of Article 3 and Annex B of the Arrangement Regarding International Trade in Textiles, the Goverment of the United States has informed the Government of the Republic of Indonesia that, beginning on May 28, 1982 and extending through May 27, 1983, imports of cotton textile products in Categories 340 and 347/348 will be limited to respective levels of 235,256 dozen and 537,661 dozen.

Accordingly, in the letter published below the Chairman of the Committee for the Implementation of Textile Agreements directs the Commissioner of Customs to prohibit entry into the United States for consumption, or withdrawal from warehouse for consumption, of cotton textile products in Categories 340 and 347/348 during the twelve-month period which began on May 28, 1982 in excess of the designated levels of restraint.

Effective date: September 9, 1982.

Walter C. Lenahan,

Acting Chairman, Committee for the Implementation of Textile Agreements.

September 1, 1982.

Committee for the Implementation of Textile Agreements

Commissioner of Customs,
Department of the Treasury, Washington, D.C. 20229

Dear Mr. Commissioner: Under the terms of the Arrangement Regarding International Trade in Textiles done at Geneva on December 20, 1973, as extended on December 14, 1977 and December 22, 1981, and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended by Executive Order 11951 of January 6, 1977, you are directed, effective on September 9, 1982 and for the twelve-month period which began on May 28, 1982 and extends through May 27, 1983 to prohibit entry into the United States for consumption and withdrawal from warehouse for consumption of cotton textile products in Categories 340 and 347/348, produced or manufactured in the Republic of Indonesia in excess of the following levels of restraint:

Category	12-month level of restraint [1]
340	235,256 dozen.
347/348	537,661 dozen.

[1] The levels of restraint have not been adjusted to reflect any imports after May 27, 1982.

Cotton textile products in Categories 340 and 347/348 which have been exported to the United States prior to May 28, 1982 shall not be subject to this directive.

Cotton textile products in Categories 340 and 347/348 which have been released from the custody of the U.S. Customs Service under the provisions of 19 U.S.C. 1448(b) or 1484(a)(1)(A) prior to the effective date of this directive shall not be denied entry under this directive.

A detailed description of the textile categories in terms of T.S.U.S.A. numbers was published in the **Federal Register** on February 28, 1980 (45 FR 13172), as amended on April 23, 1980 (45 FR 27463), August 12, 1980 (45 FR 53506), December 24, 1980 (45 FR 85142), May 5, 1981 (46 FR 25121), October 5, 1981 (46 FR 48963), October 27, 1981 (46 FR

52409), February 9, 1982 (47 FR 5926) and May 13, 1982 (47 FR 20654).

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The actions taken with respect to the Government of the Republic of Indonesia and with respect to imports of cotton textile products from Indonesia have been determined by the Committee for the Implementation of Textile Agreements to involve foreign affairs functions of the United States. Therefore, these directions to the Commissioner of Customs, which are necessary for the implementation of such actions, fall within the foreign affairs exception to the rule-making provisions of 5 U.S.C. 553. This letter will be published in the **Federal Register.**

Sincerely,

Walter C. Lenahan,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 82-24521 Filed 9-3-82; 8:45 am]

BILLING CODE 3510-25-M

Amending the Import Restraint Level for Certain Cotton Apparel Products From Singapore

AGENCY: Committee for the Implementation of Textile Agreements.

ACTION: Applying swing and carryforward to the level of restraint established for cotton coasts in Category 333/334/335, produced or manufactured in the Republic of Singapore and exported during the twelve-month period which began on January 1, 1982, increasing the overall level from 182,326 dozen to 206,028 dozen. The sublimits within this category are also being increased.

(A detailed description of the textile categories in terms of T.S.U.S.A. numbers was published in the **Federal Register** on February 28, 1980 (45 FR 13172), as amended on April 23, 1980 (45 FR 27463), August 12, 1980 (45 FR 53506), December 24, 1980 (45 FR 85142), May 5, 1981 (47 FR 25121), October 5, 1981 (46 FR 48963), October 27, 1981 (46 FR 52409), February 9, 1982 (47 FR 5926), and May 13, 1982 (47 FR 20654))

SUMMARY: The Bilateral Cotton, Wool, and Man-Made Fiber Textile Agreement of August 21, 1981, as amended, between the Governments of the United States and the Republic of Singapore, provides, among other things, for percentage increases in certain categories during the agreement year (swing) and for the borrowing of designated percentages of yardages from the succeeding year's level (carryforward) with the amounts used being deducted from the level in the succeeding agreement year. Accordingly, under the terms of the bilateral agreement, the level of restraint established for cotton textile products in Category 333/334/335 is being increased to 206,028 dozen. The sublimits are being increased to 11,846 dozen for Category 333, to 62,550 dozen for Category 334, and to 162,536 dozen for Category 335.

EFFECTIVE DATE: September 3, 1982.

FOR FURTHER INFORMATION CONTACT: Ronald J. Sorini, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, Washington, D.C. 20230 (202/377-4212).

SUPPLEMENTARY INFORMATION: On December 18, 1981, there was published in the **Federal Register** (46 FR 61687), a letter dated December 15, 1981 which established levels of restraint for certain specified categories of cotton, wool, and man-made fiber textile products, including Category 333/334/335, produced or manufactured in Singapore which may be entered into the United States for consumption, or withdrawn from warehouse for consumption, during the twelve-month period which began on January 1, 1982 and extends through December 31, 1982. In the letter published below the Chairman of the Committee for the Implementation of Textile Agreements directs the Commissioner of Customs to increase the levels of restraint previously established for Category 333/334/335.

Walter C. Lenahan,

Acting Chairman, Committee for the Implementation of Textile Agreements.

August 30, 1982.

Committee for the Implementation of Textile Agreements

Commissioner of Customs,
Department of the Treasury, Washington, D.C. 20229

Dear Mr. Commissioner: On December 15, 1981, the Chairman, Committee for the Implementation of Textile Agreements directed you to prohibit entry during the twelve-month period beginning on January 1, 1982 and extending through December 31, 1982 of cotton, wool, and man-made fiber textile products, produced or manufactured in Singapore, in excess of designated levels of restraint. The Chairman further advised you that the levels of restraint are subject to adjustment.[1]

[1]The term "adjustment" refers to those provisions of the Bilateral Cotton, Wool, and Man-Made Fiber Textile Agreement on August 21, 1981, as amended between the Governments of the United States and the Republic of Singapore, which provide, in part, that: (1) within the aggregate and applicable group limits of the agreement, specific levels of restraint may be exceeded by designated percentages; (2) these same levels may be increased for carryover and carryforward; and (3) administrative arrangements for adjustments may be made to resolve minor problems arising in the implementation of the agreement.

Under the terms of the Arrangement Regarding International Trade in Textiles done at Geneva on December 20, 1973, as extended on December 15, 1977 and December 22, 1981; pursuant to the Bilateral Cotton, Wool, and Man-Made Fiber Textile Agreement of August 21, 1981, as amended, between the Governments of the United States and the Republic of Singapore; and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended by Executive Order 11951 of January 6, 1977, you are directed to prohibit, effective on September 3, 1982 and for the twelve-month period beginning on January 1, 1982 and extending through December 31, 1982, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton textile products in Category 333/334/335, produced or manufactured in Singapore, in excess of the following, adjusted levels of restraint:

Category	Adjusted 12-month level of restraint [1]
333/334/335.....	206,028 dozen which not more than 11,846 dozen shall be in Category 333; not more than 62,550 dozen shall be in Category 334; and not more than 162,536 dozen shall be in Category 335.

[1]The levels of restraint have not been adjusted to account for any imports after December 31, 1981.

The action taken with respect to the Government of the Republic of Singapore and with respect to imports of cotton textile products from Singapore has been determined by the Committee for the Implementation of Textile Agreements to involve foreign affairs functions of the United States. Therefore, these directions to the Commissioner of Customs, which are necessary for the implementation of such actions, fall within the foreign affairs exception to the rule-making provisions of 5 U.S.C. 553. This letter will be published in the **Federal Register.**

Sincerely,

Walter C. Lenahan,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 82-24523 Filed 9-3-82; 8:45 am]

BILLING CODE 3510-25-M

CONSUMER PRODUCT SAFETY COMMISSION

Privacy Act of 1974; Announcement of System of Records

AGENCY: Consumer Product Safety Commission.

ACTION: Announcement of System of Records.

SUMMARY: The Consumer Product Safety Commission is publishing notice of a proposed Office of General Counsel Timesheets system of records.

DATES: Comments must be received on or before November 8, 1982.

ADDRESSES: Comments should be sent to the Secretary, Consumer Product Safety Commission, Washington, D.C. 20207.

FOR FURTHER INFORMATION CONTACT: Joseph F. Rosenthal, Office of the General Counsel, Consumer Product Safety Commission, Washington, D.C. 20207. Telephone: (301) 492–6980.

SUPPLEMENTARY INFORMATION: The Consumer Product Safety Commission is establishing a system of records within its Office of the General Counsel to record and document, on timesheets, the activities of its attorneys throughout the course of their workdays. The records will be used for management purposes within the Office of the General Counsel.

The system of records will become effective November 8, 1982 unless comments are received which justify a contrary determination.

The President of the Senate, The Speaker of the House of Representatives, and the Officer of Management and Budget have been notified of this system.

Dated: August 31, 1982.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

Report on Privacy Act System of Records, Office of the General Counsel Timesheets—CPSC–6

This system of records will be used to document and record the daily activities of SPSC attorneys. The attorneys will be furnished pre-printed forms, divided into time segments on which they will enter, during the course of a day, their various activities.

These records will be used for normal management purposes of adjusting staffing patterns to meet workload requirements and of appraising the performance of attorneys. They will also be used by the attorneys who prepare them to make more effective use of their own time.

Authority for the system of records is found in 5 U.S.C. 3101 which directs agency heads to maintain records of agency operations, 15 U.S.C. 2053 which provides for a General Counsel function at CPSC, and 5 U.S.C. Chapter 43 which provides for employee performance appraisal systems.

This system of records should not adversely affect the privacy or other rights of employees of the Consumer Product Safety Commission since it only contains information about normal workday activities, is only used for normal internal management purposes, and only contains information furnished by the employees. There should be no effect on the principles of federalism or separation of powers since this is an internal agency system of records containing information on federal employees who perform functions expressly authorized by Congress.

As described in the enclosed system notice, the records are stored in lockable metal file cabinets with access limited to those whose official duties require access. These precautions are believed by management to be adequate to minimize the risk of unauthorized access to any personal information contained in the system.

CPSC–6

SYSTEM NAME:

Office of the General Counsel Timesheets—CPSC–6.

SYSTEM LOCATION:

Office of the General Counsel, Consumer Product Safety Commission, 5401 Westbard Avenue, Washington, D.C. 20207.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Attorneys in the Office of the General Counsel.

CATEGORIES OF RECORDS IN THE SYSTEM:

Timesheet forms filled out daily by each attorney, and containing a chronological record of the time intervals devoted to each of the attorney's activities.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

44 U.S.C.; 15 U.S.C. 2053; 5 U.S.C. Chapter 43.

PURPOSE(S):

a. To document the workload of the Office of the General Counsel and of its organizational units in order to provide a factual basis for staffing decisions.

b. To help attorneys make more effective use of their time.

c. To provide a factual basis for performance appraisals.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The system will be used solely as a management tool within the Consumer Product Safety Commission.

POLICIES AND PRACTICIES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained in file folders.

RETRIEVABILITY:

Filed by attorney name and organizational unit.

SAFEGUARDS:

Records are stored in lockable metal file cabinets with access limited to those whose official duties require access.

RETENTION AND DISPOSAL:

Records are destroyed after two and one half years.

SYSTEM MANAGER(S) AND ADDRESS:

Deputy General Counsel, Consumer Product Safety Commission, Washington, D.C. 20207.

NOTIFICATION PROCEDURE:

Freedom of Information/Privacy Act Officer, Office of the Secretary, Consumer Product Safety Commission, 5401 Westbard Avenue, Washington, D.C. 20207.

RECORD ACCESS PROCEDURES:

Same as Notification.

CONTESTING RECORD PROCEDURES:

Same as Notification.

RECORD SOURCE CATEGORIES:

Information in this system of records is provided by the individual to whom it applies.

[FR Doc. 82–24542 Filed 9–3–82; 8:45 am]

BILLING CODE 6355–01–M

DEPARTMENT OF DEFENSE

Department of the Army Engineers Corps

Intent To Prepare a Draft Supplemental Environmental Impact Statement (DSEIS) for the Proposed Mississippi River, Baton Rouge to the Gulf, GIM Supplement No. 2, Louisiana, Project.

AGENCY: Army Corps of Engineers, New Orleans District, DoD.

ACTION: Notice of Intent to Prepare a DSEIS.

SUMMARY: 1. *Proposed Action.* Future large maintenance dredging increases will be experienced in Southwest Pass and the Mississippi River below Venice, Louisiana, as a result of the rapid subsidence of the banks of the pass and river. The subsidence of these banks and the associated loss of river water over them results in increased shoaling within the pass and river. If no action is taken, these banks would eventually subside to the point where they would be underwater most of the year. The purpose of the proposed project is to minimize this shoaling in order to maintain the navigability of the pass and river. This project purpose would be accomplished by the construction of foreshore protection dikes, bank

nourishment, marsh development, spur dikes, bulkheads, replacement of inner bulkheads between the East and West Jetties of Southwest Pass, and the reinforcement and repair of the East Jetty. Freshwater outlets would be established in areas where the bank nourishment would reduce existing natural overflow from the pass and river. The purpose of these outlets would be to maintain present freshwater flows to areas adjacent to the pass and river.

2. *Alternatives.* The following three alternatives are to be evaluated in the EIS.

a. *Plan 1.* This plan would provide for the continued maintenance of the 40-foot channel in Southwest Pass and the Mississippi River below Venice, Louisiana. Maintenance dredged material would continue to be deposited over the bank in an unconfined fashion. None of the proposed project features would be implemented with this alternative.

b. *Plan 2.* This plan would provide for the implementation of all of the proposed project features with the exception of the freshwater outlets.

c. *Plan 3.* This plan would be the same as Plan 2 with the exception that the freshwater outlets feature would be included. This plan would provide for the initial establishment of two freshwater outlets. These outlets would be monitored to determine their effectiveness. Other monitoring would identify additional areas impacted by the bank nourishment that would require freshwater input.

3. *Scoping Process.*

a. Several meeting have been held with the US Fish and Wildlife Service, National Marine Fisheries Service, and the Louisiana Department of Wildlife and Fisheries concerning the proposed project features and the DSEIS. A scoping document will be distributed to interested agencies, organizations and individuals requesting their input to the preparation of the DSEIS.

b. Impacts of the proposed action on wetlands, water quality, endangered species, cultural resources, oil and gas facilities, and other significant resources will be analyzed in the DSEIS.

c. Coordination among appropriate Federal, state, and local agencies will continue throughout the public involvement process to insure compliance with applicable Federal and state environmental statutes.

4. *Scoping Meeting.* A scoping document, requesting public input to the DSEIS preparation process, will be sent to interested agencies, organizations, and individuals in lieu of conducting a scoping meeting.

5. *Availability.* The DSEIS is scheduled for filing with the US Environmental Protection Agency and issuance to the public in February 1983.

ADDRESS: Questions concerning the proposed action and the DSEIS should be directed to Mr. David Carney, US Army Corps of Engineers, Environmental Quality Section (LMNPD–RE), P.O. Box 60267, New Orleans, LA 70160, commercial telephone (504) 838–2528, FTS telephone 687–2528.

Dated: August 30, 1982.

Bruce F. Miller,

LTC, CE Deputy.

[FR Doc. 82–24470 Filed 9–3–82; 8:45 am]

BILLING CODE 3710–84–M

Office of the Secretary

DOD Advisory Group on Electron Devices; Advisory Committee Meeting

Working Group A (Mainly Microwave Devices) of the DoD Advisory Group on Electronic Devices (AGED) will meet in closed session on September 24, 1982 at the Palisades Institute for Research Services, Inc. 1925 North Lynn Street, Arlington, Virginia 22209.

The mission of the Advisory Group is to provide the Under Secretary of Defense for Research and Engineering, the Director, Defense Advanced Research Projects Agency and the Military Departments with technical advice on the conduct of economical and effective research and development programs in the area of electron devices.

The Working Group A meeting will be limited to review of research and development programs which the military propose to initiate with industry, universities or in their laboratories. This microwave device area includes programs on developments and research related to microwave tubes, solid state microwave, electronic warfare devices, millimeter wave devices, and passive devices. The review will include classified program details throughout.

In accordance with Section 10(d) of Pub. L. No. 92–463, as amended, (5 U.S.C. App 1, 10(d)(1976)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. (1976), and that accordingly, this meeting will be closed to the public.

M. S. Healy,

OSD Federal Register Liaison Officer, Department of Defense.

September 1, 1982.

[FR Doc. 82–24455 Filed 9–3–82; 8:45 am]

BILLING CODE 3810–01–M

DOD Advisory Group on Electron Devices; Advisory Committee Meeting

Working Group B (Mainly Low Power Devices) of the DoD Advisory Group on Electron Devices (AGED) will meet in closed session October 6, 1982 at the Palisades Institute for Research Services, 1925 North Lynn Street, Arlington, Virginia 22209.

The mission of the Advisory Group is to provide the Under Secretary of Defense for Research and Engineering, the Director, Defense Advanced Research Projects Agency and the Military Departments with technical advice on the conduct of economical and effective research and development programs in the area of electron devices.

The Working Group B meeting will be limited to review of research and development programs which the military propose to initiate with industry, universities or in their laboratories. The low power device area includes such programs as integrated circuits, charge coupled devices and memories. The review will include classified program details throughout.

In accordance with Section 10(d) of Pub. L. No. 92–463, as amended, (5 U.S.C. App. 1, 10(d)(1976)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552(b)(c) (1976), and that accordingly, this meeting will be closed to the public.

M. S. Healy,

OSD Federal Register Liaison Officer, Department of Defense.

September 1, 1982.

[FR Doc. 82–24454 Filed 9–3–82; 8:45 am]

BILLING CODE 3810–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project Nos. 2600–001 and 2600–002]

Bangor Hydro-Electric Co.; Application for New License and Amendment of License

September 2, 1982.

Take notice that Bangor Hydro-Electric Company (Applicant) filed on August 4, 1982, an application for license (pursuant to the Federal Power Act, 16 U.S.C. 791(a)–825(r)) for construction and operation of a water power project to be known as the West Enfield Project No. 2600. The project would be located on the Penobscot River in W. Enfield and Howland, Penobscot County, Maine. Correspondence with the Applicant should be directed to: Robert

S. Briggs, Vice President, Bangor Hydro-Electric Company, 33 State Street, Bangor, Maine 04401.

Project Description—The W. Enfield project presently consists of: (1) A dam on the Penobscot River about 980 feet long and about 20 feet high in three sections, (a) a rock-filled timber crib, topped by four-foot flashboards, and containing a 10-foot log sluice and a 30-foot raft sluice, (b) a concrete gated section, and (c) a granite masonry gate-house structure with 13 concrete gates, 7 x 7.5 feet together with an auxillary earth dam (Runaround) located on the west bank of Merrill Brook about 200 feet long and 15 feet high containing three steel gates controlling diversions to the Piscataquis River; (2) a reservoir at normal elevation 154.75 feet about 7.3 miles long with an area of about 1,050 acres; (3) a canal from the gate-house on the left bank to the powerhouse forebay about 1,390 feet long and varying from 100 to 240 feet wide; (4) a concrete-brick powerhouse in two sections containing (a) a 1,400-kw generating unit and (b) two 1,200-kw generating units, (5) an outdoor substation with three step-up 2.3–46 kV transformers aggregating 5,000 kVa capacity; (6) a substation with a step-up 2.3–12.5/7.2 kV transformer with 4,500 kVa capacity, for local distribution, and (7) appurtenant facilities:

Applicant requests that the license for the W. Enfield Project be amended by changing the expiration date of the license from December 31, 1987, to coincide with the date of issuance of a new 50 year license for the redevelopment and continued operation of the W. Enfield Project.

Applicant proposes under the new license: (1) To install a new powerhouse containing 5 new turbine-generators with a total rated capacity of 13 NW and new gate house within the power canal and located approximately 800 feet downstream of the existing power canal inlet gate structure (The existing gate structure and powerhouse would be removed); (2) to increase the hydraulic capacity to the existing canal and rehabilitate the existing canal embankment/training wall to accomodate an inlet flow to and outlet flow from the new powerhouse of up to 9,000 cfs; (3) to increase the normal water surface elevation of the reservoir by 9 inches to 155.5 feet m.s.l. by installing new flashboards with a total height of 5.6 feet (4) to install two new fishways to insure adequate passage to anadromous fishes; (5) to construct a new 800-foot-long, 46-kV transmission line. The redeveloped project would generate an additional 52,700,000 Kwh annually. Energy produced at the project would be utilized within the Applicants distribution system.

Project No. 2600 would also be subject to Federal takeover under sections 14 and 15 of the Federal Power Act. The Applicant has calculated that the estimated net investment in the project would amount to $2,295,491 as of December 31, 1981. The Applicant's estimated severance damages as of December 31, 1981, would amount to $100,000.

Comments, Protests, or Motions To Intervene—Anyone may file comments, a protest, or a motion to intervene in accordance with the requirements of the Rules 211 or 214, 18 CFR 385.211 or 385.214, 47 FR 19025–26l(1982). In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be filed on or before November 5, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letter the title "COMMENTS", "PROTESTS", or "MOTION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any comments, protests or motion to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82–24437 Filed 9–3–82; 8:45 am]

BILLING CODE 6717–01–M

[Project Nos. 5175–000 and 5176–000]

Bluepond Associates; Surrender of Preliminary Permits

September 1, 1982.

Take notice that Bluepond Associates, Permittee for the proposed Elgol Project No. 5175 and the proposed Cardiff Project No. 5176 filed a request on July 29, 1982, that its preliminary permits be terminated. The preliminary permits were issued on December 10, 1981, and November 17, 1981, respectively, and would have expired on May 1, 1983, and April 1, 1983, respectively. The projects would have been located on Silver Creek, in Jackson County, Colorado and on the Lower South Fork Michigan river in Jackson County, Colorado. Permittee is unwilling to continue with its studies at this time due to extended water rights litigation pending in state court.

The surrender of the permits is in the public interest. Therefore, the surrender of the preliminary permits for Projects Nos. 5175 and 5176 is accepted as of the date of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82–24438 Filed 9–3–82; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP82–483–000]

Colorado Interstate Gas Co.; Application

September 1, 1982.

Take notice that on August 12, 1982, Colorado Interstate Gas Company (Applicant), P.O. Box 1087, Colorado Springs, Colorado 80944, filed in Docket No. CP82–483–000 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the transportation of natural gas for Wycon Chemical Company (Wycon), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Pursuant to an agreement dated March 16, 1982, as amended, Applicant proposes to transport, on a best efforts basis, up to 30,000 Mcf of natural gas per day for Wycon from various supply sources that Wycon may acquire during the term of the contract. It is stated that Wycon currently has contracted to buy natural gas from Mountain Fuel Supply Company (Mountain Fuel) and that initial transportation quantities would be up to 18,500 dt per day, with an estimated daily average of approximately 12,000 dt. Applicant indicates that Wycon would use the subject gas as the principal ingredient in Wycon's production of ammonia-based fertilizers at its plant in Cheyenne, Wyoming.

Specifically, Applicant proposes to receive up to 18,500 Mcf of natural gas from Mountain Fuel for Wycon at two existing interconnections between Applicant and Mountain Fuel, Kanda and Green River in Sweetwater County, Wyoming. Applicant would transport and deliver the gas to Cheyenne Light, Fuel and Power Company for Wycon's

account at the existing Cheyenne and Norfolk Meter stations for redelivery to Wycon. The gas delivered by Applicant to Cheyenne for Wycon's account would have a thermal content equal to the aggregate thermal content of the volumes delivered to Applicant for Wycon's account after deducting appropriate volumes of fuel and unaccounted-for gas. Wycon would be responsible for the fuel and unaccounted-for gas associated with the volumes transported under this proposal.

For such service Applicant would charge Wycon 22.24 cents per Mcf delivered. Applicant avers that this charge is based on Applicant's transmission system cost of service, including a reasonable return on investment, exclusive of the cost of service attributable to gas used in the operation and maintenance of its transmission system and exclusive of the cost of service attributable to its gathering and storage systems.

Any person desiring to be heard or to make any protest with reference to said application should on or before September 22, 1982, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-24425 Filed 9-3-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP82-130-000]

Consumers Power Co.; Complaint

August 31, 1982.

Take notice that on August 16, 1982, Consumers Power Company (Consumers Power) submitted for filing a complaint seeking relief from the minimum bill provisions which it has with Trunkline Gas Company (Trunkline).

Consumers Power states that it currently anticipates that in 1982, the minimum bill provision will obligate it to take or pay for 191,625,000 Mcf of gas at a cost of $692,571,568. In addition, Consumers Power projects that it will be required to take or pay for the same amount of gas at a cost of $915,981,471 in 1982.

However, due to a combination of factors, such as, business recession, gas conservation, and the potential loss of markets to competing fuels, and because of Trunkline's recently announced intention to introduce LNG into its system, which might have the effect of reducing Consumer Power's sales by 6 Bcf. Consumers Power anticipates that in 1983 it could have no market for as much as 15.5 Bcf of gas, for which it is obligated to pay under the minimum bill provision. Consumers Power believes that such projected losses would make it commercially impracticable for it to comply with the minimum bill provision, would substantially frustrate its purpose in entering the contract with Trunkline, and could impair its ability to serve its customers.

Consequently, for the above mentioned and other reasons Consumers Power believes that the minimum bill provision in Trunkline's rate schedule P-2 is unjust, unreasonable, and contrary to the public interest.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 385.211 and 385.214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such petitions or protests should be filed on or before September 15, 1982. 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 petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-24426 Filed 9-3-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 3065-001]

Electro Ecology, Inc.; Application for Exemption for Small Hydroelectric Power Project Under 5 MW Capacity

September 1, 1982.

Take notice that on June 2, 1982, Electro Ecology, Inc. (Applicant) filed an application, under Section 408 of the Energy Security Act of 1980 (Act) (16 U.S.C. 2705, and 2708 *as amended*), for exemption of a proposed hydroelectric project from licensing under Part I of the Federal Power Act. The proposed small hydroelectric Project No. 3065 would be located on Wappinger Creek in the Village of Wappingers Falls, Towns of Poughkeepsie and Wappinger, Dutchess County, New York. Correspondence with the Applicant should be directed to: Mr. William E. Hovemeyer, 3 Allen Drive, Convent Station, New Jersey 07961.

Project Description—The proposed project would redevelop the existing but inoperative Wappingers Falls Plant and would consist of: (1) An existing 20-foot-high and 172-foot-long stone, mortar, and concrete dam (Clinton Dam) located at the head of a 64.5-foot-high natural falls; (2) a reservoir (Wappinger Lake) with a surface area of about 90 acres and a gross storage capacity of about 540 acre-feet at spillway crest elevation 83.5 feet m.s.l.; (3) a 40-foot-wide and 270-foot-long forebay formed by a 12-foot-high stone, mortar, and concrete wall adjoining the dam, containing a gated intake and a spillway; (4) a 9-foot-diameter and 924-foot-long riveted steel penstock; (5) a 50-foot-wide and 100-foot-long brick powerhouse containing two rebuilt turbines rated at 1,500 HP and 700 HP, connected to two new generators rated at 1,000 kW and 500 kW, respectively, and operated under an 83.5-foot head and at a flow of 277.5 cfs; (6) a new 4,160/13,200-volt substation; and (7) appurtenant facilities. Project energy would be transmitted to Central Hudson Gas and Electric Company system through a connection at the new substation.

The Applicant estimates that the project would generate approximately 8.27 million kWh per year. The power produced by the project would be sold to Central Hudson Gas and Electric Company.

Purpose of Exemption—An exemption, if issued, gives the Exemptee priority of control, development, and operation of the project under the terms of the exemption from licensing, and protects the Exemptee from permit or license applicants that would seek to take or develop the project.

Agency Comments—The U.S. Fish and Wildlife Service, The National Marine Fisheries Service, and the New York State Department of Environmental Protection are requested, for the purposes set forth in Section 408 of the Act, to submit within 60 days from the date of issuance of this notice appropriate terms and conditions to protect any fish and wildlife resources or to otherwise carry out the provisions of the Fish and Wildlife Coordination Act. General comments concerning the project and its resources are requested; however, specific terms and conditions to be included as a condition of exemption must be clearly identified in the agency letter. If an agency does not file terms and conditions within this time period, that agency will be presumed to have none. Other Federal, State, and local agencies are requested to provide any comments they may have in accordance with their duties and responsibilities. No other formal requests for comments will be made. Comments should be confined to substantive issues relevant to the granting of an exemption. If an agency does not file comments within 60 days from the date of issuance of this notice, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Competing Applications—Any qualified license applicant desiring to file a competing application must submit to the Commission, on or before October 25, 1982, either the competing license application that proposes to develop at least 7.5 megawatts in that project, or a notice of intent to file such a license application. Submission of a timely notice of intent allows an interested person to file the competing license application no later than 120 days from the date that comments, protests, etc. are due. Applications for preliminary permit will not be accepted.

A notice of intent must conform with the requirements of 18 CFR 4.33(b) and (c) (1980). A competing license application must conform with the requirements of 18 CFR 4.33(a) and (d) (1980).

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 385.211 or 385.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before October 25, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-24439 Filed 9-3-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 4749-001]

Energenics Systems, Inc.; Application for License (5 MW or Less)

September 2, 1982.

Take notice that Energenics Systems, Incorporated (Applicant) filed on June 24, 1982, an application for license (pursuant to the Federal Power Act, 16 U.S.C. 791(a)–825(r)) for construction and operation of a water power project to be known as Potholes East Canal Station 1973+00 Waterpower Project No. 4749–001. The project would be located on Potholes East Canal, near Mesa in Franklin County, Washington. Correspondence with the Applicant should be directed to: Mr. Granville J. Smith II, President, 1717 K Street, N.W. Suite 706, Washington, D.C. 20006.

Project Description—The proposed project located on Bureau of Reclamation's Columbia Basin Project's Potholes East Canal would consist of: (1) A 72-foot-long, 28-foot-wide rectangular approach channel upstream of existing check structure at station 1973+00; (2) a 90.5-foot-long, 12-foot-diameter steel penstock; (3) a powerhouse to contain one generating unit with a rated capacity of 1,860 KW; (4) a tailrace channel; (5) a switchyard and (6) a 100-foot-long tapline to connect to an existing Big Bend Electrical Cooperative line.

Purpose of Project—The project energy would be offered for sale to the City of Seattle. The Applicant estimates that the project would produce about 7.85 GWh annual energy. The total cost of the project is estimated to be $2.32 million.

Agency Comments—Federal, State, and local agencies that receive this notice through direct mailing from the Commission are requested to provide comments pursuant to the Federal Power Act, the Fish and Wildlife Coordination Act, the Endangered Species Act, the National Historic Preservation Act, the Historical and Archeological Preservation Act, the National Environmental Policy Act, Pub. L. No. 88–29, and other applicable statutes. No other formal requests for comments will be made.

Comments should be confined to substantive issues relevant to the issuance of a license. A copy of the application may be obtained directly from the Applicant. If an agency does not file comments within the time set below, it will be presumed to have no comments.

Competing Applications—Anyone desiring to file a competing application must submit to the Commission, on or before November 15, 1982, either the competing application itself (See 18 CFR 4.33 (a) and (d)) or a notice of intent (See 18 CFR 4.33 (b) and (c)) to file a competing application. Submission of a timely notice of intent allows an interested person to file an acceptable competing application no later than the time specified in § 4.33(c) or § 4.101 et seq. (1981).

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 385.211 or 385.214. In determining the appropriate action to take, the Commission will consider all protests or other comments

filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before November 15, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-24440 Filed 9-3-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 6563-000]

Energenics Systems, Inc.; Application for Preliminary Permit

August 31, 1982.

Take notice that Energenics Systems, Inc. (Applicant) filed on July 30, 1982, an application for preliminary permit pursuant to the Federal Power Act, 16 U.S.C. 791(a)–825(r) for Project No. 6563 to be known as the Muskingum River Lock & Dam No. 10 Project located on the Muskingum River in Muskingum County, Ohio. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Mr. Granville J. Smith II, Energenics Systems, Inc., 1717 K Street, N.W., Suite 706, Washington, D.C. 20006.

Project Description—The proposed project would utilize the existing Corps of Engineers' Muskingum River Lock & Dam No. 10 and would consist of: (1) A new powerhouse containing one or more generating units having a total rated capacity of 1.2 MW; (2) an existing 138–kV transmission line; and (3) appurtenant facilities. The Applicant estimates that the average annual energy output would be 5 GWh. The most likely market for the energy derived at the proposed project would be the Ohio Power Company.

Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit is 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on results of these studies Applicant would decide whether to proceed with more detailed studies, and the preparation of an application for license to construct and operate the project. Applicant estimates that the cost of the work to be performed under the preliminary permit would be $30,000.

Competing Applications—Anyone desiring to file a competing application for preliminary permit must submit to the Commission, on or before December 3, 1982, the competing application itself (see: 18 CFR 4.30 et seq. (1981). A notice of intent to file a competing application for preliminary permit will not be accepted for filing.

The Commission will accept applications for license or exemption from licensing, or a notice of intent to submit such an application in response to this notice. A notice of intent to file an application for license or exemption must be submitted to the Commission on or before November 2, 1982, and should specify the type of application forthcoming. Applications for licensing or exemption from licensing must be filed in accordance with the Commission's regulations (see: 18 CFR 4.30 et seq. or 4.101 et seq. (1981), as appropriate).

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions to Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 385.211 or 385.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before November 2, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", OR "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-24427 Filed 9-3-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 6562-000]

Energenics Systems, Inc., Application for Preliminary Permit

August 31, 1982.

Take notice that Energenics Systems, Inc. (Applicant) filed on July 30, 1982, an application for preliminary permit (pursuant to the Federal Power Act, 16 U.S.C. 791(a)–825(r)) for Project No. 6562 to be known as the Alvin R. Bush Dam Project located on Kettle Creek in Clinton County, Pennsylvania. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Mr. Granville J. Smith II, Energenics Systems, Inc., 1717 K Street, N.W., Suite 706, Washington, D.C. 20006.

Project Description—The proposed project would utilize the existing Corps of Engineers' Alvin R. Bush Dam and would consist of: (1) A new powerhouse containing one or more generating units having a total rated capacity of 5.47 MW; (2) an existing 230-kV transmission line; and (3) appurtenant facilities. The Applicant estimates that the average annual energy output would be 18.7 GWh. The most likely market for the energy derived at the proposed project would be the Pennsylvania Electric Company.

Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit is 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on results of these studies applicant would decide whether to proceed with more detailed studies, and the preparation of an application for license to construct and operate the project. Applicant estimates that the cost of the work to be performed under the preliminary permit would be $40,000.

Competing Applications—Anyone desiring to file a competing application for preliminary permit must submit to the Commission, on or before December 13, 1982, the competing application itself (see: 18 CFR 4.30 et. seq. (1981)). A notice of intent to file a competing application for preliminary permit will not be accepted for filing.

The Commission will accept applications for license or exemption from Licensing, or a notice of intent to submit such an application in response to this notice. A notice of intent to file an application for license or exemption must be submitted to the Commission on or before November 12, 1982, and should specify the type of application forthcoming. Applications for licensing or exemption from licensing must be filed in accordance with the Commission's regulations (see: 18 CFR 4.30 et. seq. or 4.101 et. seq. (1981), as appropriate).

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the application may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 385.211 or 385.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before November 12, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-24428 Filed 9-3-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. QF82-193-000]

Faber-Castell Corp.; Application for Commission Certification of Qualifying Status of a Cogeneration Facility

September 1, 1982.

On August 10, 1982, Faber-Castell Corporation, 551 Spring Place Pike, Lewisburg, Tennessee, 37091 filed with the Federal Energy Regulatory Commission (Commission) an application for certification of a facility as a qualifying cogeneration facility pursuant to § 292.207 of the Commission's rules.

The topping-cycle cogeneration facility is under construction in Lewisburg, Tennessee. The primary energy source to the facility will be Biomass in the form of wood waste (95%) and natural gas (5%). The electric power production capacity will be 125 kilowatts. Steam is used in process at varying pressures and temperatures at an annual rate of 24,245,000 lbs/year. Installation of the facility will be completed March 1983. No electric utility, electric utility holding company or any combination thereof has any ownership interest in the facility.

Any person desiring to be heard or objecting to the granting of qualifying status should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rule 211 or 214 of the Commission's Rules of Practice and Procedure. All such petitions or protests must be filed on or before October 7, 1982 and must be served on the applicant. 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 petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-24429 Filed 9-3-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 5297-001]

Forte Brothers, Inc.; Application for License (5 MW or Less)

September 2, 1982.

Take notice that Forte Brothers, Inc. (Applicant) filed on May 18, 1982, an application for license (pursuant to the Federal Power Act, 16 U.S.C. 791(a)–825(r)) for construction and operation of a water power project to be known as the Manville Dam Project No. 5297. The project would be located on the Blackstone River in Providence County, Rhode Island. Correspondence with the Applicant should be directed to: Mr. James A. Forte, 14 Whipple Street, Cumberland, Rhode Island 02864.

Project Description—The proposed run-of-river project would consist of: (1) An existing 160-foot-long and 19-foot-high granite masonry dam, of which the eastern half is owned by the Applicant and the western half is owned by the estate of Marcel Cournoyer; (2) an existing reservoir of negligible storage capacity with a surface area of 58 acres at surface elevation 89.40 feet M.S.L.; (3) proposed headworks with trash racks; (4) two proposed 135-foot-long, 10-foot by 10-foot concrete box culvert penstocks; (5) a proposed 40-foot by 75-foot concrete powerhouse containing two turbine/generator units with a total installed capacity of 1240 kW, operating under a net head of 17 feet; (6) a proposed 220-foot-long, 50-foot-wide tailrace; (7) a short transmission line; and (8) appurtenant facilities. Applicant estimates that the average annual generation would be 5,431,000 kWh. This license application was filed during the term of the Applicant's Preliminary Permit for Project No. 5297-000.

Purpose of Project—Project power would be sold to the Blackstone Valley Electric Company.

Agency Comments—Federal, State, and local agencies that receive this notice through direct mailing from the Commission are requested to provide

comments pursuant to the Federal Power Act, the Fish and Wildlife Coordination Act, the Endangered Species Act, the National Historic Preservation Act, the Historical and Archeological Preservation Act, the National Environmental Policy Act, Pub. L. No. 88-29, and other applicable statutes. No other formal requests for comments will be made.

Comments should be confined to substantive issues relevant to the issuance of a license. A copy of the application may be obtained directly from the Applicant. If an agency does not file comments within the time set below, it will be presumed to have no comments.

Competing Applications—Anyone desiring to file a competing application must submit to the Commission, on or before November 2, 1982, either the competing application itself (See 18 CFR 4.33 (a) and (d)) or a notice of intent (See 18 CFR 4.33 (b) and (c)) to file a competing application. Submission of a timely notice of intent allows an interested person to file an acceptable competing application no later than the time specified in § 4.33(c) or § 4.101 et. seq. (1981).

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 385.211 or 385.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or befofe November 2, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kennety F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-24441 Filed 9-3-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 6584-000]

General Energy Development, Inc., Application for Preliminary Permit

September 2, 1982.

Take notice that General Energy Development, Inc. (Applicant) filed on August 10, 1982, an application for preliminary permit (pursuant to the Federal Power Act, 16 U.S.C. 791(a)-825(r) for Project No. 6584 to be known as the Upper Still Creek Project located on Still Creek within Mount Hood National Forest in Clackamas County, Oregon. The application is on file with the Commission and is available for public inspection. Correspondence with the Applicant should be directed to: Mr. Carl Rounds, 1885 W. Washington Street, Stayton, Oregon 97383 and Mr. K. Marshall Volpa, 1885 W. Washington Street, Stayton, Oregon 97383.

Project Description—The proposed project would consist of: (1) A 6-foot-long diversion structure; (2) a 48-inch-diameter, 5,800-foot-long penstock; (3) a surge tank; (4) a powerhouse to contain a single generating unit with a rated capacity of 4,600 kW, operating under a head of 839 feet; and (5) a 200-foot-long, 45-kV transmission line to tie into an existing line. The estimated average annual energy output is 27,400,000 kWh.

Proposed Scope of Studies Under Permit—A preliminary permit, if issued, does not authorize construction. The Applicant seeks issuance of a preliminary permit for a period of 36 months, during which the Applicant would conduct engineering, environmental and economic feasibility studies and prepare an application for license. The estimated cost for conducting these studies and preparing an applicaton for an FERC license is $77,000.

Competing Applications—Anyone desiring to file a competing application for preliminary permit must submit to the Commission, on or before November 15, 1982, the competing application itself, or a notice of intent to file such an application (see: 18 CFR 4.30 et seq. (1981); and Docket No. RM81-15, issued October 29, 1981, 46 FR 55245, November 9, 1981).

The Commisson will accept applications for license or exemption from licensing, or a notice of intent to submit such an application in response to this notice. A notice of intent to file an applicaton for license or exemption must be submitted to the Commission on or before November 15, 1982, and should specify the type of application forthcoming. Any application for license or exemption from licensing must be filed in accordance with the Commission's regulations (see: 18 CFR 4.30 et seq. or 4.101 et seq. (1981), as appropriate).

Submission of a timely notice of intent to file an application for preliminary permit, allows an interested person to file an acceptable competing application for preliminary permit no later than January 14, 1983.

Agency Comments—Federal, State, and local agencies are invited to submit comments on the described application. (A copy of the applicaton may be obtained by agencies directly from the Applicant.) If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and procedure, 18 CFR 385.211 or 385.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before November 15, 1982.

Filing and Service or Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS" "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch,

Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-24442 Filed 9-3-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 4783-001]

Homestake Consulting and Investments, Inc.; Surrender of Preliminary Permit

September 1, 1982.

Take notice that Homestake Consulting and Investments, Inc., Permittee for the proposed Lower Hunt Creek Hydroelectric Project No. 4783, has requested that its preliminary permit be terminated. The permit was issued on January 29, 1982, and would have expired June 30, 1983. The project would have been located on the Hunt Creek in Bonner County, Idaho.

The Permittee filed its request on August 10, 1982, and the surrender of the preliminary permit for Project No. 4783 is deemed accepted as of the date of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-24445 Filed 9-3-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 4184-001]

Hydro Development, Inc.; Surrender of Preliminary Permit

September 1, 1982.

Take notice that Hydro Development, Inc., Permittee for the proposed Roaring River Hydroelectric Project No. 4184 has requested that its preliminary permit be terminated. The permit was issued on July 8, 1981, and would have expired July 1, 1983. The project would have been located on the Roaring River in Clackamas County, Oregon.

The Permittee filed its request on August 20, 1982, and the surrender of the preliminary permit for Project No. 4184 is deemed accepted as of the date of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-24443 Filed 9-3-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP82-104-001 and No. RP82-81-001]

Inter-City Minnesota Pipelines Ltd.; Proposed Changes in FERC Gas Tariff

August 31, 1982.

Take notice that on August 19, 1982, Inter-City Minnesota Pipelines Ltd. ("Inter-City") tendered for filing:

Substitute Second Revised Sheet No. 57

Inter-City states that the purpose for the filing is to shorten the notice for PGA filings from 60 to 30 days as permitted by § 154.38(d)(4)(v) of the Commission's regulations. Inter-City has requested an effective date of November 1, 1982 and states that such effective date is necessary to permit the company's revised PGA procedures to go into effect at one time and in time to permit filing of the company's 1982 PGA submission under the new procedures.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rule 211 or 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, .214). All such petitions or protests should be filed on or before September 15, 1982. 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 petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-24430 Filed 9-3-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 6548-000]

Mega Hydro, Inc.; Application for Exemption of Small Conduit Hydroelectric Facility

September 1, 1982.

Take notice that on July 21, 1982, Mega Hydro, Inc. (Applicant) filed an application, under Section 30 of the Federal Power Act (Act) (16 U.S.C. 823(a)), for exemption of a proposed hydroelectric project from requirements of Part I of the Act. The proposed Goose Valley Power Project (FERC Project No. 6548) would be located on Goose Creek in Shasta County, California.

Correspondence with the Applicant should be directed to: Mr. Fred G. Castagna, 1575 Hartnell Avenue, Redding, California 96002.

Purpose of Project—The purpose of the project is to develop the hydroelectric potential of an existing irrigation diversion. The Applicant proposes to sell project-generated power to the Pacific Gas and Electric Company.

Project Description—The proposed project would utilize an existing diversion structure at elevation 3,510 feet and a 4,400-foot-long ditch and would consist of: (1) a screened intake structure at elevation 3,493 feet; (2) a penstock 24 inches in diameter by 1,029 feet long; (3) a powerhouse at elevation 3,235 feet containing three impulse turbines, a 93-kW generator and a 187-kW generator with a total average annual output of 992,070 kWh; and (4) a transmission line 2,200 feet long.

Agency Comments—The U.S. Fish and Wildlife Service, The National Marine Fisheries Service, the State Fish and Game Commission and the Wildlife Conservation Board of California are requested, for the purposes set forth in Section 30 of the Act, to submit within 45 days from the date of issuance of this notice appropriate terms and conditions to protect any fish and wildlife resources or otherwise carry out the provisions of the Fish and Wildlife Coordination Act. General comments concerning the project and its resources are requested; however, specific terms and conditions to be included as a condition of exemption must be clearly identified in the agency letter. If an agency does not file terms and conditions within this time period, that agency will be presumed to have none. Other Federal, State, and local agencies are requested to provide comments they may have in accordance with their duties and responsibilities. No other formal requests for comments will be made. Comments should be confined to substantive issues relevant to the granting of an exemption. If an agency does not file comments within 45 days from the date of issuance of this notice, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Comments, Protests, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of its Rules of Practice and Procedure, 18 CFR 385.211 or 385.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments,

protests, or petitions to intervene must be received on or before October 25, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the orignial and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-24444 Filed 9-3-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP82-133-000]

Michigan Wisconsin Pipe Line Co.; Filing of Initial Rate Schedule

August 31, 1982.

Take notice that on August 20, 1982, Michigan Wisconsin Pipe Line Company (Michigan Wisconsin) tendered for filing, a new, Initial Rate Schedule DF-1, to be included in its FERC Gas Tariff, Original Volume No. 1, to become effective October 1, 1982, through October 31, 1984. Michigan Wisconsin states that the new rate schedule is available only to customers also served by Michigan Wisconsin under one or more of its Rate Schedules CD-1, LVS-1, or SGS-1. Sales are to be made to allow such customers to retain or increase their sales to persons with minimum annual gas requirements of 200,000 dth, which utilize gas for feedstock or process purposes, or have the capability to use No. 5 or No. 6 fuel oil or liquefied petroleum gas. Availability of gas under this Initial Rate Schedule DF-1 will not increase daily or annual availability of gas to customers, and Michigan Wisconsin will credit all revenues derived under such rate schedule in excess of related cost of gas purchased, to its Account No. 191.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 385.211 and 385.214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such petitions or protests should be filed on or before September 15, 1982. 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 petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-24431 Filed 9-3-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 6476-000]

North American Hydro, Inc.; Application for Exemption for Small Hydroelectric Power Project Under 5 MW Capacity

September 1, 1982.

Take notice that on June 30, 1982, North American Hydro, Inc. filed an application under Section 408 of the Energy Security Act of 1980 (Act) (16 U.S.C. 2705 and 2708 *as amended*), for exemption of a proposed hydroelectric project from licensing under Part I of the Federal Power Act. The proposed small hydroelectric Project No. 6476 would be located on the La Crosse River near Hamilton in La Crosse County, Wisconsin. Correspondence with the Applicant should be directed to: Mr. Charles Alsberg, North American Hydro, Inc., P.O. Box 676, Wautoma, Wisconsin 54982.

Project Description—The proposed project would consist of: (1) The existing 215-foot long, 17.5-foot high Neshonoc Dam on the La Crosse River; (2) the existing Neshonoc Lake with a surface area of 687 acres at 699.50 feet m.s.l. and a gross storage capacity of 3,100 acre-feet; (3) an existing two-story masonry powerhouse containing two proposed turbine/generator units having an estimated total installed capacity of 500 kW and producing an average annual energy output of 2.10 GWh; (4) an existing 25-foot long open-channel tailrace; (5) 150 feet of proposed 1,200 volt underground primary transmission line to connect to an existing Northern State Power Company line; and, (6) appurtenant facilities. Power generated would be sold to Northern States Power Company. The project would be operated in a peaking mode. The Applicant states that it will either purchase or hold easements on all project property.

Purpose of Exemption—An exemption, if issued, gives the Exemptee priority of control, development, and operation of the project under the terms of the exemption from licensing, and protects the Exemptee from permit or license applicants that would seek to take or develop the project.

Agency Comments—The U.S. Fish and Wildlife Service, The National Marine Fisheries Service, and the Wisconsin Department of Natural Resources are requested, for the purposes set forth in Section 408 of the Act, to submit within 60 days from the date of issuance of this notice appropriate terms and conditions to protect any fish and wildlife resources or to otherwise carry out the provisions of the Fish and Wildlife Coordination Act. General comments concerning the project and its resources are requested; however, specific terms and conditions to be included as a condition of exemption must be clearly identified in the agency letter. If an agency does not file terms and conditions within this time period, that agency will be presumed to have none. Other Federal, State, and local agencies are requested to provide any comments they may have in accordance with their duties and responsibilities. No other formal requests for comments will be made. Comments should be confined to substantive issues relevant to the granting of an exemption. If an agency does not file comments within 60 days from the date of issuance of this notice, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Competing Application—Any qualified license applicant desiring to file a competing application must submit to the Commission, on or before October 25, 1982 either the competing license application that proposes to develop at least 7.5 megawatts in that project, or notice of intent to file such a license application. Submission of a timely notice of intent allows an interested person to file the competing license application no later than 120 days from the date that comments, protests, etc. are due. Applications for preliminary permit will not be accepted.

A notice of intent must conform with the requirements of 18 CFR 4.33(b) and (c) (1980). A competing license application must conform with the requirements of 18 CFR 4.33(a) and (d) (1980).

Comments, Protests, or Petitions to Intervene—Anyone may submit comments, a protest, or a petition to

intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 385.211 or 385.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before October 25, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the tile "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragrah of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-24446 Filed 9-3-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ST81-306-001]

Oasis Pipe Line Co.; Extension Reports

September 1, 1982.

The companies listed below have filed extension reports pursuant to Section 311 of the Natural Gas Policy Act of 1978 (NGPA) and Part 284 of the Commission's regulations giving notice of their intention to continue transportation and sales of natural gas for an additional term of up to 2 years. These transactions commenced on a self-implementing basis without case-by-case Commission authorization. The Commission's regulations provide that the transportation or sales may continue for an additional term if the Commission does not act to disapprove or modify the proposed extension during the 90 days preceding the effective date of the requested extension.

The table below lists the name and addresses of each company selling or transporting pursuant to Part 284; the party receiving the gas; the date that the extension report was filed; and the effective date of the extension. A letter "B" in the Part 284 column indicates a transportation by an interstate pipeline which is extended under § 284.105. A letter "C" indicates transportation by an intrastate pipeline extended under § 284.125. A "D" indicates a sale by an intrastate pipeline extended under § 284.146. A "G(HS)" indicates transportation, sales or assignments by a Hinshaw Pipeline pursuant to a blanket certificate issued under § 284.222 of the Commission's Regulations.

Any person desiring to be heard or to make any protest with reference to said extension report should on or before September 30, 1982 file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 or 385.214). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants party to a proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

Secretary.

Docket No.	Transporter/seller	Recipient	Date filed	Part 284 subpart	Effective date
ST81-52-001	Consumers Power Co., 212 West Michigan Ave., Jackson, MI 49201	Trans Louisiana Gas Co., Inc.	8/02/82	G(HS)	10/31/82
ST81-66-001	Northern Natural Gas Co., 2223 Dodge St., Omaha, NE 68102	Columbia Gas Transmission Corp.	8/10/82	G	11/04/82
ST81-70-001	Louisiana Resources Co., P.O. Box 3102, Tulsa, OK 74101	United Gas Pipe Line Co.	8/10/82	C	11/12/82
ST81-79-001	Mississippi River Transmission Corp., 9900 Clayton Rd., St. Louis, MO 63124.	El Paso Natural Gas Co.	8/13/82	G	11/15/82
ST81-146-001	Delhi Gas Pipeline Corp., Fidelity Union Tower, Dallas, TX 75201	Northern Natural Gas Co.	8/05/82	C	12/01/82
ST81-306-001	Oasis Pipe Line Co., P.O. Box 1188, Houston, TX 77001	Natural Gas Pipeline Co. America	8/09/82	C	11/07/82

[FR Doc. 82-24433 Filed 9-3-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. QF82-201-000]

Resource Authority in Sumner County; Application for Commission Certification of Qualifying Status of a Cogeneration Facility

September 1, 1982.

On August 16, 1982, Resource Authority in Sumner County, 625 Andrews Wire Road, Gallatin, Tennessee, 37066, filed with the Federal Energy Regulatory Commission (Commission) an application for certification of a facility as a qualifying cogeneration facility pursuant to § 292.207 of the Commission's rules.

The topping-cycle cogeneration facility is located at Andrews Wire Road, Gallatin, Tennessee. The primary energy source is municipal solid waste. The electric power production capacity will be 550 kilowatts. The facility consists of two 22,500 lb/hour steam boilers, a steam turbine, an electrical generator, and necessary piping, controls, and appurtenances. The exhaust from the turbine (rated 45,000 lb/hour) is sold as process steam to nearby industries. Installation of the facility was completed in March, 1982. No electric utility, electric utility holding company or any combination thereof has any ownership interest in the facility.

Any person desiring to be heard or objecting to the granting of qualifying status should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rule 211 or 214 of the Commission's Rules of Practice and Procedure. All such petitions or protests must be filed on or before October 7, 1982 and must be served on the applicant. 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 petition to intervene. Copies of this filing are on file with the

Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-24432 Filed 9-3-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP82-474-000]

Standard Pacific Gas Line Inc.; Application

September 1, 1982.

Take notice that on August 6, 1982, Standard Pacific Gas Line Incorporated (Applicant), P.O. Box 7442, San Francisco, California 94210, filed in Docket No. CP82-474-000 an application pursuant to Section 7(b) of the Natural Gas Act for permission and approval to abandon a segment of gas transmission pipeline, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Specifically, Applicant proposes to abandon approximately 2,800 feet of 12-inch pipe and 2,830 feet of 8-inch pipe of its existing SP-4 pipeline in the Twitchell Island portion of the San Joaquin River Delta in central California. It is stated that all of the 12-inch pipe and approximately 1,530 feet of the 8-inch pipe would be sold to Pacific Gas and Electric Company (PGandE) at present book value for use in PGandE's gas gathering system in the area.

Applicant submits that the SP-4 pipeline was created in 1942 when Applicant acquired an existing pipeline from Natural Gas Corporation and that the SP-4 line was used to transport natural gas for PGandE, Pacific Public Service, and Standard Oil Company of California, the predecessor to Chevron U.S.A., Inc., from the Rio Vista gas field in the San Joaquin Dalta to Antioch, California, where it connected with the existing systems of Applicant and PGandE. Applicant explains that the SP-4 facilities on Twitchell Island were physically severed from its system in 1954 as a result of unstable ground conditions and subsidence in the area. Applicant states that it subsequently installed other connecting facilities on an adjoining island to provide gas transportion capability lost by the SP-4 outage.

It is asserted that PGandE is willing to purchase a portion of the SP-4 facilities on Twitchell Island for use in its gas gathering system for purchase of California intrastate gas production for eventual distribution to PG and E's gas customers throughout northern and central California.

Sale of the pipeline, it is asserted, would result in an annual saving of $1,243.66 in Sacramento County property taxes, and would result in revenues from the sale of $3,620.00 which represents the present book value of the facilities.

Applicant notes that there would be no interruption or impairment of service to customers, as the pipe in question has not been used since 1954.

Any person desiring to be heard or to make any protest with reference to said application should on or before September 22, 1982, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that permission and approval for the proposed abandonment are required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-24434 Filed 9-3-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP81-296]

Tennessee Gas Pipeline Co., a Division of Tenneco, Inc.; an Environmental Inspection of the Route of a Proposed Pipeline and Recommended Alternatives

August 31, 1982.

Notice is hereby given that from September 20 to September 24, 1982, members of the staff of the Federal Energy Regulatory Commission (FERC), accompanied by technicians representing Tennessee Gas Pipeline Company, will conduct an environmental inspection of the route of the proposed Tennessee/Boundary Looping Project and recommended alternatives. The inspection will be made by over-flight of the proposed and alternative routes in a helicopter provided by the company. Because of the restricted carrying capacity of the helicopter, parties wishing to join this inspection will need to arrange for their own transportation.

Further information can be obtained from James Daniel of the Environmental Evaluation Branch at (202) 357-9042.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-24435 Filed 9-3-82; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 6428-000]

Uncompahgre Valley Water Users Assoc. & Montrose Partners; Application for License (5 MW or Less)

September 2, 1982.

Take notice that Uncompahgre Valley Water Users Assoc. & Montrose Partners (Applicant) filed on June 14, 1982, an application for license (pursuant to the Federal Power Act, 16 U.S.C. 791(a)-825(r)) for construction and operation of a water power project to be known as the Shavano Falls Project No. 6428. The project would be located on the Montrose and Delta Canal in Montrose County, Colorado. Correspondence with the Applicant should be directed to: Mr. James Hokit, Uncompahgre Valley Water Users Assoc., 601 No. Park, Montrose, Colorado 81401.

Project Description—The proposed project would be constructed within the Bureau of Reclamation's right-of-way on the Montrose and Delta Canal, and would consist of: (1) Replacing an existing wooden diversion structure with an ogee overflow structure; (2) widening, from 8 to 16 feet, a 1,750-foot-long section of the existing C-P Lateral; (3) a proposed diversion structure on the

C–P Lateral; (4) a proposed 50-foot-long headrace; (5) a proposed 1,250-foot-long, 5-foot-diameter steel penstock; (6) a proposed powerhouse containing one turbine/generator unit operating under a head of 165 feet, with an installed capacity of 2,920 kW; (7) a proposed diversion structure just downstream of the proposed powerhouse; (8) a proposed 325–foot–long channel from the headrace to a point just above the falls; (9) a proposed 3.8-mile-long, 12.47-kV transmission line; and (10) appurtenant facilities. The average annual generation of 19,316 MWh would be sold to the Delta-Montrose Electrical Association.

Agency Comments—Federal, State, and local agencies that receive this notice through direct mailing from the Commission are requested to provide comments pursuant to the Federal Power Act, the Fish and Wildlife Coordination Act, the Endangered Species Act, the National Historic Preservation Act, the Historical and Archeological Preservation Act, the National Environmental Policy Act, Pub. L. No. 88–29, and other applicable statutes. No other formal requests for comments will be made.

Comments should be confined to substantive issues relevant to the issuance of a license. A copy of the application may be obtained directly from the Applicant. If an agency does not file comments within the time set below, it will be presumed to have no comments.

Competing Applications—Anyone desiring to file a competing application must submit to the Commission, on or before November 15, 1982, either the competing application itself (See 18 C.F.R. § 4.33(a) and (d) or a notice of intent (See 18 CFR 4.33(b) and (c)) to file a competing application. Submission of a timely notice of intent allows an interested person to file an acceptable competing application no later than the time specified in § 4.33(c) or § 4.101 et. seq. (1981).

Comments, Protest, or Petitions To Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 385.211 or 385.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before November 15, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82–24447 Filed 9–3–82; 8:45 am]

BILLING CODE 6717–01–M

[Project No. 6346–000]

Wawa, Inc.; Application for Exemption For Small Hydroelectric Power Project Under 5 MW Capacity

September 1, 1982.

Take notice that on May 19, 1982, Wawa, Incorporated (Applicant) filed an application, under Section 408 of the Energy Security Act of 1980 (Act) (16 U.S.C. 2705, and 2708 *as amended*), for exemption of a proposed hydroelectric project from licensing under Part I of the Federal Power Act. The proposed small hydroelectric Project No. 6346 would be located on Union Lake in Millville, Cumberland County, New Jersey. Correspondence with the Applicant should be directed to: Mr. Chris Amundsen, Technecon Analytic Research, Inc., 2400 Chestnut Street, Philadelphia, Pennsylvania 19103.

Project Description—The proposed project would consist of: (1) An existing 27-foot-high, 200-foot-long concrete spillway; (2) an existing 1,800-foot-long, 35-foot-high earth dam; (3) an existing 920-acre reservoir at elevation 27 feet M.S.L. with no usable storage capacity; (4) an existing canal intake structure; (5) an existing 1,400-foot-long power canal; (6) an existing headgate and trashrack structure; (7) an existing 9-foot-diameter, 400-foot-long steel penstock and surge tank; (8) an existing powerhouse containing a single 500-kW turbine-generator to be overhauled and put into service; (9) a tailrace channel; (10) a transmission line; (11) appurtenant facilities. Energy produced at the project would be sold to the local utility.

Purpose of Exemption—An exemption, if issued, gives the Exemptee priority of control, development, and operation of the project under the terms of the exemption from licensing, and protects the Exemptee from permit or license applicants that would seek to take or develop the project.

Agency Comments—The U.S. Fish and Wildlife Service, The National Marine Fisheries Service, and the New Jersey Division of Fish, Game and Wildlife are requested, for the purposes set forth in Section 408 of the Act, to submit within 60 days fromn the date of issuance of this notice appropriate terms and conditions to protect any fish and wildlife resources or to otherwise carry out the provisions of the Fish and Wildlife Coordination Act. General comments concerning the project and its resources are requested; however,

Competing Applications—Any qualified license applicant desiring to file a competing application must submit to the Commission, on or before October 25, 1982 either the competing license application that proposes to develop at least 7.5 megawatts in that project, or a notice of intent to file such a license application. Submission of a timely notice of intent allows an interested person to file the competing license application no later than 120 days from the date that comments, protests, etc. are due. Applications for preliminary permit will not be accepted.

A notice of intent must conform with the requirements of 18 CFR 4.33(b) and (c) (1980). A competing license application must conform with the requirements of 18 CFR 4.33(a) and (d) (1980).

Comments, Protests, or Petitions to Intervene—Anyone may submit comments, a protest, or a petition to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 385.211 or 285.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a petition to intervene in accordance with the Commission's rules may become a party to the proceeding. Any comments, protests, or petitions to intervene must be received on or before October 25, 1982.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS", "NOTICE OF INTENT TO FILE

COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", or "PETITION TO INTERVENE", as applicable, and the Project Number of this notice. Any of the above named documents must be filed by providing the original and those copies required by the Commission's regulations to: Kenneth F. Plumb, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426. An additional copy must be sent to: Fred E. Springer, Chief, Applications Branch, Division of Hydropower Licensing, Federal Energy Regulatory Commission, Room 208 RB at the above address. A copy of any notice of intent, competing application, or petition to intervene must also be served upon each representative of the Applicant specified in the first paragraph of this notice.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-24448 Filed 9-3-82; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. QF82-192-000]

Justin W. Whitney; Application for Commission Certification of Qualifying Status of a Small Power Production Facility

September 1, 1982.

On August 9, 1982, Justin W. Whitney, 6920 East 17th Street, Tulsa, Oklahoma 74112, filed with the Federal Energy Regulatory Commission (Commission) an application for certification of a facility as a qualifying small power production facility pursuant to § 292.207 of the Commission's rules.

The facility will be a 5 kilowatt wind installation located at the applicant's address. There are no other such facilities located at the same site. No electric utility, electric utility holding company or any combination thereof has any ownership interest in the facility.

Any person desiring to be heard or objecting to the granting of qualifying status should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Rule 211 or 214 of the Commission's Rules of Practice and Procedure. All such petitions or protests must be filed on or before October 7, 1982 and must be served on the applicant. 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 petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 82-24436 Filed 9-3-82; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[OPTS-51429; TSH-FRL-2203-1]

Certain Chemicals; Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substance Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in EPA statements of interim policy published in the **Federal Register** of May 15, 1979 (44 FR 28558) and November 7, 1980 (45 FR 74378). This notice announces receipt of fifty-three PMNs and provides a summary of each.

DATES:

Close of Review Period: PMN 82-584, 82-585, 82-586, 82-587 and 82-588, November 17, 1982.

PMN 82-589, November 20, 1982.

PMN 82-156, 82-157, 82-158, 82-159, 82-160, 82-161, 82-162, 82-163, 82-164, 82-165, 82-590, 82-591, 82-592, 82-593, 82-594, 82-595 and 82-596, November 21, 1982.

PMN 82-597, 82-598, 82-599, 82-600, 82-601, 82-602, 82-603, 82-604 and 82-605, November 22, 1982.

PMN 82-606, 82-607, 82-608, 82-609, 82-610, 82-611, 82-612, 82-613, 82-614, 82-615, 82-616, 82-617, 82-618, 82-619, 82-620, 82-621, 82-622, 82-623, 82-624, 82-625 and 82-626, November 23, 1982.

Written comments by: PMN 82-584, 82-585, 82-586, 82-587 and 82-588, October 18, 1982.

PMN 82-589, October 21, 1982.

PMN 82-156, 82-157, 82-158, 82-159, 82-160, 82-161, 82-162, 82-163, 82-164, 82-165, 82-590, 82-591, 82-592, 82-593, 82-594, 82-595 and 82-596, October 21, 1982.

PMN 82-597, 82-598, 82-599, 81-600, 82-601, 82-602, 82-603, 82-604 and 82-605, October 23, 1982.

PMN 82-606, 82-607, 82-608, 82-609, 82-610, 82-611, 82-612, 82-613, 82-614, 82-615, 82-616, 82-617, 82-618, 82-619, 82-620, 82-621, 82-622, 82-623, 82-624, 82-625 and 82-626, October 24, 1982.

ADDRESS: Written comments, identified by the document control number "[OPTS-51429]" and the specific PMN number should be sent to: Document Control Officer (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-409, 401 M St., SW., Washington, DC 20460 (202-382-3532).

FOR FURTHER INFORMATION CONTACT: David Dull, Acting Chief, Notice Review Branch, Chemical Control Division (TS-794), Office of Toxic Substances, Environmental Protection Agency, Rm. E-216, 401 M St., SW., Washington DC 20460 (202-382-3729).

SUPPLEMENTARY INFORMATION: The following notice contains information extracted from the non-confidential version of the submission provided by the manufacturer on the PMNs received by EPA. The complete non-confidential document is available in the Public Reading Room E-107.

PMN 82-156

Importer. Montedison USA, Inc.

Chemical. (S) Methyl-{trifluoromethyl-poly-(oxy-difluoro-methylene)-poly-[oxy-2(trifluoromethyl)-trifluoroethylene]oxy} difluoromethyl carboxylate.

Use/Import. (S) Industrial functional fluid and lubricant additive. Import range: 0-100 kg/yr.

Toxicity Data. No data submitted.

Exposure. None.

Environmental Release/Disposal. No release.

PMN 82-157

Importer. Montedison USA, Inc.

Chemical. (S) Trifluoromethyl-poly.(oxydifluoro-methylene)-poly-[oxy-2-(trifluoromethyl)-trifluoro-ethylene]oxy-difluoromethyl carbozylic acid.

Use/Import. (S) Industrial functional fluid and lubricant additive. Import range: 0-100 kg/yr.

Toxicity Data. No data submitted.

Exposure. None.

Environmental Release/Disposal. No release.

PMN 82-158

Importer. Montedison USA, Inc.

Chemical. (S) 2-{trifluoromethyl-poly-(oxy-difluoro-methylene)-poly-[oxy-2-(trifluoromethyl)-trifluoro-ethylene]oxy}2,2 difluoroethanol.

Use/Import. (S) Industrial functional fluid and lubricant additive. Import range: 0-100 kg/yr.

Toxicity Data. No data submitted.
Exposure. None.
Environmental Release/Disposal. No release.

PMN 82–159

Importer. Montedison USA, Inc.
Chemical. (S) *Aryl-[aryl*-oxycarbonyl difluoromethyl-poly-(oxydifluoromethylene)-poly-(oxydifluoromethylene)-poly-(oxytetrafluoro ethylene)oxy]-difluoromethyl carboxylate.
Use/Import. (S) Industrial functional fluid and lubricant additive. Import range: 0–100 kg/yr.
Toxicity Data. No data submitted.
Exposure. None.
Environmental Release/Disposal. No release.

PMN 82–160

Importer. Montedison USA, Inc.
Chemical. (S) Methyl[methyloxycarbonyl difluoromethyl-poly-(oxydifluoromethylene)-poly-(oxy tetrafluoro ethylene)oxy]-difluoromethyl carboxylate.
Use/Import. (S) Industrial functional fluid and lubricant additive. Import range: 0–100 kg/yr.
Toxicity Data. No data submitted.
Exposure. None.
Environmental Release/Disposal. No release.

PMN 82–161

Importer. Montedison USA, Inc.
Chemical. (S) 2-(cyano difluoromethyl-poly-(oxydifluoro-methylene)-poly-(oxytetrafluoroethylen)-oxy] 2,2-difluoroacetonitrile.
Use/Import. (S) Industrial functional fluid and lubricant additive. Import range: 0–100 kg/yr.
Toxicity Data. No data submitted.
Exposure. None.
Environmental Release/Disposal. No release.

PMN 82–162

Importer. Montedison USA, Inc.
Chemical. (S) 2-[2,2-drifluorohydroxyethyl-poly-(oxy-difluoromethylene)-poly-(oxy trifluoroethylene)oxy]-2,2-difluoroethanol.
Use/Import. (S) Industrial functional fluid and lubricant additive. Import range: 0–100 kg/yr.
Toxicity Data. No data submitted.
Exposure. None.
Environmental Release/Disposal. No release.

PMN 82–163

Importer. Montedison USA, Inc.
Chemical. (S) 2-[2,2-difluoroaminoethyl-poly-(oxydifluoro-methylene)-poly-(oxytetrafluoroethylene)oxy] 2,2-difluoro-ethylamine.
Use/Import. (S) Industrial functional fluid and lubricant additive. Import range: 0–100 kg/yr.
Toxicity Data. No data submitted.
Exposure. None.
Environmental Release/Disposal. No release.

PMN 82–164

Importer. Montedison USA, Inc.
Chemical. (S) 2-{1-[N-m-isocyanato-o-(p)-tolyl]carbamyl] 2,2-difluoroethyl-poly-(oxydifluoroethylene)-poly-tetrafluoro-ethylene)oxy}2,2-difluoroethyl-N-(m-isocyanato-o-(p)-tolyl)-carbamate.
Use-Import. (S) Industrial functional fluid and lubricant additive. Import range: 0–100 kg/yr.
Toxicity Data. No data submitted.
Exposure. None.
Environmental Release/Disposal. No release.

PMN 82–165

Importer. Montedison USA, Inc.
Chemical. (S)2[isocyanato-2,2-difluoroethyl-poly-(oxydifluoro-methylene)-poly-(oxytetrafluoroethylene)oxy]-2,2-difluoroethyl isocyanate.
Use/Import. (S) Industrial functional fluid and lubricant additive. Import range: 0–100 kg/yr.
Toxicity Data. No data submitted.
Exposure. None.
Environmental Release/Disposal. No release.

PMN 82–584

Manufacturer. Confidential.
Chemical. (S) Dimethyl ester of 4,4'-(hydroxymethylene)bis-1,2-benzenedicarboxylic acid.
Use/Production. Confidential. Prod. range: Confidential.
Toxicity Data. No data submitted.
Exposure. Minimal.
Environmental Release/Disposal. No release.

PMN 82–585

Manufacturer. Confidential.
Chemical. (S) Polymer of dimethyl ester of 4,4'-(hydroxymethylene) bis-1,2-benzenedicarboxylic acid with 4,4'-methylenedianiline.
Use/Production. Confidential. Prod. range: Confidential.
Toxicity Data. No data submitted.
Exposure. Minimal.
Environmental Release/Disposal. No release.

PMN 82–586

Manufacturer. Confidential.
Chemical. (G) Ethyl ester of tertiary butyl carbomonocyclic acid.
Use/Production. (G) Process intermediate. Prod. range: Confidential.
Toxicity Data. No data submitted.
Exposure. Manufacture and use: air, a total of 11 workers, up to 7 hrs/da, up to 50 da/yr.
Environmental Release/Disposal. Less than 10 kg/yr released to air 24 hrs/da, 50 da/yr. Disposal by publicly owned treatment works (POTW).

PMN 82–587

Manufacturer. Confidential.
Chemical. (G) Alkylbenzenesulfonic acid compound with dialkyl fatty amine.
Use/Production. (S) Pigment modifier. Prod. range: 1,300–9,000 kg/yr.
Toxicity Data. No data submitted.
Exposure. Manufacture: inhalation, a total of 6 workers, up to 8 hrs/da, up to 60 da/yr. No data submitted.
Environmental Release/Disposal. 10–100 kg/yr released to air and water. Disposal by POTW.

PMN 82–588

Manufacturer. Reilly Tar and Chemical Corporation.
Chemical. (S) 4–(1,1-dimethylethyl) pyridine.
Use/Production. (G) Intermediate. Prod. range: Confidential.
Toxicity Data. No data submitted.
Exposure. Confidential.
Environmental Release/Disposal. Release to water.

PMN 82–589

Manufacturer. Ashland Chemical Company.
Chemical. (G) Cresol novolac modified methacrylic epoxy ester.
Use/Production. (S) Reinforced thermosetting plastic. Prod. range: 250,000–1,000,000 lbs/yr.
Toxicity Data. No data submitted.
Exposure. Minimal.
Environmental Release/Disposal. Disposal by incineration and approved landfill.

PMN 82–590

Manufacturer. Confidential.
Chemical. (G) Fatty acid esters of monohydric alcohol.
Use/Production. (G) Open use. Prod. range: Confidential.
Toxicity Data. No data submitted.
Exposure. Manufacture: dermal, a total of 6 workers, up to 2 hrs/da, up to 28 da/yr.
Environmental Release/Disposal. Less than 10 kg/yr released to air and water with 100–1,000 kg/yr to land.

Disposal by biological treatment system and approved landfill.

PMN 82-591

Manufacturer. Confidential.
Chemical. (G) Fatty acid esters of monohydric alcohol.
Use/Production. (G) Open use. Prod. range: Confidential.
Toxicity Data. No data submitted.
Exposure. Manufacture: dermal, a total of 6 workers, up to 2 hrs/da, up to 28 da/yr.
Environmental Release/Disposal. Less than 10 kg/yr released to air and water with 100–1,000 kg/yr to land. Disposal by biological treatment system and approved landfill.

PMN 82-592

Manufacturer. E. I. du Pont de Nemours & Company, Inc.
Chemical. (G) Polyester polymer.
Use/Production. (S) Intermediate. Prod. range: Confidential.
Toxicity Data. No data submitted.
Exposure. Manufacture: dermal or inhalation, a total of 4 workers, 2 shift/da, 12 hrs/shift, 25 da/yr.
Environmental Release/Disposal. Minimal. Disposal by incineration.

PMN 82-593

Manufacturer. E. I. du Pont de Nemours & Company, Inc.
Chemical. (G) Polyester polymer.
Use/Production. (G) Intermediate. Prod. range: Confidential.
Toxicity Data. No data submitted.
Exposure. Manufacture: dermal or inhalation, a total of 4 workers, 2 shift/da, 12 hrs/shift, 25 da/yr.
Environmental Release/Disposal. Minimal. Disposal by incineration.

PMN 82-594

Manufacturer. E. I. du Pont de Nemours and Company, Inc.
Chemical. (G) Polymer of alkyl and substituted alkyl acrylates.
Use/Productian. Confidential. Prod. range: Confidential.
Toxicity Data. No data submitted.
Exposure. Manufacture: dermal or inhalation, a total of 2 workers, 2 shift/da, 12 hrs/shift, 12.5 da/yr.
Environmental Release/Disposal. Minimal. Disposal by incineration and approved landfill.

PMN 82-595

Manufacturer. Confidential.
Chemical. (G) Di(substitutedalkyl)dimethylammonium salt.
Use/Production. (G) Intermediate. Prod. range: Confidential.
Toxicity Data. Acute oral: 0.5–5 g/kg; Acute dermal: 5 g/kg; Skin irritation: Moderate irritant; Eye irritation: Substantial irritant.
Exposure. None.
Environmental Release/Disposal. Less than 10 kg/yr released to water. Disposal by biological treatment system and approved landfill.

PMN 82-596

Manufacturer. Confidential.
Chemical. (G) Di(substitutedalkyl)dimethylammonium salt.
Use/Production. (G) Intermediate. Prod. range: Confidential.
Toxicity Data. Acute oral: 0.5–5 g/kg; Acute dermal: 5 g/kg; Skin irritation: Moderate irritant; Eye irritation: Substantial irritant.
Exposure. None.
Environmental Release/Disposal. Less than 10 kg/yr released to water. Disposal by biological treatment system and approved landfill.

PMN 82-597

Manufacturer. Walsh Chemical Corporation.
Chemical. (S) Vinyl acetate-N-methylolacrylamide copolymer.
Use/Production. (S) Fiber coating. Prod. range: 150,000–1,000,000 kg/yr.
Toxicity Data. No data submitted.
Exposure. Processing and use: dermal, a total of 7 workers, up to 0.02 hr/da, up to 260 da/yr.
Environmental Release/Disposal. Less than 10 kg/yr released to air, water and land. Disposal by biological treatment system.

PMN 82-598

Manufacturer. Walsh Chemical Corporation.
Chemical. (S) Ethyl acrylate homopolymer.
Use/Production. (S) Latex for compounding for cloth coating. Prod. range: 25,000–300,000 kg/yr.
Toxicity Data. No data submitted.
Exposure. Processing and use: dermal, a total of 17 workers, up to 0.02 hr/da, up to 260 da/yr.
Environmental Release/Disposal. Less than 10 kg/yr released to air, water and land. Disposal by biological treatment system.

PMN 82-599

Manufacturer. Walsh Chemical Corporation.
Chemical. (S) Vinyl acetate-ethyl acrylate-N methylol acrylamide polymer.
Use/Production. (S) Binder for insulation and latex compound for cloth coating. Prod. range: 50,000–100,000 kg/yr.
Toxicity Data. No data submitted.
Exposure. processing and use: dermal, a total of 17 workers, up to 0.02 hr/da, up to 260 da/yr.
Environmental Release/Disposal. Less than 10 kg/yr released to air, water and land. Disposal by biological treatment system.

PMN 82-600

Manufacturer. Walsh Chemical Corporation.
Chemical. (S) Butyl acrylate-vinyl acetate copolymer.
Use/Production. (S) Latex for compound used to laminate. Prod. range: 50,000–10,000 kg/yr.
Toxicity data. No data submitted.
Exposure. Processing and use: dermal, a total of 17 workers, up to 0.02 hr/da, up to 260 da/yr.
Environmental Release/Disposal. Less than 10 kg/yr released to air, water and land. disposal by biological treatment system.

PMN 82-601

Manfacturer. Walsh Chemical Corporation.
Chemical. (S) Ethyl acrylate-methyl methacrylate copolymer.
Use/POroductio. (S) Latex for compound used for cloth back. Prod. range: 12,000–100,000 kg/yr.
Toxicity Data. No data submitted.
Exposure. Processing and use: dermal, a total of 17 workers, up to 0.02 hr/da, up to 260 da/yr.
Environmental Release/Disposal. Less than 10 kg/yr released to air, water and land. disposal by biological treatment system.

PMN 82-602

Manufacturer. Confidential.
Chemical. (G) Mixed glycol oligoesters of mixed dicarboxylic acids.
Use/Production. (S) Industrial component for insulating structural form. Prod. range: 50,000–150,000 kg/yr.
Toxicity Data. No data submitted.
Exposure. Manufacture, processing and use: dermal, a total of 7 workers, up to 1 hr/da, up to 200 da/yr.
Environmental Release/Disposal. Less than 10 kg/yr relased to air 24 hrs/da, 200 da/yr. Disposal by incineration.

PMN 82-603

Manufacturer. Confidential.
Chemical. (G) Mixed glycol oligoesters of aromatic dicarboxylic acid.
Use/Production. (S) Industrial component for insulating structural form. Prod. range: 20,000–150,000 kg/yr.
Toxicity Data. No data submitted.

Exposure. Manufacture, processing and use: dermal, a total of 7 workers, up to 1 hr/da, up to 200 da/yr.

Environmental Release/Disposal. Less than 10 kg/yr released to air 24 hrs/da, 200 da/yr. Disposal by incineration.

PMN 82-604

Manufacturer. Confidential.

Chemical. (G) Monouriedo silane ester.

Use/Production. (S) Additive for strength improvement of resin/mineral composities. Prod. range: Confidential.

Toxicity Data. Acute oral: Males—4.3 ml/kg, females—3.08 ml/kg; Acute dermal: Males and females—16 ml/kg; Eye irritation: Moderate irritant; Inhalation: Substantially saturated vapors killed 0 of 5 males and 2 of 5 females after 6 hrs. exposure; Ames Test: Negative; COD: 1.50 mg, Day 5–48; Day 10–60; Day 15–65; Day 20–91.

Exposure. Manufacture: dermal and inhalation, a total of 6 workers, up to 3 hrs/da, up to 15 da/yr.

Environmental Release/Disposal. Disposal by landfill.

PMN 82-605

Importer. Confidential.

Chemical. (G) Thiadiazole derivative.

Use/Import. Confidential. Import range: Confidential.

Toxicity Data. No data submitted.

Exposure. Minimal.

Environmental Release/Disposal. No data sumbitted.

PMN 82-606

Importer. Montedison USA, Inc.

Chemical. (S) Ethyl–{trifluoromethyl-poly-(oxydifluoromethylene)-poly-[oxy-2-(trifluoromethyl-trifluoroethylene] oxy}difluoromethyl carboxylate.

Use/Import. (S) Industrial functional fluid and lubricant additive. Import range: 100 kg/yr.

Toxicity Data. No data submitted.

Exposure. None.

Environmental Release/Disposal. No release.

PMN 82-607

Importer. Montedison USA, Inc.

Chemical. (S) Isopropyl-[trifluoromethyl-poly-(oxydifluoromethylene)-poly-[oxy-2-(trifluoromethyl)-trifluoroethylene]oxy]difluoromethyl carboxylate.

Use/Import. (S) Industrial functional fluid and lubricant additive. Import range: 100 kg/yr.

Toxicity Data. No data submitted.

Exposure. None.

Environmental Release/Disposal. No release.

PMN 82-608

Importer. Montedison USA, Inc.

Chemical. (S) Ethyl[ethyl oxycarbonyl difluoromethyl-poly-(oxydifluoromethylene)-poly-(oxytetrafluoroethylene)oxy]difluoromethyl carboxylate.

Use/Import. (S) Industrial functional fluid. Import range: 200–800 kg/yr.

Toxicity Data. No data submitted.

Exposure. None.

Environmental Release/Disposal. No release.

PMN 82-609

Importer. Montedison USA, Inc.

Chemical. (S) Isopropyl[methyl oxycarbonyl difluoromethyl-poly-(oxydifluoromethylene)-poly-(oxytetrafluoroethylene)oxy]difluoromethyl carboxylate.

Use/Import. (S) Industrial functional fluid. Import range: 200–800 kg/yr.

Toxicity Data. No data submitted.

Exposure. None.

Environmental Release/Disposal. No release.

PMN 82-610

Importer. Montedison USA, Inc.

Chemical. (S) 2-[2,2-difluorohydroxyethyl-poly-(oxydifluoromethylene)-poly-(oxytrifluoroethylene)oxy]-2,2-difluoroethanol.

Use/Import. (S) Industrial functional fluid. Import range: 100 kg/yr.

Toxicity Data. No data submitted.

Exposure. None.

Environmental Release/Disposal. No release.

PMN 82-611

Importer. Montedison USA, Inc.

Chemical. (S) 2-[2,2-difluorohydroxyethyl-poly-(oxydifluoromethylene)-poly-(oxytrifluoroethylene)oxy]-2,2-difluoroethanol.

Use/Import. (S) Industrial functional fluid. Import range: 100 kg/yr.

Toxicity Data. No data submitted.

Exposure. None.

Environmental Release/Disposal. No release.

PMN 82-612

Manufacturer. The Minnesota Mining and Manufacturing Company.

Chemical. Further clarification needed before information can be released to the public files.

Use/Production. (S) Testing media for electronic components and devices, vapor phase soldering and dielectric cooling for heat transfer applications. Prod. range: Further clarification needed before information can be released to the public files.

Toxicity Data. Further clarification needed before information can be released to the public files.

Exposure. Manufacture and use: dermal and inhalation, a total of 5,100 workers, up to 8 hrs/da, up to 50 da/yr.

Environmental Release/Disposal. Disposal by wastewater treatment system, incineration and landfill.

PMN 82-613

Manufacturer. The Minnesota Mining and Manufacturing Company.

Chemical. Further clarification needed before information can be released to the public files.

Use/Production. (S) Testing media for electronic components and devices, vapor phase soldering and dielectric cooling for heat transfer applications. Prod. range: Further clarification needed before information can be released to the public files.

Toxicity Data. Further clarification needed before information can be released to the public files.

Exposure. Manufacture and use: dermal and inhalation, a total of 5,100 workers, up to 8 hrs/da, up to 50 da/yr.

Environmental Release/Disposal. Disposal by wastewater treatment system, incineration and landfill.

PMN 82-614

Manufactures. The Minnesota Mining and Manufacturing Company.

Chemical. Further clarification needed before information can be released to the public files.

Use/Production. (S) Testing media for electronic components and devices, vapor phase soldering and dielectric cooling for heat transfer applications. Prod. range: Further clarification needed before information can be released to the public files.

Toxicity Data. Further clarification needed before information can be released to the public files.

Exposure. Manufacture and use: dermal and inhalation, a total of 5,100 workers, up to 8 hrs/da, up to 50 da/yr.

Environmental Release/Disposal. Disposal by wastewater treatment system, incineration and landfill.

PMN 82-615

Manufacturer. The Minnesota Mining and Manufacturing Company.

Chemical. Further clarification needed before information can be released to the public files.

Use/Production. (S) Testing media for electronic components and devices, vapor phase soldering and dielectric cooling for heat transfer applications. Prod. range: Further clarification needed

before information can be released to the public files.

Toxicity Data. Further clarification needed before information can be released to the public files.

Exposure. Manufacture and use: dermal and inhalation, a total of 5,100 workers, up to 8 hrs/da, up to 50 da/yr.

Environmental Release/Disposal. Disposal by wastewater treatment system, incineration and landfill.

PMN 82-616

Manufacturer. The Minnesota Mining and Manufacturing Company.

Chemical. Further clarification needed before information can be released to the public files.

Use/Production. (S) Testing media for electronic components and devices, vapor phase soldering and dielectric cooling for heat transfer applications. Prod. range: Further clarification needed before information can be released to the public files.

Toxicity Data. Further clarification needed before information can be released to the public files.

Exposure. Manufacture and use: dermal and inhalation, a total of 5,100 workers, up to 8 hrs/da, up to 50 da/yr.

Environmental Release/Disposal. Disposal by wastewater treatment system, incineration and landfill.

PMN 82-617

Manufacturer. The Minnesota Mining and Manufacturing Company.

Chemical. Further clarification needed before information can be released to the public files.

Use/Production. (S) Testing media for electronic components and devices, vapor phase soldering and dielectic cooling for heat transfer applications. Prod. range: Further clarification needed before information can be released to the public files.

Toxicity Data. Further clarification needed before information can be released to the public files.

Exposure. Manufacture and use: dermal and inhalation, a total of 5,100 workers, up to 8 hrs/da, up to 50 da/yr.

Environmental Release/Disposal. Disposal by wastewater treatment system, incineration and landfill.

PMN 82-618

Manufacturer. The Minnesota Mining and Manufacturing Company.

Chemical. Further clarification needed before information can be released to the public files.

Use/Production. (S) Testing media for electronic components and devices, vapor phase soldering and dielectric cooling for heat transfer applications. Prod. range: Further clarification needed before information can be released to the public files.

Toxicity Data. Further clarification needed before information can be released to the public files.

Exposure. Manufacture and use: dermal and inhalation, a total of 5,100 workers, up to 8 hrs/da, up to 50 da/yr.

Environmental Release/Disposal. Disposal by wastewater treatment system, incineration and landfill.

PMN 82-619

Manufacturer. The Minnesota Mining and Manufacturing Company.

Chemical. Further clarification needed before information can be released to the public files.

Use/Production. (S) Testing media for electronic components and devices, vapor phase soldering and dielectric cooling for heat transfer applications. Prod. range: Further clarification needed before information can be released to the public files.

Toxicity Data. Further clarification needed before information can be released to the public files.

Exposure. Manufacture and use: dermal and inhalation, a total of 5,100 workers, up to 8 hrs/da, up to 50 da/yr.

Environmental Release/Disposal. Disposal by wastewater treatment system, incineration and landfill.

PMN 82-620

Manufacturer. The Minnesota Mining and Manufacturing Company.

Chemical. Further clarification needed before information can be released to the public files.

Use/Production. (S) Testing media for electronic components and devices, vapor phase soldering and dielectric cooling for heat transfer applications. Prod. range: Further clarification needed before information can be released to the public files.

Toxicity Data. Further clarification needed for information can be released to the public files.

Exposure. Manufacture and use: dermal and inhalation, a total of 5,100 workers, up to 8 hrs/da, up to 50 da/yr.

Environmental Release/Disposal. Disposal by wastewater treatment system, incineration and landfill.

PMN 82-621

Manufacturer. The Minnesota Mining and Manufacturing Company.

Chemical. Further clarification needed before information can be released to the public files.

Use/Production. (S) Testing media for electronic components and devices, vapor phase soldering and dielectric cooling for heat transfer applications. Prod. range: Further clarification needed before information can be released to the public files.

Toxicity Data. Further clarification needed for information can be released to the public files.

Exposure. Manufacture and use: dermal and inhalation, a total of 5,100 workers, up to 8 hrs/da, up to 50 da/yr.

Environmental Release/Disposal. Disposal by wastewater treatment system, incineration and landfill.

PMN 82-622

Manufacturer. The Minnesota Mining and Manufacturing Company.

Chemical. Further clarification needed before information can be released to the public files.

Use/Production. (S) Testing media for electronic components and devices, vapor phase soldering and dielectric cooling for heat transfer applications. Prod. range: Further clarification needed before information can be released to the public files.

Toxicity Data. Further clarification needed before information can be released to the public files.

Exposure. Manufacture and use: dermal and inhalation, a total of 5,100 workers, up to 8 hrs/da, up to 50 da/yr.

Environmental Release/Disposal. Disposal by wastewater treatment system, incineration and landfill.

PMN 82-623

Manufacturer. The Minnesota Mining and Manufacturing Company.

Chemical. Further clarification needed before information can be released to the public files.

Use/Production. (S) Testing media for electronic components and devices, vapor phase soldering and dielectric cooling for heat transfer applications. Prod. range: Further clarification needed before information can be released to the public files.

Toxicity Data. Further clarification needed for information can be released to the public files.

Exposure. Manufacture and use: dermal and inhalation, a total of 5,100 workers, up to 8 hrs/da, up to 50 da/yr.

Environmental Release/Disposal. Disposal by wastewater treatment system, incineration and landfill.

PMN 82-624

Manufacturer. The Minnesota Mining and Manufacturing Company.

Chemical. Further clarification needed before information can be released to the public files.

Use/Production. (S) Testing media for electronic components and devices, vapor phase soldering and dielectric cooling for heat transfer applications.

Prod. range: Further clarification needed before information can be released to the public files.

Toxicity Data. Further clarification needed before information can be released to the public files.

Exposure. Manufacture and use: dermal and inhalation, a total of 5,100 workers, up to 8 hrs/da, up to 50 da/yr.

Environmental Release/Disposal. Disposal by wastewater treatment system, incineration and landfill.

PMN 82-625

Manufacturer. The Minnesota Mining and Manufacturing Company.

Chemical. Further clarification needed before information can be released to the public files.

Use/Production. (S) Testing media for electronic components and devices, vapor phase soldering and dielectric cooling for heat transfer applications. Prod. range: Further clarification needed before information can be released to the public files.

Toxicity Data. Further clarification needed before information can be released to the public files.

Exposure. Manufacture and use: dermal and inhalation, a total of 5,100 workers, up to 8 hrs/da, up to 50 da/yr.

Environmental Release/Disposal. Disposal by wastewater treatment system, incineration and landfill.

PMN 82-626

Manufacturer. The Minnesota Mining and Manufacturing Company.

Chemical. Further clarification needed before information can be released to the public files.

Use/Production. (S) Testing media for electronic components and devices, vapor phase soldering and dielectric cooling for heat transfer applications. Prod. range: Further clarification needed before the information can be released to the public files.

Toxicity Data. Further clarification needed before information can be released to the public files.

Exposure. Manufacture and use: dermal and inhalation, a total of 5,100 workers, up to 8 hrs/da, up to 50 da/yr.

Environmental Release/Disposal. Disposal by wastewater treatment system, incineration and landfill.

Dated: August 30, 1982.

Woodson W. Bercaw,

Acting Director, Management Support Division.

[FR Doc. 82-24484 Filed 9-3-82; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION

[General Docket 82-334]

Establishment of a Spectrum Utilization Policy for the Fixed and Mobile Services' Use of Certain Bands Between 17.7 and 40 GHz

Order Extending Time To File Comments

Adopted: August 26, 1982.

Released: August 31, 1982.

1. A joint request from the General Electric Company, Microwave Imaging Products Section; M/A-COM Incorporated; and Rockwell International Corporation has been filed requesting a twenty-seven (27) day extension of time to file comments in the above captioned *Notice of Inquiry* (FCC 82-286, adopted 23 June 1982) (Public Notice—7-23-82; 47 FR 31959)). The parties filing the request state that additional time is required because it is necessary to coordinate a variety of technical materials within the petitioning companies, and this cannot be completed in the allotted time due to vacations and other scheduling difficulties during the summer months. The petitioners, manufacturers of microwave equipment, also state that the additional time requested will assure that the most comprehensive filings on technical specifications can be made to the Commission.

2. Because the outcome of this proceeding is likely to form the basis for a revised spectrum utilization policy for the fixed and mobile services' use of spectrum between 17.7 and 40.0 GHz, it is desirable to have as extensive and comprehensive as possible a record to draw upon; the Commission feels that it would be in the public interest to grant an extension of time to file comments. Therefore, an extension of time from September 7, 1982 to October 4, 1982 for filing comments and from October 7, 1982 to November 7, 1982 for filing reply comments is hereby granted pursuant to § 0.241(d) of the Commission's Rules.

Robert Powers,

Deputy Chief Scientist.

[FR Doc. 82-24483 Filed 9-3-82; 8:45 am]

BILLING CODE 6712-01-M

Public Information Collection Requirements Submitted to Office of Management and Budget for Review

August 31, 1982.

On August 27, 1982, the Federal Communications Commission submitted the following information collection requirements to OMB for review and clearance under the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Copies of these submissions are available from Richard D. Goodfriend, Agency Clearance Officer, (202) 632-7513. Comments should be sent to Edward H. Clarke, Office of Management and Budget, OIRA, Room 3201 NEOB, 726 Jackson Place, NW., Washington, D.C. 20503.

Title: Application for Radio Station Authorization in the Private Radio Services (Industrial, Land Transportation, Public Safety, Radio Location, Special Emergency and General Mobile).
Form No.: FCC 574 (Formerly FCC Form 400).
Action: New (Replacement).
Respondents: Individuals, associations, partnerships, corporations and local governmental entities eligible for a radio station authorization in the Private Land Mobile Radio Services.
Estimated Annual Burden: 132,000 Responses; 726,000 Hours.

Title: Supplemental Information for Trunked and Conventional Systems (806-821 MHz and 851-866 MHz Bands).
Form No.: FCC 574-A (Formerly FCC Form 400-S).
Action: New (Replacement).
Respondents: Individuals, associations, partnerships, corporations and local governmental entities eligible for a radio station authorization in the Private Land Mobile Radio Services.
Estimated Annual Burden: 16,500 Responses; 2,750 Hours.

Title: Private Fixed, Mobile, and Radio Location Services Supplementary Information to FCC Form 574.
Form No.: FCC 574-B.
Action: New.
Respondents: Individuals, associations, partnerships, corporations and local governmental entities eligible for a radio station authorization in the Private Land Mobile Radio Services.
Estimated Annual Burden: 400 Responses; 3,200 Hours.

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc. 82-24530 Filed 9-3-82; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL RESERVE SYSTEM

MB Sub, Inc.; Formation of Bank Holding Co.

MB Sub, Inc., St. Louis, Missouri, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to

become a bank holding company by acquiring 100 percent of the voting shares of First Missouri Banks, Inc., Manchester, Missouri, a registered bank holding company. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

MB Sub, Inc., St. Louis, Missouri, has also applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)), and § 225.4(b)(2) of the Board's Regulation Y (12 CFR 225.4(b)(2)), for permission to indirectly acquire voting shares of First Missouri Insurance Group, Inc., Manchester, Missouri; First Properties, Inc., Manchester, Missouri; and St. Louis Computer Center, Inc., Creve Coeur, Missouri, subsidiaries of First Missouri Banks, Inc., Manchester, Missouri.

Applicant states that the proposed subsidiaries would engage in the activities of underwriting credit insurance, data processing and holding real estate. These activities would be performed from offices of Applicant's subsidiary in Manchester, Missouri (with respect to underwriting credit insurance and holding real estate); and St. Louis, Missouri (with respect to data processing), and the geographic areas to be served are Phoenix, Arizona (with respect to underwriting credit insurance); Manchester, Missouri (with respect to holding real estate); and Creve Coeur, Missouri (with respect to data processing). Such activities have been specified by the Board in § 225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of § 225.4(b).

Interested persons may express their views on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of St. Louis.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than September 30, 1982.

Board of Governors of the Federal Reserve System, August 31, 1982.

Dolores S. Smith,

Assistant Secretary of the Board.

[FR Doc. 82-24480 Filed 9-3-82; 8:45 am]

BILLING CODE 6210-01-M

Acquisition of Bank Shares by a Bank Holding Company

The company listed in this notice has applied for the Board's approval under section 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to acquire voting shares or assets of a bank. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors, or at the Federal Reserve Bank indicated. With respect to the application, interested persons may express their views in writing to the address indicated. Any comment on the application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

A. Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551:

1. *Manufactures Bancorp, Inc.*, St. Louis, Missouri; to acquire 100 percent of the voting shares or assets of First Missouri Bank, Inc., Manchester, Missouri. This application may be inspected at the Federal Reserve Bank of St. Louis. Comments on this application must be received not later than September 30, 1982.

Board of Governors of the Federal Reserve System, August 31, 1982.

Dolores S. Smith,

Assistant Secretary of the Board.

[FR Doc. 82-24481 Filed 9-3-82; 8:45 am]

BILLING CODE 6210-01-M

Bank Holding Companies; Proposed de Novo Nonbank Activities

The bank holding companies listed in this notice have applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.4(b)(1) of the Board's Regulation Y (12 CFR 225.4(b)(1)), for permission to engage *de novo* (or continue to engage in an activity earlier commenced *de novo*), directly or indirectly, solely in the activities indicated, which have been determined by the Board of Governors to be closely related to banking.

With respect to each application, interested persons may express their views on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interest, or unsound banking practices." Any comment on an application that requests a hearing must include a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of that proposal.

Each application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank indicated for that application. Comments and requests for hearings should identify clearly the specific application to which they relate, and should be submitted in writing and received by the appropriate Federal Reserve Bank not later than the date indicated for each application.

A. Federal Reserve Bank of New York (A. Marshall Puckett, Vice President) 33 Liberty Street, New York, New York 10045:

1. *Citicorp*, New York, New York (extending credit, servicing related insurance activities; Washington): To expand the activities and service areas of four existing offices of Citicorp Washington Financial Center, Inc. to include the proposed *de novo* activities of: the making, acquiring and servicing, for its own account and for the account of others, of extensions of credit to individuals secured by liens on residential or nonresidential real estate; and the sale of mortgage life and mortgage disability insurance directly related to extensions of mortgage loans. The proposed service area for each of the offices shall be the entire state of Washington for the aforementioned proposed activities and for the following activities which have been previously approved for those offices of Citicorp Washington Financial Center, Inc.: the making or acquiring of loans and other extensions of credit, secured or unsecured, for consumer and other purposes; the extension of loans to

dealers for the financing of inventory (floor planning) and working capital purposes; the purchasing and servicing for its own account of sales finance contracts; the sale of credit related life and accident and health or decreasing or level (in the case of single payment loans) term life insurance by licensed agents or brokers, as required; the sale of credit related property and casualty insurance protecting real and personal property subject to a security agreement with Citicorp Washington Financial Center, Inc. and to the extent permissible under applicable state insurance laws and regulations; and the servicing, for any person, of loans and other extensions of credit. The aforementioned activities will be conducted from offices in the following four locations: Spokane, Seattle, Bellevue, and Tacoma, Washington. Comments on this application must be received not later than September 29, 1982.

B. **Federal Reserve Bank of San Francisco** (Harry W. Green, Vice President) 400 Sansome Street, San Francisco, California 94120:

1. *Bancorp Hawaii,* Honolulu, Hawaii (insurance activities; Territory of Saipan): To engage, through its subsidiary, Bancorp Life Insurance Company of Hawaii, Inc., in underwriting as a reinsurer the credit life insurance sold by Bank of Hawaii, a wholly-owned subsidiary of Bancorp Hawaii, Inc., in conjunction with its short term consumer lending activities. These activities would be conducted from an office in Phoenix, Arizona, serving the Bank's retail customers in the Territory of Saipan. Comments on this application must be received not later than September 29, 1982.

Board of Governors of the Federal Reserve System, August 30, 1982.

Dolores S. Smith,

Assistant Secretary of the Board.

[FR Doc. 82-24478 Filed 9-3-82; 8:45 am]

BILLING CODE 6210-01-M

Formation of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become bank holding companies by acquiring voting shares and/or assets of a bank. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application may be inspected at the offices of the Board of Governors, or at the Federal Reserve Bank indicated for that application. With respect to each application, interested persons may express their views in writing to the address indicated for that application. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

A. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Liberty Bancorp of Owasso, Inc.,* Owasso, Oklahoma; to become a bank holding company by acquiring 80 percent of the voting shares of Liberty Bank of Owasso, Owasso, Oklahoma. Comments on this application must be received not later than September 29, 1982.

B. **Federal Reserve Bank of Dallas** (Anthony J. Montelaro, Assistant Vice President) 400 South Akard Street, Dallas, Texas 75222:

2. *First Graham Bancorp, Inc.,* Graham, Texas; to become a bank holding company by acquiring 100 percent of the voting shares of First National Bank in Graham, Graham, Texas. Comments on this application must be received not later than September 29, 1982.

Board of Governors of the Federal Reserve System, August 30, 1982.

Dolores S. Smith,

Assistant Secretary of the Board.

[FR Doc. 82-24479 Filed 9-3-82; 8:45 am]

BILLING CODE 6210-01-M

FEDERAL TRADE COMMISSION

Early Termination of the Waiting Period of the Premerger Notification Rules; Impresit-Girola-Lodigiani-Impregilo S.p.A.

AGENCY: Federal Trade Commission.

ACTION: Granting of request for early termination of the waiting period of the premerger notification rules.

SUMMARY: Impresit-Girola-Lodigiani-Impregilo S.p.A. is granted early termination of the waiting period provided by law and the premerger notification rules with respect to the proposed acquisition of all voting securities of S. A. Healy Company. The grant was made by the Federal Trade Commission and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice in response to a request for early termination submitted by Impresit-Girola-Lodigiani-Impregilo S.p.A. Neither agency intends to take any action with respect to this acquisition during the waiting period.

EFFECTIVE DATE: August 9, 1982.

FOR FURTHER INFORMATION CONTACT: Patricia A. Foster, Compliance Specialist, Premerger Notification Office, Bureau of Competition, Room 311, Federal Trade Commission, Washington, D.C. 20580, (202) 523-3894.

SUPPLEMENTARY INFORMATION: Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Commission and Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register.**

By direction of the Commission.

James A. Tobin,

Acting Secretary.

[FR Doc. 82-24473 Filed 9-3-82; 8:45 am]

BILLING CODE 6750-01-M

Early Termination of the Waiting Period of the Premerger Notification Rules; Hudson Bay Mining & Smelting Co., Limited

AGENCY: Federal Trade Commission.

ACTION: Granting of request for early termination of the waiting period of the premerger notification rules.

SUMMARY: Hudson Bay Mining & Smelting Co., Limited is granted early termination of the waiting period provided by law and the premerger notification rules with respect to the proposed acquisition of all voting securities of Plateau Petroleum, Inc. The grant was made by the Federal Trade Commission and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice in response to a request for early termination submitted by Adobe Oil & Gas Corporation. Neither agency intends to take any action with respect to this acquisition during the waiting period.

EFFECTIVE DATE: August 13, 1982.

FOR FURTHER INFORMATION CONTACT: Patricia A. Foster, Compliance Specialist, Premerger Notification Office, Bureau of Competition, Room 311, Federal Trade Commission, Washington, D.C. 20580, (202) 523-3894.

SUPPLEMENTARY INFORMATION: Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisition to give the Commission and Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the Federal Register.

By direction of the Commission.

James A. Tobin,

Acting Secretary.

[FR Doc. 82-24474 Filed 9-3-82; 8:45 am]

BILLING CODE 6750-01-M

Early Termination of the Waiting Period of the Premerger Notification Rules: Regie Nationale des Usines Renault

AGENCY: Federal Trade Commission.

ACTION: Granting of request for early termination of the waiting period of the premerger notification rules.

SUMMARY: Regie Nationale des Usines Renault is granted early termination of the waiting period provided by law and the premerger notification rules with respect to the proposed acquisition of certain voting securities of Mack Truck, Inc. The grant was made by the Federal Commission and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice in response to a request for early termination submitted by both parties. Neither agency intends to take any action with respect to this acquisition during the waiting period.

EFFECTIVE DATE: August 11, 1982.

FOR FURTHER INFORMATION CONTACT: Patricia A. Foster, Compliance Specialist, Premerger Notification Office, Bureau of Competition, Room 311, Federal Trade Commission, Washington, D.C. 20580, (202) 523-3894.

SUPPLEMENTARY INFORMATION: Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers of acquisitions to give the Commission and Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the Federal Register.

By direction of the Commission.

James A. Tobin,

Acting Secretary.

[FR Doc. 82-24475 Filed 9-3-82; 8:45 am]

BILLING CODE 6750-01-M

GENERAL SERVICES ADMINISTRATION

Report of Utilization of Federal Licenses

AGENCY: General Services Administration.

ACTION: Notice of new information collection.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. Chapter 35), the General Services Administration plans to request the Office of Management and Budget to review and approve a new information collection requirement for the collection of data.

DATES: Comments on the information collection must be submitted on or before September 30, 1982.

ADDRESSES: Send comments to Franklin S. Reeder, GSA Desk Officer, Room 3235, NEOB, Washington, D.C. 20503, and to Anthony Artigliere, GSA Clearance Officer, General Services Administration (ORAI), Washington, D.C. 20405.

FOR FURTHER INFORMATION CONTACT: James Flowers, Directives and Reports Management Branch (202-566-1164).

SUPPLEMENTARY INFORMATION: a. *Purpose.* The requirement is necessary to provide the Federal Government data in order to determine whether compliance of obligations is being made by organizations and/or individuals which are granted Federal licenses.

b. *Obtaining copies of proposal.* A copy of the information collection proposal may be obtained from the Directives and Reports Management Branch (ORAI), Room 3011, GS Building, Washington, D.C. 20405, telephone 566-1164.

Clarence A. Lee, Jr.,

Director of Administrative Services.

[FR Doc. 82-24472 Filed 9-3-82; 8:45 am]

BILLING CODE 6820-34-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 80N-0370]

Prescription Drugs; Revocation of Final Guideline Patient Package Inserts and Withdrawal of Draft Guideline Patient Package Inserts

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is revoking the final guideline patient package inserts for 5 classes of drugs and is withdrawing the draft guideline patient package inserts for 5 other classes of drugs. Elsewhere in this issue of the Federal Register, the agency is revoking the regulations that established general requirements for the preparation and distribution of patient package inserts for prescription drug products. Those regulations had established a pilot program that would have been applied to 10 classes of drugs for 3 years. This notice revokes the draft and final guidelines which described how manufacturers might comply with the regulations with respect to affected classes of drug.

EFFECTIVE DATE: September 7, 1982.

FOR FURTHER INFORMATION CONTACT: Eileen Hodkinson, National Center for Drugs and Biologics (HFD-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6490.

SUPPLEMENTARY INFORMATION: In the Federal Register, of September 12, 1980 (45 FR 60754), FDA adopted final regulations that established requirements and procedures for the preparation and distribution of patient package inserts for prescription drugs for human use (21 CFR Part 203). The final rule stated that the agency would limit the initial implementation of the patient package insert program to 10 drugs or drug classes for 3 years. Although the regulations were effective October 14, 1980, they did not apply to particular drugs or drug classes until 180 days after publication of a separate notice in the Federal Register specifically apply the regulations to a drug or drug class. The regulations also provided that FDA may publish guidelines for patient package inserts for drugs or drug classes. Once these guidelines were final, use of them would constitute compliance with the regulations governing the content of the inserts, but strict adherence to the guidelines was not required.

In a notice published in the **Federal Register** of September 12, 1980 (45 FR 60785), the agency issued for comment 10 draft guideline patient package inserts for the following drugs or drug classes to which it intended to apply the patient package insert regulations initially: Ampicillins, benzodiazepines, cimetidine, clofibrate, digoxin, methoxsalen, propoxyphene, phenytoin, thiazides, and warfarin. The agency published final guidelines for cimetidine, clofibrate, and propoxyphene and announced the applicability of the regulations to these drugs effective May 25, 1981 (45 FR 78516; November 25, 1980). FDA then published final guidelines for ampicillin and phenytoin and announced the applicability of the regulations to these additional drugs effective July 1, 1981 (46 FR 160; January 2, 1981). FDA also substituted another drug for one of the 10 original drugs in the implementation program (Benedectin for warfarin) and published a draft guideline for comment in the **Federal Register** of December 5, 1980 (45 FR 80740).

In the **Federal Register** of April 28, 1981 (45 FR 23739 and 23815), the agency stayed the effective dates of the 5 final guideline patient package inserts and the effective dates of the amendments to the patient package insert regulations which listed these drugs as ones that must be dispensed with patient package inserts. The agency took this action to permit further review of questions that continued to be raised about the program and to review the rulemaking with respect to Executive Order 12291 (46 FR 13193; February 19, 1981).

Elsewhere in this issue of the **Federal Register**, the agency is revoking the regulations that established the patient package insert requirements. A full discussion of the reasons for the revocation of the regulations and, consequently, these guidelines is found in that notice. By this notice, the agency is revoking, for the same reasons, the 5 final guideline patient package inserts and is withdrawing the 5 remaining draft guideline patient package inserts that were issued in conjunction with those regulations.

This notice is issued under § 10.90(b)(5) of FDA's administrative practices and procedures regulations (21 CFR 10.90(b)(5)), which authorizes the agency to revoke a guideline and to publish a notice of its revocation. Under section 10.90(b)(7) interested persons may submit written comments on these guidelines, which comments will be considered in determining whether reinstitution of any guideline is warranted.

Notices issuing draft guideline patient package inserts published in the **Federal Register** of September 12, 1980 (45 FR 60785) for benzodiazepines, digoxim, methoxsalen, thiazides, and in the **Federal Register** of December 5, 1980 (45 FR 80740) for Bendectin, are hereby withdrawn.

Notices establishing final guideline patient package inserts published in the **Federal Register** of November 25, 1980 (45 FR 78516) for cimetidine, clofibrate, and propoxyphene, and in the **Federal Register** of January 2, 1981 (46 FR 160) for ampicillin and phenytoin, are hereby revoked.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

Dated: August 16, 1982.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82-24451 Filed 9-3-82; 8:45 am]

BILLING CODE 4160-01-M

Social Security Administration

Statement of Organization, Functions, and Delegations of Authority

Part S of the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (HHS) covers the Social Security Administration (SSA). Sections SG.00, SG.10 and SG.20 of the SSA statement, as most recently published in the **Federal Register** on November 28, 1980 (45 FR 79168-72), described the mission, organization and functions of SSA's Office of Hearings and Appeals (OHA). The Office statement is being revised to implement a consolidation and centralization of management and administrative services in OHA, with the aim of improving both the efficiency and economy of operations by providing line authority under one management official.

Notice is given that Sections SG.10 and SG.20 are amended to: eliminate the positions of Deputy Associate Commissioner for Hearings and Appeals, Operations and Deputy Associate Commissioner for Hearings and Appeals, Programs, and transfer their functions to the new position of Deputy Assistant Commissioner for Hearings and Appeals; and consolidate the five existing divisions which comprise the Office of Facilities and Personnel Administration and the Office of Management Coordination without changing each division's functions, into a newly titled Office of Management Services.

The OHA material is amended as follows:

Sec. SG.10

Amend "B" to read as follows:

B. The Deputy Associate Commissioner for Hearings and Appeals (SGA).

Delete "C."

Revise "L" to read as follows:

L. The Office of Management Services (SGH).

1. Division of Personnel Management (SGH1).

2. Division of Facilities (SGH2).

3. Division of Financial Management (SGH3).

4. Division of Management Analysis (SGH4).

5. Division of Management Information Systems (SGH5).

Delete "M."

Redesignate paragraphs "D," "E," "F," "G," "H," "I," "J," "K," "L" and "N" as "C," "D," "E," "F," "G," "H," "J," "K" and "L," respectively.

Sec. SG.20

Amend "B" to read as follows:

B. The Deputy Associate Commissioner for Hearings and Appeals (SGA) assists the Associate Commissioner in carrying out his/her OHA-wide responsibilities and performs other duties as the Associate Commissioner may prescribe. In addition, the Deputy serves as a member of the Appeals Council and, in the absence of the Associate Commissioner, serves as chairperson.

Delete "C."

Revise "L" to read as follows:

L. The Office of Management Services (SGH) plans, develops and administers the OHA personnel management program, including recruitment and placement; position classification; incentive awards; employee services; labor management relations; employee development and training. It plans and directs OHA administrative support activities, including space; forms and records; property management; procurement and supply; security; equipment control and maintenance; preparation of visual aids and mail/messenger services. It plans and executes a program establishing requirements for and complying with established occupational health and safety concepts, regulations, standards and procedures. The Office also plans and directs the OHA management analysis program, which includes the design, development, implementation and appraisal of management policies and programs, and researches management techniques and technological developments having possible utility for OHA. It directs

OHA's operational and management systems planning programs, assures effective coordination of the OHA management information systems with the SSA systems and maintains a case control and statistical reporting system on the adjudication process. It plans, develops and coordinates OHA's financial management program and provides financial guidance and control in the area of budget formulation and execution, work measurement and workload forecasting, pay and travel, position control, contract services and fiscal operations. The Office of Management Services includes the following components and functions:

1. *Division of Personnel Mangement (SGH1).*

a. Plans, develops and administers OHA's personnel management program, including recruitment and placement; position classification and pay administration; incentive awards; employee services; employee-management relations and related activities.

b. Evaluates the effectiveness of OHA's personnel management functions and activities, resolves personnel management problems and participates in the implementation of employee-management cooperation and equal opportunity programs.

c. Institutes required improvements in OHA's personnel management policy and procedures, consistent with SSA/HHS personnel policies and procedures.

d. Acts on behalf of the Associate Commissioner to recruit, examine and appoint Administrative Law Judges, consistent with SSA/HHS/OPM policies and procedures.

2. *Division of Facilities (SGH2).*

a. Plans, directs and provides administrative support services in the areas of space planning and utilization; forms and records management; property management; equipment control and maintenance; preparation of visual aids and exhibits; safety and self-protection, including emergency planning; procurement and supply; mail and messenger services and library reference.

b. Coordinates services provided to OHA by SSA, HHS, OPM and other agencies, such as building maintenance and communication services.

3. *Division of Financial Management (SGH3).*

a. Plans, develops and coordinates OHA's financial management programs, advising the Associate Commissioner of the financial impact on all decisions which affect OHA.

b. Formulates and executes budgetary requirements and controls in the areas of resource management, work measurement and workload forecasting; administrative cost allocation; cost-benefit analysis; pay and travel; ceiling control; contract services; fiscal operations and regional interface on the budget process.

4. *Division of Management Analysis (SGH4).*

a. Plans, develops and coordinates OHA's organizational and administrative planning and analysis programs, and conducts an OHA-wide management analysis program to design, develop and implement management policies, procedures and methods for improving the effectiveness, efficiency and economy of operations.

b. Plans, develops, conducts and administers the OHA organization and position control system, and coordinates an OHA program for resource utilization.

c. Participates in continuing research of current management techniques and technological developments having possible application to OHA needs.

d. Implements and administers the SSA Administrative Directives System within OHA.

5. *Division of Management Information Systems (SGH5).*

a. Provides OHA leadership and direction for operational and management information systems planning, encompassing both ADP and non-ADP systems.

b. Establishes systems standards and plans overall specifications for OHA needs.

c. Reviews and evaluates proposed systems and equipment changes for conformance with long-range OHA goals and to ensure integration with other SSA systems.

d. Maintains a case control and statistical reporting system on the adjudication process to be used by management for planning, coordination, communication and control.

e. Administers OHA's ADP systems, security, reports management program and work measurement program.

f. Applies mathematical analysis, statistical techniques, model building and cost-benefit analysis to define problem areas and provide alternative course of action to facilitate management decisions.

Delete "M."

Redesignate paragraphs "D," "E," "F," "G," "H," "I," "J," "K," "L," and "N," as "C," "D," "E," "F," "G," "H," "I," "J," "K," and "L," respectively.

Dated: August 24, 1982.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82-24464 Filed 9-3-82; 8:45 am]

BILLING CODE 4190-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

[Docket No. N-82-1153]

Privacy Act of 1974; Proposed Amendment to System of Records

AGENCY: Department of Housing and Urban Development.

ACTION: Notice of proposed amendment to existing system of records.

SUMMARY: The Department is giving notice that it intends to amend the following Privacy Act system of records: HUD/DEPT-37, Personnel Travel System.

EFFECTIVE DATE: The amendment shall become effective without further notice in 30 calendar days (October 7, 1982) unless comments are received on or before that date which would result in a contrary determination.

ADDRESS: Rules Docket Clerk, Room 10278, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, D.C. 20410.

FOR FURTHER INFORMATION CONTACT: Robert English, Departmental Privacy Act Officer, Telephone 202-755-5320. This is not a toll free number.

SUPPLEMENTARY INFORMATION: The Department proposes to amend the Personnel Travel System (HUD/DEPT-37). This system contains Departmental travel records, including vouchers, requests, advances, receipts for requests, and orders. The Department is amending the system to specify that both the Director, Office of Finance and Accounting and the Director, Office of Administrative Services have management responsibility with respect to the system. Accordingly, the Director, Office of Administrative Services has been added as a system manager.

The prefatory statement containing General Routine Uses applicable to most of the Department's systems of records was published at 46 FR 34322 (August 6, 1982). Appendix A, which lists the addresses of HUD's Field Offices, was published at 47 FR 34331 (August 6, 1982). Previously, the system was published at 46 FR 54889 (November 4, 1981). The notice is published below in its entirety, as amended. A report of the Department's intention to amend this

system was filed with the Speaker of the House, the President of the Senate, and the Office of Management and Budget on July 12, 1982.

(5 U.S.C. 552a 88 Stat. 1896; Sec. 7 (d) Department of HUD Act (42 U.S.C. 3535(d)))

Issued at Washington, D.C. August 30, 1982.

Judith L. Tardy,

Assistant Secretary for Administration.

HUD/DEPT-37

SYSTEM NAME:

Personnel Travel System.

SYSTEM LOCATION:

All Department offices maintain employee travel records. For a complete listing of offices, with addresses, see Appendix A.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

HUD personnel.

CATEGORIES OF RECORDS IN THE SYSTEM:

All travel records, including vouchers, requests, advances, receipts for requests, orders.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 7(d) of the Department of Housing and Urban Development Act of 1965, P.L. 89–174; Budget and Accounting Act of 1950, 31 U.S.C. 66a.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USES AND THE PURPOSES OF SUCH USERS:

See Routine Uses paragraphs in prefatory statement. Other routine uses: to Treasury—for payment of vouchers; vouchers and receipts are available to GAO and GSA for audit purposes and vouchers are verified by private transporters.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

In file folders and on magnetic tape/disc/drum.

RETRIEVABILITY:

Almost always retrievable by name, occasionally by Social Security number.

SAFEGUARDS:

Lockable desks or file cabinets; computer records are maintained in secure areas with access limited to authorized personnel and technical restraints employed with regard to accessing the records.

RETENTION AND DISPOSAL:

Records are active and kept up-to-date. Files purged in accordance with HUD Handbook.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Finance and Accounting, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, D.C. 20410.

For Transportation Requests: Director, Office of Administrative Services, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, D.C. 20410.

NOTIFICATION PROCEDURES:

For information, assistance, or inquiry about existence of records, contact the Privacy Act Officer at the appropriate location, in accordance with 24 CFR Part 16. A list of all locations is given in Appendix A.

RECORD ACCESS PROCEDURES:

The Department's rules for providing access to records to the individual concerned appeared in 24 CFR Part 16. If additional information or assistance is required, contact the Privacy Act Officer at the appropriate location. A list of all locations is given in Appendix A.

CONTESTING RECORD PROCEDURES:

The Department's rules for contesting the contents of records and appealing initial denials, by the individual concerned, appear in 24 CFR Part 16. If additional information or assistance is needed, it may be obtained by contacting: (i) in relation to contesting contents of record, the Privacy Act Officer at the appropriate location. A list of all locations is given in Appendix A; (ii) in relation to appeals of initial denials, the HUD Departmental Privacy Appeals Officer, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, D.C. 20410.

RECORD SOURCE CATEGORIES:

Subject individual and supervisors.

[FR Doc. 82–24515 Filed 9–3–82; 8:45 am]

BILLING CODE 4210–01–M

[Docket No. N–82–1154]

Submission of Proposed Information Collections to OMB

AGENCY: Office of Administration, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirements described below have been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposals.

ADDRESS: Interested persons are invited to submit comments regarding these proposals. Comments should refer to the proposal by name and should be sent to: Robert Neal, OMB Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, D.C. 20503.

FOR FURTHER INFORMATION CONTACT: Robert G. Masarsky, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street SW., Washington, D.C. 20410, telephone (202) 755–5310. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposals described below for the collection of information to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35).

The Notice lists the following information (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the agency form number, if applicable; (4) how frequently information submissions will be required; (5) what members of the public will be affected by the proposal; (6) an estimate of the total number of hours needed to prepare the information submission; (7) whether the proposal is new or an extension or reinstatement of an information collection requirement; and (8) the names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Copies of the proposed forms and other available documents submitted to OMB may be obtained from Robert G. Masarsky, Reports Management Officer for the Department. His address and telephone number are listed above. Comments regarding the proposals should be sent to the OMB Desk Officer at the address listed above.

The proposed information collection requirements are described as follows:

Notice of Submission of Proposed Information Collection to OMB

- Proposal: Request for Construction Change—Project Mortgages

Office: Housing
Form number: HUD–92437
Frequency of submission: On Occasion
Affected public: Businesses or Other Institutions (except farms)
Estimated burden hours: 30,000
Status: Extension
Contact: Linda Cheatham, HUD, (202) 755–8686; Robert Neal, OMB, (202) 395–6880

(Sec. 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; Sec. 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d))

- Proposal: Weekly Opinion Poll of Mortgage Market Conditions

Office: Housing

Form number: HUD-9333
Frequency of submission: Weekly
Affected public: Businesses or Other Institutions (except farms)
Estimated burden hours: 130
Status: New
Contact: Arnold H. Diamond, HUD, (202) 426-4325; Robert Neal, OMB, (202) 395-6880

Authority: Sec. 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; Sec. 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

- Proposal: Contractor's Subcontractor's Certification Concerning Labor Standards and Prevailing Wage Requirements

Office: Housing
Form number: FHA-2482/2482A/2482A-EH
Frequency of submission: On Occasion
Affected public: Businesses or Other Institutions (except farms)
Estimated burden hours: 18,500
Status: Extension
Contact: Jack Kaufman, HUD, (202) 755-6223; Robert Neal, OMB, (202) 395-6880

Authority: Sec. 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; Sec. 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: August 18, 1982.

Judith L. Tardy,

Assistant Secretary for Administration.

[FR Doc. 82-24514 Filed 9-3-82; 8:45 am]

BILLING CODE 4210-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[Spokane 018889]

Washington; Order Providing for Opening of Public Lands

1. In an exchange of lands made pursuant to Section 8 of the Act of June 28, 1934, 48 Stat. 1269, 1272, as amended and supplemented, 43 U.S.C. 315g (1976), the following land has been reconveyed to the United States:

Willamette Meridian

T. 23 N., R. 23 E.,
Sec. 21, All.

The area described contains 640 acres in Douglas County, Washington.

2. At 9:30 a.m., on October 11, 1982, the land will be open to operation of the public land laws generally, subject to valid existing rights, the provisions of existing withdrawals, and the requirements of applicable law. All valid applications received at or prior to 9:30 a.m., on October 11, 1982, will be considered as simultaneously filed at that time. Those received thereafter will be considered in the order of filing.

3. At 9:30 a.m., on October 11, 1982, the land will be open to location under the United States mining laws and to applications and offers under the mineral leasing laws.

Inquiries concerning the land should be addressed to the State Director, Bureau of Land Management, P.O. Box 2965, Portland, Oregon 97208.

Dated: August 25, 1982.

Champ C. Vaughan,

Acting Chief, Branch of Lands and Minerals Operations.

[FR Doc. 82-24465 Filed 9-3-82; 8:45 am]

BILLING CODE 4310-84-M

Fish and Wildlife Service

Information Collection Submitted for Review

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed information collection requirement and related forms and explanatory material may be obtained by contacting the Service's clearance officer at the phone number listed below. Comments and suggestions on the requirement should be made directly to the Service clearance officer and the Office of Management and Budget reviewing official, Mr. Jeff Hill, at 202-395-7340.

Title: Declaration for Importation or Exportation of Fish or Wildlife.

Bureau Form Number: 3-177.

Frequency: On occasion.

Description of Respondents: Individuals or households, state or local governments, and businesses or other institutions.

Annual Responses: 60,000.

Annual Burden Hours: 15,000.

Service Clearance Officer: Arthur J. Ferguson, 202-653-8770.

Don W. Minnich,

Acting Associate Director, Wildlife Resources

August 25, 1982.

[FR Doc. 82-24469 Filed 9-3-82; 8:45 am]

BILLING CODE 4310-55-M

Endangered Species Permit; Receipt of Applications

The applicants listed below wish to conduct certain activities with endangered species:

Applicant: San Francisco Zoo, San Francisco, CA—PRT 2-9590

The applicant requests a permit to import two female snow leopards (*Panthera uncia*) from the Shanghai Zoo, People's Republic of China for enhancement of propagation.

Applicant: Rare Feline Breeding Center, Inc., Center Hill, FL—PRT 2-9587

The applicant requests a permit to import one female captive-born snow leopard (*Panthera uncia*) from the Marwell Zoo, Winchester, England for enhancement of propagation.

Applicant: Duke University Primate Center, Durham, NC—PRT 2-9595

The applicant requests a permit to import 12 mongoose lemurs (*Lemur mongoz*) from the Islamique Federale des Comores, Africa for enhancement of propagation and survival.

Applicant: Atlanta Zoological Park, Atlanta, GA—PRT 2-9497

The applicant requests a permit to import preserved feces, intestine and whole specimens of captive-held reptiles from foreign zoos, research facilities and private collectors for scientific research.

Applicant: Lincoln Park Zoo, Chicago, IL—PRT 2-9455

The applicant requests a permit to import one male captive-bred lowland gorilla (*Gorilla gorilla*) from the Royal Rotterdam Zoo, the Netherlands for enhancement of propagation.

Applicant: Miami-Metrozoo, Miami, FL—PRT 2-9565

The applicant requests a permit to purchase in interstate commerce two (2) males and three (3) female captive-bred Eld's deer (*Cervus eldi*) from F.J. Zeehandelaar, Inc., New Rochelle, New York for enhancement of propagation.

Applicant: New York Zoological Society, Bronx, NY—PRT 2-9562

The applicant requests a permit to import one male captive-bred proboscis monkey (*Nasalis larvatus*) from the Zoologisch-Botabischer Garten, West Germany, for enhancement of propagation.

Applicant: Patuxent Wildlife Research Center, Laurel, MD—PRT 2-9574

The applicant requests a permit to export frozen whooping crane (*Grus americana*) carcasses to the National Museum of Natural Sciences, Ottawa, Canada for scientific research.

Humane care and treatment during transport, if applicable, has been indicated by the applicants.

Documents and other information submitted with these applications are available to the public during normal business hours in Room 601, 1000 N. Glebe Rd., Arlington, Virginia, or by writing to the U.S. Fish & Wildlife Service, WPO, P.O. Box 3654, Arlington, VA 22203.

Interested persons may comment on these applications on or before October 7, 1982 by submitting written data,

views, or arguments to the above address. Please refer to the file number when submitting comments.

Dated: September 1, 1982.

R. K. Robinson,

Chief, Branch of Permits, Federal Wildlife Permit Office.

[FR Doc. 82-24519 Filed 9-3-82; 8:45 am]

BILLING CODE 4310-55-M

National Park Service

Canyon de Chelly National Monument, Arizona; Availability of Statement Findings Regarding Floodplain Management and Wetland Protection

AGENCY: National Park Service, Interior

ACTION: Notice of availability of Statement of Findings.

SUMMARY: Pursuant to requirements specified in Executive Order 11988 (May 24, 1977), for Floodplain Management, Executive Order 11990 (May 24, 1977) for Protection of Wetlands, and their implementing guidelines, and the National Park Service Floodplain Management and Wetland Protection Guidelines (**Federal Register**, Vol. 45, No. 104—Wednesday, May 28, 1980), the National Park Service, Department of the Interior, gives notice that a statement of findings has been prepared for the Development Concept Plan (DCP) for the Headquarters Area of Canyon de Chelly National Monument, Arizona.

The Development Concept Plan calls for orderly improvement, replacement, and expansion of concession and park facilities within the existing developed areas which are located within the overflow storage area of the 100-year flood event.

FOR FURTHER INFORMATION OR FOR A COPY OF THE STATEMENT OF FINDINGS CONTACT:

Robert I. Kerr, Regional Director, Southwest Region, National Park Service, P.O. Box 728, Santa Fe, New Mexico 87501, Telephone: (505) 988-6380.

Dated: August 24, 1982.

Robert I. Kerr,

Regional Director, Southwest Region.

[FR Doc. 82-24499 Filed 9-3-82; 8:45 am]

BILLING CODE 4310-70-M

National Capital Region, Public Affairs; Public Meeting

The National Park Service is seeking public comments and suggestions on the planning of the 1982 Christmas Pageant of Peace, which opens December 16 on the Ellipse, south of the White House.

A public meeting will be held at the National Capital Region Headquarters, 1100 Ohio Drive, SW., Room 112, on October 4 at 10 a.m.

Interested persons who would like to comment at the meeting should notify the National Park Service by September 30, by calling the Office of Public Affairs between 9 a.m. and 4 p.m., weekdays at 426-6700.

Dated: August 31, 1982.

Manus J. Fish, Jr.,

Regional Director, National Capital Region.

[FR Doc. 82-24500 Filed 9-3-82; 8:45 am]

BILLING CODE 4310-70-M

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before August 27, 1982. Pursuant to § 60.13 of 36 CFR Part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, U.S. Department of the Interior, Washington, DC 20243. Written comments should be submitted by September 22, 1982.

Carol D. Shull

Chief of Registration, National Register.

CONNECTICUT

Tolland County

Somers, *Somers Historic District*, Main and Battle Sts., Bugbee Lane, and Springfield Rd.

Windham County

Brooklyn, *Brooklyn Green Historic District*, CT 169, 205, and 6, Wolf Den, Brown, Prince Hill, and Hyde Rds.

Hampton, *Hampton Hill Historic District*, Main St., Old Route 6, Cedar Swamp Rd.

IDAHO

Elmore County

Glenns Ferry, *Amstutz Apartments*, 320 S. Ada St.

INDIANA

Floyd County

Bridgeport vicinity, *Farnsley, Gabriel, House*, N of Bridgeport off IN 111.

Marion County

Indianapolis, *Meier, George Phillip, House*, 3128 N. Pennsylvania St.

LOUISIANA

Franklin Parish

Winnesboro, *Jackson Street Historic District*, Jackson St.

Iberville Parish

Plaquemine, *St. Basil's Academy*, 311 Church St.

Madison Parish

Tallulah vicinity, *Montrose Plantation House*, SE of Tallulah on LA 603

Orleans Parish

New Orleans, *Jung Hotel*, 1500 Canal St.

New Orleans, *McDonogh School No. 6, 4849 Chestnut St.*

St. Landry Parish

Opelousas, *Labyche-Estorge House*, 427 N. Market St.

St. Mary Parish

Franklin, *Arlington Plantation House*, 56 E. Main St.

Tagnipahoa Parish

Ponchatoula, *Ponchatoula Commercial Historic District*, roughly bounded by 5th, 7th, Hickory and Oak Sts.

Independence, *Independence Historic District*, Roughly bounded by LA 40, 5th St., Anzalone, and E. and W. Railroad Aves.

Loranger, *Loranger Methodist Church*, Allman Ave. and Magnolia Blvd.

Tensas Parish

Waterproof vicinity, *Moro Plantation House*, W of Waterproof off LA 566

MISSOURI

Buchanan County

St. Joseph, *Vosteen-Hauck House*, 913 N. 2nd St.

Gasconade County

Hermann vicinity, *Vallet-Danuser House*, E of Hermann on MO 100

Howard County

Fayette, *Oakwood*, 1 Leonard Ave.

Laclede County

Lebanon, *Ploger-Moneymaker Place*, 291 Harwood Ave.

Lafayette County

Lexington vicinity, *Hicklin Hearthstone*, E of Lexington on US 24

Marion County

Palmyra vicinty, *Wilson, Ephraim J., Farm Complex*, E of Palmyra off MO 168

Pettis County

Hughesville vicinity, *Thomson, Gen. David, House*, S of Hughesville on SR H

Pike County

Louisiana, *Luce-Dyer House*, 220 N. 3rd St.

St. Charles County

St. Charles, *Watson, Samuel Stewart, House*, 205 S. Duchesne Dr.

St. Louis County

Webster Groves, *Webster College-Eden Theological Seminary Collegiate District*, 470 and 475 E. Lockwood Ave.

Texas County

Plato vicinity, *Bates-Geers House*, E of Plata on Slabtown Rd.

Worth County

Grant City, *Worth County Courthouse*, Public Sq.

NEW JERSEY

Sussex County

Sussex vicinity, *First Presbyterian Church of Wantage*, N of Sussex on NJ 23

NEW MEXICO

Bernalillo County

Albuquerque, *Kromer House*, 1024 El Pueblo Rd. NW

NEW YORK

Essex County

Whallonsburg vicinity, *Essex County Home and Farm*, SW of Whallonsburg on NY 22

Genessee County

Batavia, *Genesee County Courthouse Historic District*, Bounded by Porter and Jefferson Aves., and Main, Court, and Ellicott Sts.

Richmond County

Rossville vicinity, *Sandy Ground Historic Archeological District (A085-01-2258-D03*

Rockland County

Upper Nyack, *Empire Hook and Ladder Company No. 1*, 330 N. Broadway

NORTH CAROLINA

Buncombe County

Fairview vicinity, *Lanning, John A., House*, W of Fairview on SR 3128

Chatham County

Pittsboro, *Clegg, Luther, House (Pittsboro MRA)*, S of Pittsboro on SR 1012
Pittsboro, *Freeman, Lewis, House (Pittsboro MRA)*, 205 W. Salisbury St.
Pittsboro, *Hall-London House (Pittsboro MRA)*, 206 Hillsboro St.
Pittsboro, *Kelvin (Pittsboro MRA)*, 503 W. Salisbury St.
Pittsboro, *London Cottage (Pittsboro MRA)*, N of Pittsboro on SR 1516
Pittsboro, *McClenahan House (Pittsboro MRA)*,
Pittsboro, *Moore-Manning House (Pittsboro MRA)*, 400 Hillsboro St.
Pittsboro, *Reid House (Pittsboro MRA)*, 200 W. Salisbury St.
Pittsboro, *St. Lawrence, Patrick, House (Pittsboro MRA)*,
Pittsboro, *Terry, A. P., House (Pittsboro MRA)*, 601 Womack St.

Franklin County

Bunn vicinity, *Baker Farm*, SW of Bunn on SR 1720

Gates County

Gates vicinity, *Freeman House*, N of Gates on US 13

Guilford County

Greensboro, *Dixon-Leftwich-Murphy House*, 507 Church St.

Northampton County

Murfreesboro vicinity, *Parker, Francis, House*, W of Murfreesboro on US 158

Rowan County

Bear Poplar vicinity, *Hall Family House*, NE of Bear Poplar on NC 801
Bear Poplar vicinity, *Wood Grove*, E of Bear Poplar on SR 1743
Enochville vicinity, *Kerr, Gen. William, House*, NW of Enochville on SR 1353
Faith vicinity, *Shuping's Mill Complex*, S of Faith on NC 152
Five Points vicinity, *Corriher Grange Hall*, NW of Five Points on SR 1555
Mt. Ulla, *Rankin-Sherrill House*, NC 801

Scotland County

Laurinburg, *Blue, Mag, House*, W of Laurinburg on SR 1118

OREGON

Lane County

Eugene, *East Skinner Butte Historic District*, Pearl and High Sts., and 2nd and 3rd Aves.
Eugene, *Quackenbush Hardware Store*, 160 E. Broadway

Umatilla County

Pendleton, *Milarkey Building (Pendleton Drug Building)*, 203 S. Main St.
Weston, *Weston Commercial Historic District*, E. Main St. between Water and Broad Sts.

Yamhill County

Lafayette, *Kelty, James M. and Paul R., House*, 675 3rd St.

SOUTH DAKOTA

Custer County

Custer vicinity, *Wind Cave National Park Historic District*, E of Custer off US 385

WEST VIRGINIA

Wood County

Parkersburg, *Auditorium Theater/ Parkersburg Office Supply (Downtown Parkersburg MRA)*, 320 5th St.
Parkersburg, *Bethel AME Church (Downtown Parkersburg MRA)*, 820 Clay St.
Parkersburg, *Blennerhassett Hotel (Downtown Parkersburg MRA)*, 316 Market St.
Parkersburg, *Carnegie Library (Downtown Parkersburg MRA)*, 725 Green St.
Parkersburg, *Case House (Downtown Parkersburg MRA)*, 710 Ann St.
Parkersburg, *Chancellor Hardware (Downtown Parkersburg MRA)*, 114 3rd St.
Parkersburg, *Citizens National Bank (Downtown Parkersburg MRA)*, 219 4th St.
Parkersburg, *Elks Club (Downtown Parkersburg MRA)*, 515 Juliana St.
Parkersburg, *First Baptist Church (Downtown Parkersburg MRA)*, 813 Market St.
Parkersburg, *First Presbyterian Church/ Calvary Temple Evangelical Church (Downtown Parkersburg MRA)*, 946 Market St.
Parkersburg, *Gould House/Greater Parkersburg Chamber of Commerce (Downtown Parkersburg MRA)*, 720 Juliana St.
Parkersburg, *Guaranty Building (Downtown Parkersburg MRA)*, 217 4th St.
Parkersburg, *House at 10th and Avery Sts. (Downtown Parkersburg MRA)*, 10th and Avery Sts.
Parkersburg, *Logan, Henry, Memorial AME Church (Downtown Parkersburg MRA)*, Ann & 6th Sts.
Parkersburg, *Masonic Temple (Downtown Parkersburg MRA)*, 900 Market St.
Parkersburg, *Mather Building/Franklin & DeHaven Jewelers (Downtown Parkersburg MRA)*, 405 Market St.
Parkersburg, *Oeldorf Building/Wetherell's Jewelers (Downtown Parkersburg MRA)*, 809 Market St.
Parkersburg, *Parkersburg Woman's Club (Downtown Parkersburg MRA)*, 323 9th St.
Parkersburg, *Robb Apartments (Downtown Parkersburg MRA)*, 201 8th St.
Parkersburg, *Sharon Lodge #28 I.O.O.F. (Downtown Parkersburg MRA)*, 316 5th St.
Parkersburg, *Sixth Street Railroad Bridge (Downtown Parkersburg MRA)*, 6th Street
Parkersburg, *Smith Building (Downtown Parkersburg MRA)*, 310½ Market St.
Parkersburg, *Smoot Theater (Downtown Parkersburg MRA)*, 213 5th St.
Parkersburg, *Trinity Episcopal Church Rectory (Downtown Parkersburg MRA)*, 430 Juliana St.
Parkersburg, *Trinity Protestant Episcopal Church (Downtown Parkersburg MRA)*, 424 Juliana St.
Parkersburg, *Union Trust & Deposit Co./ Union Trust National Bank (Downtown Parkersburg MRA)*, 700 Market St.
Parkersburg, *Wait, Walton, House (Downtown Parkersburg MRA)*, 1232 Murdoch Ave.
Parkersburg, *West Central WV Community Action, Assoc., Inc. (Downtown Parkersburg MRA)*, 804 Ann St.
Parkersburg, *Windmill Quaker State (Downtown Parkersburg MRA)*, 800 Murdoch Ave.

WISCONSIN

Chippewa County

Chippewa Falls, *Goldsmith Memorial Chapel (Notre Dame Parish TR)*, Allen St.
Chippewa Falls, *McDonell High School (Notre Dame Parish TR)*, 3 S. High St.
Chippewa Falls, *Notre Dame Church (Notre Dame Parish TR)*, 117 Allen St.

Dane County

Madison, *Ott, John George, House*, 754 Jenifer St.

Milwaukee County

Milwaukee, *Woman's Club of Wisconsin, (The Athenaeum)*, 813 E. Kilbourn Ave.

Outagamie County

Greenville, *Greenville State Bank*, 252 Municipal Dr.

Waukesha County

Waukesha, *Putney Block*, 301 W. Main St., 816 and 802 Grand Ave.

[FR Doc. 82-24498 Filed 9-3-82; 8:45 am]
BILLING CODE 4310-70-M

Office of the Secretary

Federal-State Task Force on the Hawaiian Homes Commission Act; Meeting

AGENCY: Interior Department.

ACTION: Notice of meeting.

SUMMARY: Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Federal-State Task Force on the Hawaiian Homes Commission Act. This meeting will be open to the public. Attendance by the public will be limited to space available.

DATE: September 20, 1982 at 9:00 a.m.

ADDRESS: Conference Room 1, Third Floor, Old Federal Building, 335 Merchant Street, Honolulu, Hawaii, 96813.

FOR FURTHER INFORMATION CONTACT: Executive Assistant to the Secretary Stephen P. Shipley, U.S. Department of the Interior, 18th and C Sts., NW., Washington, D.C. 20240; (202) 343–7351.

Dated: September 2, 1982.

James G. Watt,

Secretary of the Interior.

[FR Doc. 82–24592 Filed 9–3–82; 8:45 am]

BILLING CODE 4310–10–M

Federal-State Task Force on the Hawaiian Homes Commission Act; Notice of Intent To Establish

Pursuant to Pub. L. 94–463, notice is hereby given of the intent to establish the Federal-State Task Force on the Hawaiian Homes Commission Act. Following consultation with the General Services Administration, the Secretary intends to establish the Task Force to advise the Secretary of the Interior and the Governor of Hawaii on ways to better effectuate the purposes of the Hawaiian Homes Commission Act (HHCA).

Further information regarding the Task Force may be obtained from Stephen P. Shipley, Executive Assistant to the Secretary, U.S. Department of the Interior, 18th and C Streets, N.W., Washington, D.C. 20240; (202) 343–7351.

The certification of establishment is published below.

Certification

I hereby certify that the Federal-State Task Force on the Hawaiian Homes Commission Act is in the public interest in connection with the performance of duties imposed on the Department of the Interior by the Hawaiian Homes Commission Act, 42 Stat. 108 and the Hawaii Statehood Act, Pub. L. 86–3.

Dated: September 2, 1982.

James G. Watt,

Secretary of the Interior.

[FR Doc. 82–24593 Filed 9–3–82; 8:45 am]

BILLING CODE 4310–10–M

INTERSTATE COMMERCE COMMISSION

Motor Carriers; Permanent Authority Decisions; Decision-Notice

The following applications, filed on or after February 9, 1981, are governed by Special Rule of the Commission's Rules of Practice, see 49 CFR 1100.251. Special Rule 251 was published in the **Federal Register** of December 31, 1980, at 45 FR 86771. For compliance procedures, refer to the **Federal Register** issue of December 3, 1980, at 45 FR 80109.

Persons wishing to oppose an application must follow the rules under 49 CFR 1100.252. A copy of any application, including all supporting evidence, can be obtained from applicant's representative upon request and payment to applicant's representative of $10.00.

Amendments to the request for authority are not allowed. Some of the applications may have been modified prior to publication to conform to the Commission's policy of simplifying grants of operating authority.

Findings

With the exception of those applications involving duly noted problems (e.g., unresolved common control, fitness, water carrier dual operations, or jurisdictional questions) we find, preliminarily, that each applicant has demonstrated a public need for the proposed operations and that it is fit, willing, and able to perform the service proposed, and to conform to the requirements of Title 49, Subtitle IV, United States Code, and the Commission's regulations. This presumption shall not be deemed to exist where the application is opposed. Except where noted, this decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In the absence of legally sufficient opposition in the form of verified statements filed on or before 45 days from date of publication, (or, if the application later becomes unopposed) appropriate authorizing documents will be issued to applicants with regulated operations (except those with duly noted problems) and will remain in full effect only as long as the applicant maintains appropriate compliance. The unopposed applications involving new entrants will be subject to the issuance of an effective notice setting forth the compliance requirements which must be satisfied before the authority will be issued. Once this compliance is met, the authority will be issued.

Within 60 days after publication an applicant may file a verified statement in rebuttal to any statement in opposition.

To the extent that any of the authority granted may duplicate an applicant's other authority, the duplication shall be construed as conferring only a single operating right.

Note.—All applications are for authority to operate as a motor common carrier in interstate or foreign commerce over irregular routes, unless noted otherwise. Applications for motor contract carrier authority are those where service is for a named shipper "under contract".

Please direct status inquiries to the Ombudsman's Office, (202) 275–7326.

Volume No. OP2–205

Decided: August 27, 1982.

By the Commission, Review Board No. 1, Members Parker, Chandler, and Fortier.

MC 25562 (Sub-36), filed August 13, 1982. Applicant: A. R. GUNDRY, INC., 85 Stanton St., Rochester, NY 14611. Representative: J. A. Kundtz, 1100 National City Bank Bldg., Cleveland, OH 44114, 216–566–5639. Transporting *commodities in bulk,* between points in the U.S., under continuing contract(s) with Atlantic Richfield Company, of Los Angeles, CA.

MC 72243 (Sub-76), filed August 19, 1982. Applicant: THE AETNA FREIGHT LINES, INC., 2507 Youngstown Rd., S.E., P.O. Box 350, Warren, OH 44482. Representative: Paul F. Beery, 275 east State St., Columbus, OH 43215, (614) 228–8575. Transporting *metal products; those commodities which because of size or weight require the use of special equipment; machinery; lumber and wood products; building materials; clay, concrete, glass and stone products; transportation equipment; rubber and plastic products; Mercer commodities; and forest products,* between FL, GA, NC, SC, and VA, on the one hand, and, on the other, those points in the U.S. in and east of MN, SD, WY, CO, and NM.

MC 143483 (Sub-6), filed August 12, 1982. Applicant: QUIK HAUL, INC., 307 West Dumble St., P.O. Drawer "D", Alvin, TX 77511. Representative: Fred R. Lindsey (same address as applicant), (713) 331–9222. Transporting *tower cranes, personnel/material hoists, concrete pumps, and accessories,* between Houston, TX, on the one hand,

and, on the other, points in the U.S. (except AK and HI).

MC 143503 (Sub-35), filed August 16, 1982. applicant: MERCHANTS HOME DELIVERY SERVICE, INC., P.O. Box 5067, Oxnard, CA 93031. Representative: David B. Schneider, 210 W. Park Ave., Suite 1120, Oklahoma City, OK 73102, (405) 232–9990. transporting *general commodities* (except classes A and B explosives, household goods and commodities in bulk), between points in the U.S., under continuing contract(s) with Scandinavian Design, Inc., of Natick, MA.

MC 146423 (Sub-19), filed August 12, 1982. applicant: STEPHEN HROBUCHAK, d.b.a. TRANSCONTINENTAL REFRIGERATED LINES, P.O. Box 1456, Scranton, PA 18501. Representative: Joseph A. Keating, Jr., 121 South Main St., Taylor, PA 18517, (717) 344–8030. Transporting *general commodities* (except classes A and B explosives, commodities in bulk, and household goods), between NJ (except Somerset County); NY (except Broome, Cayuga, Chenango, Chemung, Cortland, Onandaga, Schuyler, Seneca, Steuben, Tioga, Tompkins and Yates Counties); and PA (except Bradford, Carbon, Columbia, Franklin, Lackawanna, Lehigh, Luzerne, Lycoming, Monroe, Montour, Northumberland, Pike, Schuylkill, Tioga, and Wayne Counties), on the one hand, and, on the other, points in the U.S. (except AK and HI).

MC 150783 (Sub-28), filed August 16, 1982. Applicant: SCHEDULED TRUCKWAYS, INC., Box 757, Rogers, AR 72756. Representative: Harry J. Jordan, Suite 502, Solar Bldg. 1000, 16th St., N.W., Washington, D.C. 20036, (202) 783–8131. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S. (except AK and HI). Condition: The person or persons who appear to be engaged in common control of another regulated carrier must either file an application under 49 U.S.C. 11343(A) or submit an affidavit indicating why such approval is unnecessary to the Secretary's office. In order to expedite issuance of any authority please submit a copy of the affidavit or proof of filing the application(s) for common control to Team 2, Room 2379.

MC 155723 (Sub-2), filed July 20, 1982 (correction), previously published in the **Federal Register** issued of August 6, 1982, and republished, as corrected, this issue. Applicant: SYSTEM 81 EXPRESS, INC., P.O. Box 23243, Knoxville, TN 37922. Representative: William P. Jackson, Jr., 3426 North Washington Blvd., P.O. Box 1240, Arlington, VA 22210, 703–525–4050. Transporting * * * and (4) *such commodities* as are dealt in or used by chain, grocery, drug, hardware and food business houses, between points in the U.S. (except AK and HI).

Note.—The purpose of this republication is to correct the commodity description under part (4) of the application. The rest of the previous publication remains the same.

MC 163413, filed August 16, 1982. Applicant: PARCEL DELIVERY SERVICE, INC., 1040 Matley Lane, Reno, NV 89502. Representative: E. J. Tosolini, (same address as applicant), (702) 329–1377. Transporting *general commodities* (except classes A and B explosives, commodities in bulk, and household goods), between Carson City and points in Washoe and Douglas Counties, NV, and Placer, El Dorado and Nevada Counties, CA.

MC 163432, filed August 16, 1982. Applicant: GEORGE H. BORTZ III, d.b.a. G-FOUR TRUCKING CO., P.O. Box 305, Smithfield, PA 15478. Representative: Arthur J. Diskin, 402 Law & Finance Bldg., Pittsburgh, PA 15219, (412) 281–9494. Transporting *coal and bulk commodities,* between points in PA, OH, WV, VA, NY, MD, NJ and DC, under continuing contract(s) with Falco Coal Company of Smithfield, PA, and Center Coals, Inc., of Pittsburgh, PA.

MC 163433, filed August 16, 1982. Applicant: RALPH J. CRESTA, d.b.a. NATIONAL WRECKER SERVICE, 1 Raynes St., Portsmouth, NH 03801. Representative: Robert G. Parks, 20 Walnut St., Suite 101, Wellesley Hills, MA 02181, (617) 235–5571. Transporting *motor vehicles,* between points in NH and MA, on the one hand, and, on the other, points in CT, ME, MA, NH, RI, and VT.

MC 163452, filed August 17, 1982. Applicant: KENBRENT REFRIGERATED EXPRESS BC LTD., P.O. Box 159, Sardis, British Columbia, Canada VOX 1Y0. Representative: Jim Pitzer, 15 South Grady Way—Suite 321, Renton, WA 98055–3273, 206–235–1111. Transporting *food and related products,* between ports of entry on the international boundary line between the U.S. and Canada at points in WA, ID, and MT, on the one hand, and, on the other, points in WA, OR, and CA.

MC 163473, filed August 19, 1982. Applicant: BUENA VISTA TRUCKING, INC., 4212 Armour Ave., Bakersfield, CA 93308. Representative: Earl N. Miles, 3704 Candlewood Dr., Bakersfield, CA 93306, (805) 872–1106. Transporting *food and related products,* between points in the U.S., under continuing contract(s) with Tom's Foods, of Fresno, CA.

Volume No. OP3–137

Decided: August 30, 1982.

By the Commission, Review Board No. 2, Members Carleton, Williams, and Ewing. (Member Ewing not participating.)

MC 69454 (Sub-15), filed August 19, 1982. Applicant: DITTO FREIGHT LINES, 1575 Industrial Ave., San Jose, CA 95112. Representative: Daniel W. Baker, 100 Pine St., Suite 2550, San Francisco, CA 94111, (415) 986–1414. Transporting *general commodities* (except classes A and B explosives), between points in the U.S. (except AK and HI).

MC 106884 (Sub-6), filed August 19, 1982. Applicant: FUCCY HAULING & EXCAVATING, INC., P.O. Box 687, New Cumberland, WV 26047. Representative: Dean N. Wolfe, Suite 200, 444 N. Frederick Ave., Gaithersburg, MD 20877, (301) 840–8565. Transporting *commodities in bulk,* between points in the U.S. (except AK and HI), under continuing contract(s) with Starvaggi Industries, Inc., of Weirton, WV, and Crescent Brick Co. Inc., of Clearfield, PA.

MC 113624 (Sub-90), filed August 20, 1982. Applicant: WARD TRANSPORT, INC., P.O. Box 735, Pueblo, CO 81002. Representative: Leslie R. Kehl, 1660 Lincoln St., Suite 1600, Denver, CO 80264, (303) 861–4028. Transpprting *commodites in bulk,* between points in AZ, CA, CO, ID, IL, IA, KS, MN, MO, MT, NE, NV, NM, ND, OK, OR, SD, TX, UT, WA, and WY.

MC 145014 (Sub-3), filed August 19, 1982. Applicant: PARENT TRUCKING, INC., 4653 Turtle Rd., Turner, MI 48765. Representative: David Parent, 3051 Curtice Rd., Coleman, MI 48618, (517) 756–5221. Transporting *plastics and plastic products,* between points in the U.S. (except AK and HI), under continuing contract(s) with Robinson Industries, Inc., of Coleman, MI.

MC 148815 (Sub-5), filed August 20, 1982. Applicant: HUSKER DISTRIBUTION INC., 5900 Superior, No. 3, Lincoln, NE 68504. Representative: Lavern R. Holdeman, 1610 South 70th Street, No. 200, Lincoln, NE 68506, (402) 488–0985. Transporting *general commodites* (except classes A and B explosives, household goods, and commodities in bulk), between points in Lancaster County, NE, on the one hand, and, on the other, points in NE.

MC 148874 (Sub-10), filed August 16, 1982. Applicant: PROFICIENT FOOD COMPANY, 17872 Cartwright Road, Irvine, CA 92705. Representative: Floyd L. Farano, 2555 E. Chapman Ave., Suite 415, Fullerton, CA 92631, (714) 773–4111.

Transporting *alcoholic beverages,* between points in MI, IN, KY, FL, NY, MO, CT, MD, CA, and IL, under continuing contract(s) with Federated Industries, Inc., of Chicago, IL.

MC 153915 (Sub-2), filed August 17, 1982. Applicant: FLORIDA EXPRESS CARRIER, INC., One Malaga Street, St. Augustine, FL 32084. Representative: Mark J. Andrews, Suite 1100, 1660 L Street, N.W., Washington, DC 20036, (202) 452–7438. Transporting *general commodities* (except household goods, commodities in bulk and classes A and B explosives), between points in NC, SC, GA, AL and FL.

MC 154405 (Sub-2), filed August 19, 1982. Applicant: JAMES GOAD, d.b.a. JOPLIN PITTSBURG EXPRESS, Route 2, Box 4, Liberal, MO 64762. Representative: Bruce McCurry, 910 Plaza Towers, Springfield, MO 65804, (417) 883–7311. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in Jasper County, MO, Benton and Washington Counties, AR, Anderson, Franklin, Johnson, Linn, Miami, Montgomery, and Wilson Counties, KS, and Adair, Cherokee, Craig, Delaware, Mayes, Nowatta, Rogers, Tulsa, Wagoner, and Washington Counties, OK.

MC 160534, filed August 18, 1982. Applicant: VANDOLF PARISH, d/b/a/ PARISH CHARTER LINES, 148 Hedge Rd., Menlo Park, CA 94025. Representative: Vandolf Parish (same address as applicant), (415) 325–7275. Transporting *passengers and their baggage,* in charter and special operations, beginning at points in San Francisco, San Mateo, Santa Clara, Marin, Alameda, and Contra Costa Counties, CA, and extending to points in CA, OR, WA, ID, UT, NE, AZ, and NM.

MC 163465, filed August 19, 1982. Applicant: MARION EXPRESS, INC., 2079 Canaan Township Rd., Edison, OH 43320. Representative: Edward G. Bazelon, 29 South LaSalle St., Suite 905, Chicago, IL 60603. Transporting *general commodities* (except classes A and B explosives, household goods, and commodities in bulk), between points in the U.S. (except AK and HI), under continuing contract(s) with (1) Field Container Corporation, of Elk Grove Village, IL, (2) Eastfield Corporation, of Baltimore, MD, (3) Southfield Corporation of Tuscaloosa, AL and (4) J. G. Clark Corporation, of Edison, OH.

MC 163505, filed August 23, 1982. Applicant: EDUCATIONAL TRAVEL EXPERIENCES, INC., 1325 North West St., P.O. Box 603, Carlisle, PA 17013. Representative: Clyde M. Barr, Jr. (same address as applicant), (717) 245–2826. As a *broker,* at Carlisle, PA, in arranging for the transportation by motor vehicle of *passengers and their baggage,* between points in U.S.

Volume No. OP4–316

Decided: August 31, 1982.

By the Commission, Review Board No. 2, Members Carleton, Ewing, and Williams. (Member Ewing not participating.)

MC 106956 (Sub-11), filed August 23, 1982. Applicant: SYLVESTER TRUCKING CO., 7901 Sylvania Ave., Sylvania, OH 43560. Representative: Wilhelmina Boersma, 1600 First Federal Bldg., Detroit, MI 48226, (313) 964–6492. Transporting *metal products,* between points in OH and GA.

MC 118696 (Sub-50), filed August 23, 1982. Applicant: FERREE FURNITURE EXPRESS, INC., 252 Wildwood Rd., Hammond, IN 46234. Representative: John F. Wickes, Jr., 1301 Merchants Plaza, Indianapolis, IN 46204, (317) 638–1301. Transporting *general commodities* (except classes A and B explosives, household goods and commodities in bulk), between points in the U.S. (except AK and HI), under continuing contract(s) with ITOFCA, Inc. of Downers Grove, IL.

MC 145217 (Sub-6), filed August 23, 1982. Applicant: RICHARD McNAY, INC., Rural Route 8, Quincy, IL 62301. Representative: Joel H. Steiner, 29 S LaSalle St., Suite 905, Chicago, IL 60603. Transporting *lime, limestone* and *limestone products,* between points in St. Genevieve County, MO, on the one hand, and, on the other, points in IL, MO and IA.

MC 148616 (Sub-7), filed August 23, 1982. Applicant: TRANSPORT WEST, INC., P.O. Box 2015, Eugene, OR 97402. Representative: Gene E. Cook (same address as applicant), (503) 689–6615. Transporting *general commodities* (except classes A and B explosives, household goods and commodities in bulk), between points in AZ, CA, CO, ID, MT, NM, NV, OK, OR, TX, UT, WA and WY.

MC 152726 (Sub-3), filed August 20, 1982. Applicant: CENTRAL VALLEY TRANSPORTATION, INC., P.O. Box 125, Howard, PA 16841. Representative: Raymond A. Richards, 35 Curtice Park, Webster, NY 14580, (716) 265–9510. Transporting *scrap materials,* between points in NY, NJ and PA.

MC 160286 (Sub-1), filed August 20, 1982. Applicant: GARY WAYNE RUSHING, d.b.a. CHUCKWAGON TRUCKING, P.O. Box 542, Cold Springs, TX 77331. Representative: Claude E. Ferebee, 3910 FM 1960 West, Suite 106, Houston, TX 77068, (713) 537–8156. Transporting *Mercer commodities,* between points in AR, CO, LA, MS, NM, OK, TX and WY.

MC 163496, filed August 20, 1982. Applicant: L. B. GUIGNARD, INC., P.O. Box 26067, Charlotte, NC 28213. Representative: Charles Ephriam, 918 16th St., NW, Suite 406, Washington, DC 20006, (202) 833–1170. Transporting *general commodities* (except classes A and B explosives and household goods), between points in the U.S. (except AK and HI), under continuing contract(s) with Quaker State Oil Refining Corp. of Oil City, PA, National Gypsum Company of Charlotte, NC, Bowater Carolina Company of Catawba, SC and Bowater Southern Paper Company of Calhoun, TN. Condition: The person or persons who appear to be engaged in common control of applicant and another regulated carrier must either file an application under 49 U.S.C. 11343(A) or submit an affidavit indicating why such approval is unnecessary to the Secretary's office. In order to expedite issuance of any authority, please submit a copy of the affidavit or proof of filing the application for common control to Team 4, Room 2410.

MC 163506, filed August 23, 1982. Applicant: ANDREW CANNIZZARO, d.b.a. ROLAND LEASING, 72–10th St., Woodbridge, NJ 07075. Representative: Michael R. Werner, 241 Cedar Lane, Teaneck, NJ 07666, (201) 836–1144. Transporting *chemicals and related products,* between points in NJ, on the one hand, and, on the other, points in, RI, NY, PA, KY, VA, MD, IL and IN.

Volume No. OP4–318

Decided: August 31, 1982.

By the Commission, Review Board No. 2, Members Carleton, Ewing, and Williams. (Member Ewing not participating.)

MC 128866 (Sub-62), filed August 24, 1982. Applicant: B&B TRUCKING, INC., P.O. Box 2830, Cresson Rd. & I–295, Cherry Hill, NJ 08034. Representative: James A. Caulfield, 4801 Massachusetts Ave., N.W., Washington, DC 20016, (202) 686–0995. Transporting *frozen foods,* between points in the U.S., under continuing contract(s) with The Kitchens of Sara Lee, Inc., of Deerfield, IL.

MC 152896 (Sub-2), filed August 23, 1982. Applicant: ROY NEAL WHEELER, SR., ROY NEAL WHEELER, JR., and PHILIP VERNE WHEELER, d.b.a WHEELER & SONS TRUCKING, 1607 Oro Dam Blvd. West, Oroville, CA 95965. Representative: Robert G. Harrison, 4299 James Dr., Carson City, NV 89701, (702) 882–5649. Transporting *metal articles, building and construction materials, wood products, clay,*

concrete, glass or stone products, and *ores and minerals,* between points in WA, OR, CA, NV, MT, ID, UT, AZ, NM, CO, WY, TX, LA, FL, IL, IN.

MC 163516, filed August 24, 1982. Applicant: EVERIDGE BROS. TRUCKING, INC., P.O. Box 6, Lilly, GA 31051. Representative: J. L. Fant, P.O. Box 577, Jonesboro, GA 30237, (404) 477–1525. Transporting *general commodities* (except classes A and B explosives, and household goods), between points in AL, FL, and GA, under continuing contract(s) with International Minerals and Chemical Corporation, of Americus, GA.

MC 163526, filed August 23, 1982. Applicant: TRINITY PAPER & PLASTICS, INC., 529 5th Ave. New York, NY 10017. Representative: Ronald I. Shapss, 450 7th Ave., New York, NY 10123, (212) 239–4610. Transporting (1) *general commodities* (except classes A and B explosvies, household goods, and commodities in bulk), between points in the U.S. (except AK and HI), under continuing contract(s) with TG & Y Stores Company, of Oklahoma City, OK; and (2) *rubber and plastic products,* between points in the U.S. (except AK and HI), under continuing contract(s) with Southern Petro Chemical, Inc., of Roswell, GA.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-24463 Filed 9-3-82; 8:45 am]

BILLING CODE 7035-01-M

Motor Carriers; Permanent Authority Decisions; Decision-Notice

The following applications, filed on or after February 9, 1981, are governed by Special Rule of the Commission's Rules of Practice, see 49 CFR 1100.251. Special Rule 251 was published in the **Federal Register** on December 31, 1980, at 45 FR 86771. For compliance procedures, refer to the **Federal Register** issue of December 3, 1980, at 45 FR 80109.

Persons wishing to oppose an application must follow the rules under 49 CFR 1100.252. Applications may be protested *only* on the grounds that applicant is not fit, willing, and able to provide the transportation service or to comply with the appropriate statutes and Commission regulations. A copy of any application, including all supporting evidence, can be obtained from applicant's representative upon request and payment to applicant's representative of $10.00.

Amendments to the request for authority are not allowed. Some of the applications may have been modified prior to publication to conform to the Commission's policy of simplifying grants of operating authority.

Findings

With the exception of those applications involving duly noted problems (e.g., unresolved common control, fitness, water carrier dual operations, or jurisdictional questions) we find, preliminarily, that each applicant has demonstrated a public need for the proposed operations and that it is fit, willing, and able to perform the service proposed, and to conform to the requirements of Title 49, Subtitle IV, United States Code, and the Commission's regulations. This presumption shall not be deemed to exist where the application is opposed. Except where noted, this decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In the absence of legally sufficient opposition in the form of verified statements filed on or before 45 days from date of publication (or, if the application later become unopposed), appropriate authorizing documents will be issued to applicants with regulated operations (except those with duly noted problems) and will remain in full effect only as long as the applicant maintains appropriate compliance. The unopposed applications involving new entrants will be subject to the issuance of an effective notice setting forth the compliance requirements which must be satisfied before the authority will be issued. Once this compliance is met, the authority will be issued.

Within 60 days after publication an applicant may file a verified statement in rebuttal to any statement in opposition.

To the extent that any of the authority granted may duplicate an applicant's other authority, the duplication shall be construed as conferring only a single operating right.

Note.—All applications are for authority to operate as a motor common carrier in interstate or foreign commerce over irregular routes, unless noted otherwise. Applications for motor contract carrier authority are those where service is for a named shipper "under contract".

Please direct status inquiries to the Ombudsman's Office, (202) 275–7326.

Volume No. OP2–204

Decided: August 27, 1982.

By the Commission, Review Board No. 1, Members Parker, Chandler, and Fortier.

MC 163362, filed August 12, 1982. Applicant: BOYD MURPHY, JR., 1481–6530 Rd., Montrose, CO 81401. Representative: Boyd Murphy, Jr. (same address as applicant), (303) 249–3380. Transporting *food and other edible products and byproducts intended for human consumption* (except alcoholic beverages and drugs), *agriculture lime stone and fertilizers, and other soil conditioners* by the owner of the motor vehicle in such vehicle, between points in the U.S. (except AK and HI).

MC 163363, filed August 12, 1982. Applicant: TIM CHENOWETH d.b.a. CHENOWETH TRANSIT, Rt. 1, Stark City, MO 64866. Representative: Tim Chenoweth (same address as applicant), (417) 638–5369. Transporting *food and other edible products and byproducts* intended for human consumption (except alcoholic beverages and drugs), *agricultural limestone and fertilizers and other soil conditioners,* by the owner of the motor vehicle in the vehicle, between points in the U.S. (except AK and HI).

MC 163453, filed August 16, 1982. Applicant: R & M DISTRIBUTORS, INC., 9 Carriage Lane, Canton, MA 02021. Representative: David M. Marshall, 101 State St., Suite 304, Springfield, MA 01103, (413) 732–1136. As a *broker* of *general commodities* (except household goods), between points in the U.S. (except AK and HI).

Volume No. OP3–136

Decided: August 30, 1982.

By the Commission, Review Board No. 2, Members Carleton, Williams, and Ewing. (Member Ewing not participating.)

MC 116325 (Sub-95), filed August 16, 1982. Applicant: JENNINGS BOND, d.b.a BOND ENTERPRISES, P.O. Box 8, Lutesville, MO 63762. Representative: Jennings Bond (same address as applicant), (314) 238–2601. As a *broker* of *general commodities* (except household goods), between points in the U.S.

MC 152744 (Sub-11), filed August 16, 1982. Applicant: CITADEL TRANSPORT, INC., 180 N. Michigan Avenue, Suite 400, Chicago, IL 60601. Representative: Thomas M. O'Brien, (same address as applicant), (312) 263–1600. Transporting for or on behalf of the United States Government, *general commodities* (except used household goods, hazardous or secret materials, and sensitive weapons and munitions), between points in the U.S. (except AK and HI).

MC 155244 (Sub-1), filed August 13, 1982. Applicant: TOTAL ARMORED CAR SERVICE, INC., 13800 W. Seven Mile Rd., Detroit, MI 48235. Representative: William B. Elmer, 615 E. Eighth St., P.O. Box 801, Traverse City,

MI 49685–0801, (616) 941–5313. Transporting *shipments weighing 100 pounds or less* if transported in a motor vehicle in which no one package exceeds 100 pounds, between points in the U.S. (except AK and HI).

MC 156374 (Sub-1), filed August 19, 1982. Applicant: OVERLAND TRANSPORT, INC., 8125 Rosebank Ave., Baltimore, MD 21222. Representative: Mark D. Russell, Suite 348, Pennsylvania Bldg., 425 13th St. NW., Washington, D.C. 20004, (202) 737–2188. Transporting for or on behalf of the U.S. Government, *general commodities* (except used household goods, hazardous or secet materials, and sensitive weapons and munitions), between points in the U.S. (except AK and HI).

MC 163264, filed August 4, 1982. Applicant: MITCH GIBBON, d.b.a. MITCH GIBBON TRUCKING, RR 1, Fargo, ND 58103. Representative: Betty Nygaard, Box 682, W. Fargo, ND 58078, (701) 282–5014. Transporting *food and other edible products and byproducts intended for human consumption* (except alcoholic beverages and drugs), *agricultural limestone and fertilizer, and other soil conditioners* by the owner of the motor vehicle in such vehicle, between points in the U.S. (except HI).

MC 163415, filed August 16, 1982. Applicant: B & E TRANSPORTATION BROKERS, INC., 970 Kensington Avenue, Buffalo, NY 14215. Representative: Ronald W. Malin, Bankers of Trust Bldg., 4th Floor, Jamestown, NY 14701, (716) 664–5210. As a *broker* of *general commodities* (except household goods), between points in the U.S. (except AK and HI).

MC 163475, filed August 19, 1982. Applicant: R.G.V. INC., P.O. Box 265, Tavares, FL 32778. Representative: E. Stephen Heisley, 1919 Pennsylvania Ave. NW., Suite 500, Washington, DC 20006, (202) 828–5015. As a *broker* of *general commodities* (except household goods), between points in the U.S. (except AK and HI).

Volume No. OP4–317

Decided: August 31, 1982.

By the Commission, Review Board No. 2, Members Carleton, Ewing, and Williams. (Member Ewing not participating.)

MC 163456, filed August 18, 1982. Applicant: HENRY A. LYNCH TRUCKING COMPANY, INC., 6710 Forrest Ave., P.O. Box 470, Blanchard, LA 71009. Representative: Henry A. Lynch (same address as applicant), (318) 929–3098. Transporting *food and other edible products and byproducts intended for human consumption* (except alcoholic beverages and drugs), *agricultural limestone and fertilizers, and other soil conditioners* by the owner of the motor vehicle in such vehicle, between points in the U.S. (except AK and HI).

MC 163536, filed August 24, 1982. Applicant: ADVERTISING DISTRIBUTORS OF MARYLAND, INC., d.b.a. HARTE-HANKS TRANSPORTATION SERVICES, 100 Alco Place, Baltimore, MD 21227. Representative: Richard S. Ewing, 1200 New Hampshire Ave. NW., Washington, DC 20036, (202) 872–6671. As a broker of *general commodities* (except household goods), between points in the U.S. (except AK and HI).

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-24462 Filed 9-3-82; 8:45 am]

BILLING CODE 7035-01-M

[Volume No. 292]

Motor Carriers; Permanent Authority Decisions; Restriction Removals; Decision-Notice

Decided: August 31, 1982.

The following restriction removal applications, filed after December 28, 1980, are governed by 49 CFR 1137. Part 1137 was published in the **Federal Register** of December 31, 1980, at 45 FR 86747.

Persons wishing to file a comment to an application must follow the rules under 49 CFR 1137.12. A copy of any application can be obtained from any applicant upon request and payment to applicant of $10.00.

Amendments to the restriction removal applications are not allowed.

Some of the applications may have been modified prior to publication to conform to the special provisions applicable to restriction removal.

Canadian Carrier Applicants: In the event an application to transport property, filed by a Canadian domiciled motor carrier, is unopposed, it will be reopened on the Commission's own motion for receipt of additional evidence and further consideration in light of the record developed in Ex Parte No. MC–157, *Investigation Into Canadian Law and Policy Regarding Applications of American Motor Carriers For Canadian Operating Authority.*

Findings

We find, preliminarily, that each applicant has demonstrated that its requested removal of restrictions or broadening of unduly narrow authority is consistent with the criteria set forth in 49 U.S.C. 10922(h).

In the absence of comments filed within 25 days of publication of this decision-notice, appropriate reformed authority will be issued to each applicant. Prior to beginning operations under the newly issued authority, compliance must be made with the normal statutory and regulatory requirements for common and contract carriers.

By the Commission, Restriction Removal Board, Members Shaffer, Higgins, and Williams.

Agatha L. Mergenovich,

Secretary.

FF 500 (Sub-2)X, filed August 23, 1982. Applicant: SURF-AIR, INC., 2090 Jonesboro Road, S.E., Atlanta, Georgia 30315. Representative: William W. West (same address as applicant). Lead permit: Broaden general commodities (except classes A and B explosives, household goods as defined by the Commission, commodities which because of size or weight require use of special equipment, motor vehicles and unaccompanied baggage, to "general commodities (except classes A and B explosives and household goods as defined by the Commission)" and remove restriction to transportation of shipments having immediate prior or subsequent air forwarder service.

FF–521 (Sub-2)X, filed August 19, 1982. Applicant: HARBOUR FORWARDING CO., INC., P.O. Box 4–3050, Anchorage, AK 99509. Representative: Robert J. Gallagher, 1000 Connecticut Ave., N.W., Suite 1200, Washington, DC 20036. No. FF–521F permit, (1) broaden used household goods to "household goods;" and (2) remove the restriction against the transportation of import-export traffic.

MC -2736 (Sub-2)X, filed August 19, 1982. Applicant: L. S. DAY MOVING AND STORAGE, INC., 109 Westboro St., Dayton, OH 45408. Representative: Earl N. Merwin, 85 East Gay St., Columbus, OH 43215. Sub-No. 1 certificate, broaden (1) to "household goods and furniture and fixtures" from household goods; and (2) to countywide: Butler, Champaign, Clark, Clinton, Darke, Greene, Miami, Montgomery, Preble and Warren Counties, OH (Dayton and points within 25 miles thereof).

MC 10223 (Sub-13)X, filed August 11, 1982. Applicant: CARL BROWN, ESTELLE FUNK, and ALBERT R. FUNK, A Partnership, d.b.a. MACK TRANSPORTATION COMPANY, 4330 Torresdale Ave., Philadelphia, PA 19124. Representative: Francis W. Doyle, 323 Maple Ave., Southampton, PA 18966. Lead and Subs 3, 4, 7, 9, 11 and 12 certificates: (A) Remove (1) all

exceptions from its general commodities authority, except classes A and B explosives, household goods and commodities in bulk, lead and Sub 3; (2) "originating at and/or destined to" restriction at named points, lead and Subs 3, 7, and 12; (3) "except in bulk" restriction, Subs 4 and 12; (B) broaden to (1) county-wide authority: (a) lead, Essex County, NJ and Bucks County, PA (Bloomfield, NJ and Langhorne, PA); (b) lead and Subs 3, 4, 7, Philadelphia, Montgomery, Chester, Delaware and Bucks Counties, PA, and Hunterdon, Mercer, Monmouth, Burlington, Camden, Gloucester and Salem Counties, NJ and New Castle County, DE (Philadelphia, or facilities at Philadelphia, PA); (c) Sub 9, Essex County, NJ and Bucks, Delaware and Montgomery Counties, PA (facilities at Bloomfield, NJ, and Langhorne, Springfield and Montgomeryville, PA); (d) Sub 11, Middlesex County, NJ (facilities at Edison Township); and, (e) Sub 12, Lehigh County, PA (facilities at Fogelsville); and (2) radial authority, Subs 4, 7 and 9.

MC 118475 (Sub-6)X, filed August 20, 1982. Applicant: H & S WAREHOUSE, INC., P.O. Box 227, Fairbanks, AK 99701. Representative: Arthur R. Hauver, Suite 200, 750 West Second Ave., Anchorage, AK 99501. Sub 2 certificate, (1) eliminate all restrictions in the general commodities authority "except classes A and B explosives, and commodities in bulk;" (2) broaden the territorial description to: Third and Fourth Judicial Districts, AK (from Valdez and Fairbanks); and (3) eliminate restrictions against service at territories less extensive than county-wide: (a) "points on the Kenai Peninsula south of an imaginary line running east-west through Girdwood, AK, and points east of an imaginary line constituting a southward extension of the U.S. (Alaska)-Canada (Yukon Territory) Boundary line, other than Haines, AK" in the general commodities authority; and (b) "points east of an imaginary line consituting a southward extension of the U.S. (Alaska)-Canada (Yukon Territory) Boundary line, other than Haines and Juneau, AK" in the household goods authority.

MC 134134 (Sub-108)X, filed July 20, 1982. Applicant: MAINLINER MOTOR EXPRESS, INC., 4202 Dahlman Ave., Omaha, NE 68107. Representative: James F. Crosby, 7363 Pacific St., Suite 210B, Omaha, NE 68114. No. MC–128801 and Subs 2, 5, and 8F permits (acquired in MC–F–14822): broaden to (1) "food and related products" from fresh and/or frozen meats, lead and Sub 5; (2) "metal products and waste or scrap materials not identified by industry producing" from non-ferrous metals and alloys, and scrap non-ferrous metal articles, Sub-2; and (3) "metal products" from aluminum plate, aluminum sheet, and aluminum blanks, Sub-8F; and (B) "between points in the U.S. (except Alaska and Hawaii)" under continuing contract(s) with named shippers, all Subs.

MC 136647 (Sub-23)X9, filed July 12, 1982. Applicant: GREEN MOUNTAIN CARRIERS, INC., P.O. Box 1319, Albany, NY 12201. Representative: James M. Burns, 1383 Main Street, Suite 413, Springfield, MA 01103. No. MC–136647 Subs 18 and 19 certificates and No. MC–143989 and Subs 1, 2, 3, and 5F permits (1) expand printing paper to "pulp, paper, and related products" and bananas to "food and related products" in Sub 19; (2) authorize county wide authority for city wide authority as follows: Clinton County, NY for Rouses Point, NY; Passaic County, NJ for Little Falls and Clifton, NJ; Cuyahoga, Lake, Lorain, Medina, Summit, and Geauga Counties, OH for Cleveland, OH; Cook County, IL for Niles, IL; De Kalb County, GA for Chamblee, GA; Cobb, Clayton, Douglas, Fayette, Henry, Rockdale, Gwinett, De Kalb and Fulton Counties, GA for Atlanta, GA; Bergen, Hudson, Middlesex, Morris, Passaic, Union, and Essex Counties, NJ and Bronx, Kings, New York, Queens and Richmond Counties, NY, for Newark, NJ; Ocean County, NJ for Lakewood, NJ; Oakland, Macomb, Monroe, Wastenaw, St. Clair, Livingston, and Wayne Counties, MI for Detroit, MI; and Will, Kane, Lake, and McHenry and Cook and DuPage Counties, IL and Lake and Porter Counties, MI for Chicago, IL in Sub 18; Clinton County, NY for Rouses Point, NY; Lake, Cuyahoga, Lorain, Medina, Summit and Geauga Counties, OH for Cleveland, OH; Johnson County, KS for Lenexa, KS; Dallas County, TX for Mesquite, TX; Orange, Ventura, Los Angeles Counties, CA for Los Angeles, CA; Snohomish, Kitsap, and King Counties, WA for Seattle, WA; De Kalb County, GA for Chamblee, GA; St. Lawrence County, NY for Newton Falls, NY; Windham County, VT for Bratteboro, VT; Albany County, NY for Albany, NY, in Sub 19; (3) to radial authority in Subs 18 and 19; (4) eliminate the "in vehicles equipped with mechanical temperature control units" restriction in Sub 18; (5) delete plantsite restrictions in Sub 18; in MC–143989 and Subs 1, 2, 3, and 5F permits: (6) broaden territorial description to between points in the U.S. under contract(s) with a named shipper in the lead and Subs 1, 2, and 3; (7) expand the commodity description from frozen food stuffs to "food and related products" in Sub 3; from plastic materials to "rubber and plastic products" in Sub 5F; from printing paper (except newsprint), to "pulp, paper, and related products" in the lead and Subs 1 and 2.

MC 144218 (Sub-11)X, filed August 18, 1982. Applicant: FELDSPAR TRUCKING COMPANY, INC., P.O. Box 858, Spruce Pine, NC 28777. Representative: Joseph L. Steinfeld, Jr., 915 Pennsylvania Bldg., 425–13th Street, N.W., Washington, DC 20004. Sub 9 certificate: Broaden (1) olivine to "clay, concrete, glass or stone products", and (2) to radial authority.

MC 144329 (Sub-5)X, filed August 19, 1982. Applicant: JOE RIDDLE AND CHARLES RIDDLE d.b.a. RIDDLE TRUCKING COMPANY, Rt. 6, Tazewell, TN 37879. Representative: William P. Jackson, Jr., P.O. Box 1240, Arlington, VA 22210. Lead and Subs 1F and 4F, (1) broaden (a) coal, in bulk, in dump vehicles to "commodities in bulk", in lead and Sub 4, and (b) stone and gravel, in dump trucks to "clay, concrete, glass or stone products, and ores and minerals", in Sub 1; and (2) change one-way to radial authority in lead and all Subs.

MC 146574 (Sub-6)X, filed August 20, 1982. Applicant: PARKER BROTHERS TRUCKING CORPORATION, 322 Bacon St., Lake City, MI 49651. Representative: Karl L. Gotting, 1200 Bank of Lansing Bldg., Lansing, MI 48933. Sub 4 permit: (1) Broaden raw forgings and steel to "metal and metal products", and (2) expand the territorial description to "between points in the U.S. under continuing contract(s) with named shippers."

MC 146827 (Sub-4)X, filed August 19, 1982. Applicant: DONOVAN L. SPRY, d.b.a. W. J. SPRY & SONS, P.O. Box 36, Chili, WI 54420. Representative: Richard A. Westley, 4506 Regent St., Suite 100, P.O. Box 5086, Madison, WI 53705–0086. Sub 2F certificate: Broaden territorial description from Chili, Granton and Neilsville to Clark County, WI.

MC 146909 (Sub-2)X, filed August 20, 1982. Applicant: PIONEER VAN LINES, INC., 1810 Park Place Bldg., Seattle, WA 98101. Representative: J. G. Dail, Jr., P.O. Box LL, McLean, VA 22101. Sub 1X certificate: remove the restriction prohibiting the transportation of traffic to "points in the Alaska Panhandle located east of an imaginary line constituting a southward extension of the U.S. (Alaska)-Canada (Yukon Territory) boundary line," defining a territory less extension than a county-wide equivalent.

MC 147746 (Sub-5)X, filed August 24, 1982. Applicant: TRI-UNION EXPRESS, INC., 3680 179th St., Hammond, IN

46323. Representative: Kenneth F. Dudley, P.O. Box 279, Ottumwa, IA 52501. Sub-1 certificate: Broaden (1) iron and steel articles to "metal products"; and (2) Chicago, IL to Cook, Du Page, Kane, Lake and Will Counties, IL, and Lake and Porter Counties, IN.

MC 148383 (Sub-3)X, filed August 24, 1982. Applicant: H. PRUITT TRUCKING, INC., 2333 Wadsworth, Saginaw, MI 48601. Representative: Robert E. McFarland, 2855 Coolidge Rd., Suite 201A, Troy, MI 48084. Sub 2F permit, broaden (1) To "commodities in bulk," from waste and reclaimed petroleum and petroleum products, in bulk, in tank vehicles, and petroleum and petroleum products, in bulk, in tank vehicles; and (2) to "between points in the U.S.," under continuing contract(s) with the named shipper.

MC 152125 (Sub-3)X, filed August 24, 1982. Applicant: MIDWEST CONTAINER SERVICES, INC., 5717 Hamlet Ave., Cleveland, OH 44115. Representative: Marvin L. Szymkowicz, Suite 310, 1725 Eye St., N.W., Washington, DC 20006. Sub 2F certificate, remove restriction limiting service "in foreign commerce only," and substitute: "in interstate or foreign commerce."

MC 158445 (Sub-1)X, filed August 24, 1982. Applicant: DAN PATCH MOTOR FREIGHT, INC., Box 5, Route 22A, Bridport, VT 05734. Representative: Mark L. Sperry, P.O. Drawer 351, Middlebury, VT 05753. Lead permit: broaden the territorial description to between points in the U.S., under continuing contract(s) with named shipper.

[FR Doc. 82-24461 Filed 9-3-82; 8:45 am]
BILLING CODE 7035-01-M

[Finance Docket No. 30014]

Rail Carriers; Carolina and Northwestern Railway Company—Trackage Rights Over Norfolk and Western Railway Company Exemption; Notice of Exemption

August 31, 1982.

Carolina and Northwestern Railway Company (C&NW) and Norfolk and Western Railway Company (NW), commonly controlled rail carriers, filed a notice of exemption under 49 U.S.C. 10505 and 49 CFR 111.2(d)(3), notifying the Commission that NW agreed to grant C&NW trackage rights in the City of Chesapeake, VA, effective August 18, 1982. The trackage rights will extend from Milepost V-4.92 on NW's Sewells Point Branch line to Milepost N-2.5 on NW's Lambert's Point line and over the existing connection to Milepost S-1.5 at NS Junction, a distance of approximately 1 mile.

The transaction falls within the exemption described at 1111.2(d)(3) because (1) the transaction involves two subsidiaries which are operated as part of one corporate family; (2) no significant service or operational changes are proposed; and (3) there will be no change in the competitive balance with carriers outside the corporate family.

As a condition to use of the exemption, the employee protective conditions set forth in *Norfolk and Western Ry. Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified by *Mendocino Coast Ry., Inc.,—Lease and Operate*, 360 I.C.C. 653 (1980) will be imposed. This will satisfy the statutory requirements of 49 U.S.C. 10505(g)(2).

By the Commission, Heber P. Hardy, Director, Office of Proceedings.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 82-24459 Filed 9-3-82; 8:45 am]
BILLING CODE 7035-01-M

Motor Carriers; Permanent Authority Decisions; Decision-Notice

Correction

In FR Doc. 82-21273 appearing at page 34210, in the issue for Friday, August 6, 1982, the following applications were inadvertantly omitted. On page 34211, in the middle column, above "Volume No. OP2-174" insert the following:

MC 162442, filed July 20, 1982. Applicant: FRANK G. PROBST, d.b.a. F.G.P. & SONS, 1301 South Pearl St., Janesville, WI 53545. Representative: Richard A. Westley, 4506 Regent St., Suite 100, P.O. Box 5086, Madison, WI 53705-0086, 608-238-3119. Transporting *food and related products*, between points in the U.S. (except AK and HI), under continuing contract(s) with Seneca Foods Corporation, of Janesville, WI.

MC 162842, filed July 6, 1982. Applicant: ARTHUR O. FISK, 6079 South Avenue, Williamson, NY 14589. Representative: Arthur O. Fisk, (same as applicant), (315) 589-2239. Transporting *pulp, paper and related products*, between Newark, NY, on the one hand, and, on the other, points in NC, SC, AL, FL, GA and TN.

MC 162853, filed July 7, 1982. Applicant: PARADIS MAIL SERVICE, INC., Box 21E, Brooks, MN 56715. Representative: Thomas J. Van Osdel, 15 Broadway, Suite 502, Fargo, ND 58102, (701) 235-4487. Transporting *malt beverages* and *such commodities* as are dealt in or used by beverage distributors, between Milwaukee, WI and Grand Forks, ND, under a continuing contract(s) with McKinnon Company, Inc., of Grand Forks, ND.

BILLING CODE 1505-01-M

INTERNATIONAL DEVELOPMENT COOPERATION AGENCY

Agency for International Development

[Delegation of Authority No. 98]

Deputy Administrator and Assistant Administrators; Delegation of Authority

Pursuant to the authority delegated to me by IDCA Delegation of Authority No. 1 from the Director of the International Development Cooperation Agency (44 FR 57521) and in accordance with the provisions of section 624(b) of the Foreign Assistance Act of 1961, as amended (22 U.S.C. 2384), it is directed as follows:

In the event of the absence, death, resignation, or disability of the Administrator, the following designated officers of the Agency for International Development shall, in the order of succession indicated, act as Administrator:

(1) Deputy Administrator.

(2) Assistant Administrator for Program and Policy Coordination.

(3) Senior Assistant Administrator for Science and Technology.

This Delegation of Authority amends and supersedes Delegation of Authority No. 98 of January 19, 1982 (47 FR 5054, 5055).

This Delegation of Authority is effective immediately.

Dated: August 20, 1982.

M. Peter McPherson,

Administrator.

[FR Doc. 82-24467 Filed 9-3-82; 8:45 am]
BILLING CODE 6116-01-M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

National Advisory Committee on Occupational Safety and Health; Meeting

Notice is hereby given that the National Advisory Committee on Occupational Safety and Health (NACOSH) will meet in Washington, D.C. on September 23-24, 1982. The meeting will begin at 9:30 a.m. on Thursday September 23 in Room N-5437 of the Frances Perkins Department of

Labor Building (formerly the New Department of Labor Building), Third Street and Constitution Avenue, N.W., Washington, D.C. The public is invited to attend.

The National Advisory Committee was established under section 7(a) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 656) to advise the Secretary of Labor and the Secretary of Health and Human Services on matters relating to the Administration of the Act.

New members will be sworn in at this meeting. The agenda will include status reports on safety and health standards and discussions of matters concerning the Occupational Safety and Health Administration.

Written data or views concerning these agenda items may be submitted to the Division of Consumer Affairs. Such documents which are received before the scheduled meeting dates, preferably with 20 copies, will be presented to the Committee and included in the official record of the proceedings.

Anyone who wishes to make an oral presentation should notify the Division of Consumer Affairs before the meeting date. The request should include the amount of time desired, the capacity in which the person will appear and a brief outline of the content of the presentation. Oral presentations will be scheduled at the discretion of the chairperson of the Committee to the extent which time permits.

For additional information contact: Clarence Page, Division of Consumer Affairs, Occupational Safety and Health Administration, Room N–3635, Third Street and Constitution Avenue N.W., Washington, D.C. 20210, Telephone (202) 523–8024.

Official records of the meeting will be available for public inspection at the Division of Consumer Affairs.

Signed at Washington, D.C. this 1st day of September 1982.

Thorne G. Auchter,

Assistant Secretary of Labor.

[FR Doc. 82–24544 Filed 9–3–82; 8:45 am]

BILLING CODE 4510–26–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (82–48)]

NASA Advisory Council (NAC); Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting postponement.

SUMMARY: The scheduled meeting on September 9–10, 1982, of the NAC, Space Systems and Technology Advisory Committee, Ad Hoc Informal Advisory Subcommittee on Computer Sciences, published in the **Federal Register** August 12, 1982 (47 FR 35049), has been postponed until further notice.

FOR FURTHER INFORMATION CONTACT: Mr. Lee B. Holcomb, National Aeronautics and Space Administration, Code RTC–6, Washington, D.C. 20546 (202/755–2364).

Richard L. Daniels,

Director, Management Support Office, Office of Management.

August 31, 1982.

[FR Doc. 82–24477 Filed 9–3–82; 8:45 am]

BILLING CODE 7510–01–M

NATIONAL COMMISSION ON SOCIAL SECURITY REFORM

Meeting

AGENCY: National Commission on Social Security Reform.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forth-coming meeting of the National Commission on Social Security Reform. This notice also describes the functions of the Commission. Notice of this meeting is required under Section 10(a)(2) of the Federal Advisory Committee Act. This document is intended to notify the general public of their opportunity to attend.

DATE: September 20, 1982, 2:00 p.m. to 6:00 p.m.

ADDRESS: Room 2172 Rayburn House Office Building, Washington, DC 20515.

FOR FURTHER INFORMATION CONTACT: Robert J. Myers, Executive Director, 736 Jackson Place, NW., Washington, DC 20503; Telephone (202) 395–5132.

SUPPLEMENTARY INFORMATION: The National Commission on Social Security Reform is established by Executive Order No. 12335 dated December 16, 1981 to provide appropriate recommendations to the Secretary of Health and Human Services, the President, and the Congress on long-term reforms to put Social Security back on a sound financial footing.

The meeting of the Commission is open to the public. The proposed agenda includes:

Discussion on the financial status of the Social Security program in the 1980s and 1990s.

Such new business as the Chairman or the membership may put before the Commission.

Records are kept of all Commission proceedings, and are available for public inspection at the office of The Executive Director, National Commission on Social Security Reform, 736 Jackson Place, NW., Washington, DC 20503.

Robert J. Myers,

Executive Director.

[FR Doc. 82–24502 Filed 9–3–82; 8:45 am]

BILLING CODE 3115–01–M

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards; Meeting

In accordance with the purposes of Sections 29 and 182b. of the Atomic Energy Act (42 U.S.C. 2039, 2232b.), the Advisory Committee on Reactor Safeguards will hold a meeting on September 9–11, 1982, in Room 1046, 1717 H Street, NW., Washington, DC. Notice of this meeting was published in the **Federal Register** on August 25, 1982 (47 FR 37319).

The agenda for the subject meeting will be as follows:

Thursday, September 9, 1982

8:30 A.M.–8:45 A.M.: Opening Session (Open)—The Committee will hear and discuss the report of the ACRS Chairman regarding miscellaneous matters relating to ACRS activities.

8:45 A.M.–3:30 P.M.: Safety Goals for Nuclear Power Plants (Open)—The Committee will hear the report of its Subcommittee regarding proposed Safety Goals for nuclear power plants, the proposed NRC Action Plan for implementation of the Safety Goals and proposed rules for backfitting of safety related improvements in nuclear power plants. The Committee will also meet with members of the NRC Staff to hear reports on and to discuss these topics.

Portions of this session will be closed as necessary to discuss information the premature release of which would be likely to significantly frustrate the performance of the Committee's statutory function.

3:30 P.M.–5:30 P.M.: Consideration of Severe Accidents in Nuclear Reactor Regulation (Open)—The members of the Committee will hear the report of the ACRS Subcommittee regarding consideration of severe accidents and related views on nuclear reactor regulation. The Committee will meet with representatives of the NRC Staff to hear reports on and to discuss this matter.

Portions of this session will be closed as necessary to discuss information the premature release of which would be likely to significantly frustrate the performance of the Committee's statutory function.

5:30 P.M.–6:00 P.M.: Future ACRS Activities (Open)—The members will discuss anticipated ACRS Subcommittee activity and proposed ACRS activities including review of the CRBR.

Friday, September 10, 1982

8:30 A.M.–9:30 A.M.: Human Factors Integrated Program Plan (Open)—The members of the Committee will hear the report of its Subcommittee and consultants who may be present regarding the proposed NRC Action Plan for an integrated human factors program. The Committee will also meet with representatives of the NRC Staff to hear reports on and to discuss this matter.

9:30 A.M.–10:15 A.M.: Naval Reactors Program (Closed)—The Committee will meet with representatives of DOE, Naval Reactors, to discuss naval reactors policies, practices and operating experience.

This session will be closed to permit discussion of classified information applicable to naval reactors.

10:15 A.M.–12:15 P.M.: Transportation of Radioactive Materials (Open)—The ACRS members will hear the report of its Subcommittee and consultants who may be present regarding the proposed NRC rule (10 CFR Part 71) regarding packaging of radioactive materials for shipment and NRC procedures for certification of packages for shipment of radioactive materials.

1:00 P.M.–2:00 P.M.: Discuss topics for Discussion with NRC Commissioners (Open)—The ACRS members will discuss proposed topics for discussion with the NRC Commissioners including safety goals for nuclear power plants and consideration of severe accidents in the regulatory process.

2:00 P.M.–3:30 P.M.: Meeting with NRC Commissioners (Open)—The members of the Committee will meet with the NRC Commissioners to discuss items noted above.

3:30 P.M.–4:30 P.M.: Regulatory Activities (Open)—The Committee will hear and discuss the reports of its subcommittees on safety related issues including proposed changes in NRC Rules and Regulatory Guides such as Regulatory Guide 1.145, Revision 1, Atmospheric Dispersion Models for Potential Accident Consequence Assessments at Nuclear Power Plants and a report by the Reactor Operations Subcommittee.

4:30 P.M.–5:30 P.M.: Proposed ACRS Reports to NRC (Open)—The members of the Committee will discuss proposed ACRS reports on packaging of radioactive materials for shipment and reactor pressure vessel liquid level instrumentation.

Saturday, September 11, 1982

8:30 A.M.–12:30 P.M. and 1:30 P.M.–2:30 P.M.: Proposed ACRS Reports to NRC (Open)—The ACRS members will discuss proposed ACRS reports to NRC regarding items discussed during this meeting.

Procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on September 30, 1981 (46 FR 47903). In accordance with these procedures, oral or written statements may be presented by members of the public, recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Committee, its consultants, and Staff. Persons desiring to make oral statements should notify the ACRS Executive Director as far in advance as practicable so that appropriate arrangements can be made to allow the necessary time during the meeting for such statements. Use of still, motion picture and television cameras during this meeting may be limited to selected portions of the meeting as determined by the Chairman. Information regarding the time to be set aside for this purpose may be obtained by a telephone call to the ACRS Executive Director (R. F. Fraley) prior to the meeting. In view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the ACRS Executive Director if such rescheduling would result in major inconvenience.

I have determined in accordance with Subsection 10(d) of P.L. 92–463 that it is necessary to close portions of this meeting as noted above to discuss preliminary information the premature release of which would be likely to significantly frustrate the performance of the Committee's statutory function (5 U.S.C. 552b(c)(9)) and to discuss classified information (5 U.S.C. 552b(c)(1)).

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted can be obtained by a prepaid telephone call to the ACRS Executive Director, Mr. Raymond F. Fraley (telephone 202/634–3265), between 8:15 A.M. and 5:00 P.M. e.d.t.

Dated: August 31, 1982.

John C. Hoyle,

Advisory Committee Management Officer.

[FR Doc. 82–24520 Filed 9–3–82; 8:45 am]

BILLING CODE 7590–01–M

[Docket Nos. 50–440 and 50–441]

Availability of Final Environmental Statement for the Perry Nuclear Power Plant, Units 1 and 2

Notice is hereby given that the Final Environmental Statement (NUREG–0884) has been prepared by the Commission's Office of Nuclear Reactor Regulation related to the proposed operation of the Perry Nuclear Power Plant, Units 1 and 2, to be operated by the Cleveland Electric Illuminating Company. The Construction Permit holders are the Cleveland Electric Illuminating Company, the Duquesne Light Company, the Ohio Edison Company, the Pennsylvania Power Company and the Toledo Edison Company. The plant is located on the southern shore of Lake Erie, about 35 miles northeast of Cleveland, Ohio.

The Final Environmental Statement (FES) is available for inspection by the public in the Commission's Public Document Room at 1717 H Street, N.W., Washington, D.C. 20555, and at the Perry Public Library, 3753 Main Street, Perry, Ohio 44081. The FES is also being made available at the State Clearinghouse, Office of Budget and Management, 30 East Broad Street, 39th Floor, Columbus, Ohio 43215.

Requests for copies of NUREG–0884 should be addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Technical Information and Document Control.

The notice of availability of the Draft Environmental Statement for the Perry Nuclear Power Plant, Units 1 and 2, which requested comments from interested persons was published in the **Federal Register** on March 26, 1982 (47 FR 13067).

The comments received from Federal, State and local agencies, and interested members of the public have been included as appendices in the Final Environmental Statement.

Copies of the FES (NUREG–0884) may be purchased at current rates from the Division of Technical Information and Document Control, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. GPO Deposit Account Holders may charge their orders by calling (301) 492–9530. Copies are also available for purchase through the National Technical Information Service, Springfield, Virginia 22161.

Dated at Bethesda, Maryland this 27th day of August 1982.

For the Nuclear Regulatory Commission.

A. Bournia,

Acting Chief, Licensing Branch No. 2, Division of Licensing.

[FR Doc. 82–24508 Filed 9–3–82; 8:45 am]

BILLING CODE 7590–01–M

[Supporting Amendments No. 6 to CPPR–126 and CPPR–127; Docket Nos. 50–445 and 50–446]

Texas Utilities Generating Company, et al.; Change in Allowable Groundwater Withdrawal Rate; Comanche Peak Steam Electric Station Units 1 and 2

The U.S. Nuclear Regulatory Commission (the Commission) has reviewed the amendments to Construction Permits CPPR–126 and CPPR–127 relating to the withdrawal of groundwater during construction of the

Comanche Peak Steam Electric Station, Units 1 and 2, located in Somervell County, Texas. The construction permits were issued to the Texas Utilities Generating Company. The amendments would increase the allowable annual average groundwater withdrawal rate from 30 gpm to 40 gpm until completion of construction.

In accordance with 10 CFR Part 51, the Commission's staff has prepared an environmental impact appraisal (EIA) for the amendment. The Commission has concluded that an environmental impact statement for this action is not warranted, because there will be no adverse environmental impacts affecting the quality of the human environment attributable to the proposed action that would be in addition to those impacts evaluated in the Commission's Final Environmental Statement for Comanche Peak Steam Electric Station, Units 1 and 2, issued June 1974. A negative declaration is, therefore, appropriate.

The environmental impact appraisal (EIA) is available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. and at the local public document room located at the Somervell County Public Library, On The Square, Glen Rose, Texas. A copy of the EIA may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Maryland, this 27th day of August 1982.

For the Nuclear Regulatory Commission.

William F. Kane,

Acting Chief, Licensing Branch No. 1, Division of Licensing.

[FR Doc. 82-24511 Filed 9-3-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50-237/249]

Commonwealth Edison Co.; Issuance of Amendments to Operating Licenses and Negative Declaration

Pursuant to the Atomic Safety and Licensing Board's (ASLB), "Final Initial Decision," dated August 17, 1982, the U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 74 to Provisional Operating License No. DPR-19 and Amendment No. 66 to Facility Operating License No. DPR-25, to Commonwealth Edison Company (the licensee), which revised the licenses for operation of the Dresden Nuclear Power Station, Units 2 and 3. The Unit 2 amendment also revised the Technical Specifications. The Dresden Station is located in Grundy County, Illinois. The amendments are effective as of the date of issuance.

The amendments approve the installation of 33 high-density spent fuel storage racks for Dresden Units 2 and 3. With respect to Unit 3, the Commission previously issued a license condition and approved Technical Specification changes for installation of 5 racks by License Amendment No. 56 dated October 29, 1981, pursuant to a Partial Initial Decision by the ASLB dated September 24, 1981.

The amendment for Unit 2 approves the installation and use of 33 high-density fuel storage racks (License Condition 3.N) and authorizes a Technical Specification change which requires the effective subcritical multiplication factor (K_{eff}) in the spent fuel pool be maintained below 0.95. The Unit 3 amendment modifies License Condition 3.M.1 to authorize the installation and use of 33, rather than 5, high-density fuel storage racks.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendments. These amendments complete the proposed action encompassed within the scope of the Notice of Proposed Issuance of Amendments to Operating Licenses which was published in the **Federal Register** on August 11, 1978 (43 FR 35763). In a Notice of Hearing dated March 29, 1979, the ASLB granted the State of Illinois' petition to intervene. The ASLB's "Final Initial Decision," dated August 17, 1982, completes this portion of the adjudicatory process.

The Commission has issued an Environmental Impact Appraisal dated June 5, 1980 for this action and has concluded that an Environmental Impact Statement for this action is not warranted because the action will not significantly affect the quality of the human environment.

For further details with respect to this action, see (1) the application for amendment dated May 11, 1978, also see licensee letters dated January 12 and 24, 1979, May 30, 1979, June 12, 1979, August 17, 1979, October 19 and 29, 1979, December 2, 1980, January 29, 1981, June 8, 1981, October 2, 1981 and January 20, 1982; (2) the Commission's related Safety Evaluation and Environmental Impact Appraisal, dated June 5, 1980 and Supplemental Safety Evaluation issued to the ASLB May 28, 1982 (Tr. 1231); (3) Amendment No. 56 to DPR-25, dated October 29, 1981; (4) Amendment No. 74 to License No. DPR-19; (5) Amendment No. 66 to License No. DPR-25, including the Commission's letter of transmittal; (6) the ASLB's Partial Initial Decision, dated September 24, 1981, and (7) the ASLB's Final Initial Decision dated August 17, 1982, including the exhibits listed in Appendix A-1. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C., and at the Morris Public Library, 604 Liberty Street, Morris, Illinois 60451. A copy of items (3), (4) and (5) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C., Attention: Director, Division of Licensing.

Dated at Bethesda, Md., this 27th day of August 1982.

For the Nuclear Regulatory Commission.

Dennis M. Crutchfield,

Chief, Operating Reactors Branch No. 5, Division of Licensing.

[FR Doc. 82-24504 Filed 9-3-82; 8:45 am]

BILLING CODE 7590-01-M

Draft Regulatory Guide; Issuance and Availability

The Nuclear Regulatory Commission has issued for public comment a draft of a proposed revision to a guide in its Regulatory Guide Series together with a draft of the associated value/impact statement. This series has been developed to describe and make available to the public methods acceptable to the NRC staff of implementing specific parts of the Commission's regulations and, in some cases, to delineate techniques used by the staff in evaluating specific problems or postulated accidents and to provide guidance to applicants concerning certain of the information needed by the staff in its review of applications for permits and licenses.

The draft, temporarily identified by its task number, CE 219-4 (which should be mentioned in all correspondence concerning this draft guide), is proposed Revision 1 to Regulatory Guide 3.15 and is entitled "Standard Format and Content of License Applications for Storage Only of Unirradiated Reactor Fuel and Associated Radioactive Material." The guide is being developed to describe the detailed information that is needed by the NRC staff in its review of an application for a license to authorize the receipt, possession, and storage of unirradiated fuel assemblies and associated radioactive materials for eventual use in a nuclear reactor and to suggest a format for its presentation.

This draft guide and the associated value/impact statement are being issued to involve the public in the early stages of the development of a regulatory position in this area. They have not received complete staff review and do not represent an official NRC staff position.

Public comments are being solicited on both drafts, the guide (including any implementation schedule) and the draft value/impact statement. Comments on the draft value/impact statement should be accompanied by supporting data. Comments on both drafts should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch, by November 5, 1982.

Although a time limit is given for comments on these drafts, comments and suggestions in connection with (1) items for inclusion in guides currently being developed or (2) improvements in all published guides are encouraged at any time.

Regulatory guides are available for inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C. Requests for single copies of draft guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Technical Information and Document Control. Telephone requests cannot be accommodated. Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

(5 U.S.C. 552(a))

Dated at Rockville, Md., this 30th day of August 1982.

For the Nuclear Regulatory Commission.

G. A. Arlotto,

Director, Division of Engineering Technology, Office of Nuclear Regulatory Research.

[FR Doc. 82-24513 Filed 9-3-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-247]

Consolidated Edison Co. of New York, Inc.; Issuance of Amendment to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 79 to Facility Operating License No. DPR-26, issued to the Consolidated Edison Company of New York, Inc. (the licensee), which revised Technical Specifications for operation of the Indian Point Nuclear Generating Unit No. 2 (the facility) located in Buchanan, Westchester County, New York. The amendment is effective 21 days from the date of issuance.

The amendment revises their Technical Specifications to require certain condensate valves to be open when the plant is above 350°F and provide for testing of the steam generator low level AFWS automatic actuation logic.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment. Prior public notice of this amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of this amendment.

For further details with respect to this action, see (1) the application for amendment dated August 11, 1980, (2) Amendment No. 79 to License No. DPR-26, and (3) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. and at the White Plains Public Library, 100 Martine Avenue, White Plains, New York. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Md., this 30th day of August 1982.

For the Nuclear Regulatory Commission.

Steven A. Varga,

Chief, Operating Reactors Branch No. 1, Division of Licensing.

[FR Doc. 82-24505 Filed 9-3-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-298, License No. DPR-46, EA 82-46]

Nebraska Public Power District Cooper Nuclear Power Station; Order Extending Time To Reply to Order Modifying License Effective Immediately

Issued: August 9, 1982.

I

The Nebraska Public Power District (the "licensee") is the holder of Facility Operating License No. DPR-46 (the "license") which authorizes the operation of the Cooper Nuclear Power Station (the "facility"). The facility consists of a boiling water reactor located at the licensee's site in Nemaha County, Nebraska.

II

On August 9, 1982, the Commission, by the Director of the Office of Inspection and Enforcement issued an Order Modifying License Effective Immediately (the "Order"). This Order required that the licensee submit by September 8, 1982, to the Administrator of Region IV of the Nuclear Regulatory Commission (NRC), for review and approval, a comprehensive plan of action that will yield an independent appraisal of current organizational responsibilities, management controls, staffing levels and competence, communications systems and practices both at and between the corporate office and the facility, with recommendations for changes in the aforementioned areas that would provide assurance that the licensee will implement NRC requirements.

III

On August 19, 1982, the licensee requested a 30 day extension of time within which to respond to the Order. The reason given to justify this extension is that an extensive effort is required to identify, assemble and analyze all the information required to prepare the licensee's response to the Order.

IV

Accordingly, for good cause shown and pursuant to 10 CFR Part 2, it is hereby ordered that the time for submission of the plan required by Section IV of the Order and the time to request a hearing on the Order be extended to October 8, 1982.

Dated at Bethesda, Md., this 24th day of August 1982.

For the Nuclear Regulatory Commission.

Richard C. DeYoung,

Director, Office of Inspection and Enforcement.

[FR Doc. 82-24506 Filed 9-3-82; 8:45 am]

BILLING CODE 7590-01-M

[ASLBP Docket No. 76-334-07-AN; Commission Docket No. P-564A]

Pacific Gas & Electric Co. (Stanislaus Nuclear Project, Unit 1); Antitrust; Oral Argument

September 1, 1982.

Please Take Notice that pursuant to the Memorandum and Order in this proceeding of June 10, 1982, an oral argument will be held on applicant's motion for withdrawal, commencing on September 21, 1982, at 9:30 a.m. local time in Room 1200 of the State Building, 350 McAllister Street, San Francisco, California.

Legal memoranda to be relied upon at the oral argument not previously served in this matter, should be served on the other parties and the presiding officer by September 14, 1982.

It is so Ordered.

Dated at Bethesda, Md., this 1st day of September 1982.

Atomic Safety and Licensing Board.

Morton B. Margulies,

Administrative Law Judge.

[FR Doc. 82-24507 Filed 9-3-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-395]

Virgil C. Summer Nuclear Station, Unit No. 2; Issuance of Amendment to Facility Operating License No. NPF-12

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 2 to Facility Operating License No. NPF-12, issued to South Carolina Electric & Gas Company and South Carolina Public Service Authority (the licensees) for the Virgil C. Summer Nuclear Station, Unit No. 1 (the facility) located in Fairfield County, South Carolina. This amendment corrects certain inconsistencies in the Technical Specifications regarding containment radiation monitors and the containment purge and exhaust isolation. The amendment is effective as of its date of issuance.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations. The Commission has made appropriate findings as required by the Act and the Commission's regulations in 10 CFR Chapter I, which are set forth in the license amendment. Prior public notice of this amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) an environmental impact statement, or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of this amendment.

For further details with respect to this action, see (1) South Carolina Electric & Gas Company letter, dated August 13, 1982, (2) Amendment No. 2 to Facility Operating License No. NPF-12 with Appendix A Technical Specifications page changes, and (3) the Commission's related safety evaluation.

All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. 20555 and the Fairfield County Library, Garden and Washington Streets, Winnsboro, South Carolina 29180. A copy of Amendment No. 2 may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Md., this 27th day of August 1982.

For the Nuclear Regulatory Commission.

William F. Kane,

Acting Chief, Licensing Branch No. 1, Division of Licensing.

[FR Doc. 82-24509 Filed 9-3-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50-445 and 50-446]

Texas Utilities Generating Co., et al. (Comanche Peak Steam Electric Station, Units 1 and 2); Application for Operating License; Evidentiary Hearing (Resumed)

August 30, 1982.

Please take notice that a resumption of evidentiary hearing will be held in this operating license proceeding before an Atomic Safety and Licensing Board (Board), pursuant to the Atomic Energy Act of 1954 as amended (the Act), and the Regulations in Title 10, Code of Federal Regulations (CFR), Part 50, "Licensing of Production and Utilization Facilities," Part 51, "Licensing and Regulatory Policy and Procedures for Environmental Protection," and Part 2, "Rules of Practice." Prior segments of the evidentiary hearing were held December 2, 1981; June 7–11, 1982; and July 26–30, 1982.

This continuation of evidentiary hearing will commence on September 13, 1982 at 8:30 a.m., local time, at the Metro Center Hotel, 600 Commerce Street, Fort Worth, Texas 76102 and will continue through September 17, 1982. The hearing will address remaining matters in controversy from Contentin 5 (QA/QC), and the issues involved in Contention 22 (Emergency Planning). The matters attempted to be raised in CASE's Motion to Add New Contention 26 (August 26, 1982) and responses thereto may be considered at that time.

Written limited appearance statements may be submitted to the Board at any time prior to closing the record in this phase of the proceeding. Oral statements will only be received at times designated by the Board in order not to interfere with the taking of evidence in this adjudicatory proceeding. Both oral and written statements will be made a part of the official record.

It is so ordered.

For the Atomic Safety and Licensing Board.

Marshall E. Miller,

Chairman, Administrative Judge.

August 30, 1982.

[FR Doc. 82-24510 Filed 9-3-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50-445 and 50-446]

Texas Utilities Generating Co., et al.; Issuance of Amendments to Construction Permits

In the matter of Texas Utilities Generating Company, Dallas Power & Light Company, Texas Electric Service Company, Texas Power & Light Company, Texas Municipal Power Agency, Brazos Electric Power Cooperative, Inc., Tex-La Electric Cooperative of Texas, Inc.; notice of issuance of amendments to construction permits.

Notice is hereby given that the U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 6 to Construction Permit No. CPPR-126 and Amendment No. 6 to Construction Permit No. CPPR-127. The amendments increase the allowable annual average groundwater withdrawal from 30 gpm to 40 gpm until completion of construction. The amendments are effective as of the date of issuance.

The application for the amendments complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate

findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment. Prior public notice of this amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has prepared an environmental impact appraisal for the amendment and has concluded that an environmental impact statement for this particular action is not warranted because there will be no environmental impact attributable to the action other than that which has already been predicted and described in the Commission's Final Environmental Statement for the facility, dated June 1974.

For further details with respect to this action, see (1) the application for amendment, dated July 26, 1982, (2) Amendment No. 6 to CPPR-126, (3) Amendment No. 6 to CPPR-127, (4) the Environmental Impact Appraisal and (5) the Negative Declaration supporting the amendments to the construction permits. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C., and at the Somervell County Public Library, On The Square, Glen Rose, Texas 76403. In addition, a copy of the above items (2), (3), (4), and (5) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing, Office of Nuclear Reactor Regulation.

Dated at Bethesda, Maryland this 27th day of August 1982.

For the Nuclear Regulatory Commission.

William F. Kane,

Acting Chief, Licensing Branch No. 1, Division of Licensing.

[FR Doc. 82-24512 Filed 9-3-82; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-389A]

Florida Power & Light Co., et al.; Receipt of Additional Antitrust Information: Time for Submission of Views on Antitrust Matters

Note.—This document originally appeared in the **Federal Register** of Monday, August 16, 1982. It is reprinted in this issue at the request of the Nuclear Regulatory Commission.

Florida Power & Light Company, pursuant to Section 103 of the Atomic Energy Act of 1954, as amended, has filed information requested by the Attorney General for antitrust review as required by 10 CFR Part 50, Appendix L. This information concerns a proposed additional ownership participant, the Florida Municipal Power Agency in the St. Lucie Plant, Unit 2. Florida Power & Light Company and the Orlando Utilities Commission of the City of Orlando are the current permit holders. The change involves the transfer of ownership from the Florida Power & Light Company to Florida Municipal Power Agency.

The information was filed in connection with the application submitted by the construction permit holders for an operating license for a pressurized water reactor. Construction was authorized on May 2, 1977, at the St. Lucie 2 site located on Hutchinson Island in St. Lucie County, Florida.

The original application was docketed on September 4, 1973, and the Notice of Receipt of Application for Construction Permits and Facility Licenses and Availability of Applicants' Environmental Report; Time for Submission of Views on Antitrust Matters was published in the **Federal Register** on September 21, 1973 (38 FR 27106). The Notice of Receipt of Application for Facility Operating Licenses; Notice of Availability of Applicant's Environmental Report; and the Notice of Consideration of Issuance of Facility Operating License and Notice of Opportunity for Hearing was published in the **Federal Register** on March 9, 1981 (46 FR 15831).

A copy of the above documents are available for public examination and copying for a fee at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. 20555 and at the Indian River Community College Library, 3900 Virginia Avenue, Ft. Pierce, Florida 33450.

Any person who wishes to have his views on the antitrust matters with respect to the Florida Municipal Power Agency presented to the Attorney General for consideration or who desires additional information regarding the matters covered by this notice, should submit such views or requests for additional information to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Chief, Antitrust and Economic Analysis Branch, Division of Engineering, Office of Nuclear Reactor Regulation, on or before October 15, 1982.

Dated at Bethesda, Maryland, this 2nd day of August 1982.

For the Nuclear Regulatory Commission.

Frank J. Miraglia,

Chief, Licensing Branch No. 3, Division of Licensing.

[FR Doc. 82-22290 Filed 8-13-82; 8:45 am]

BILLING CODE 7590-01-M

SMALL BUSINESS ADMINISTRATION

[Application No. 02/02-0445]

BPC Washington Partners; Application for License To Operate as a Small Business Investment Company

An application for a License to operate as a small business investment company under the provisions of the Small Business Investment Act of 1958, as amended (15 U.S.C. 661 *et seq.*), has been filed by BPC Washington Partners (BPC Washington), 730 Third Avenue, Suite 2500, New York, New York 10017, with the Small Business Administration (SBA) pursuant to 13 CFR 107.102 (1982).

BPC Washington is a limited partnership to be managed by general partner, BPC Washington Corporation, a Delaware corporation.

The officers and directors of the General Partner of BPC Washington are as follows:

John H. Merkensteijn, III, 140 East 56th Street, Apt. No. 9-F, New York, New York 10022—Chairman of the Board, Director

Jack H. Edwards, 4530 South Verbena No. 320, Denver, Colorado 80237—President, Treasurer, Director

Edwin S. Matthews, Jr., 52 East 91st Street, New York, New York 10028—Secretary

John P. Holmes, 10 East 68th Street, New York, New York—Director

Roger L. Jarvis, 12712 St. Johns, Oklahoma City, Oklahoma—Director

Allan Anthony McLellan, 199 Douglas Drive, Toronto, Ontario, Canada M4W2B6—Director

Howard W. Phillips, 730 Third Avenue, Suite 2500, New York, New York 10017—Director

The Applicant proposed to begin operations with $6,000,000 paid-in capital and paid-in surplus. BPC Washington will conduct its activities principally in the states of New York, Texas, Oklahoma and Louisiana.

Matters involved in SBA's consideration of the application include the general business reputation and character of the proposed owners and management, and the probability of successful operation of the company under their management, including adequate profitability and financial soundness, in accordance with the Small Business Act of 1958, as amended, and the SBA Rules and Regulations.

Notice is hereby given that any person may not later than September 22, 1982 submit to SBA written comments on the proposed Applicant. Any such communication should be addressed to the Deputy Associate Administrator for

Investment, Small Business Administration, 1441 L Street, NW., Washington, D.C. 20416.

A copy of this notice shall be published in a newspaper of general circulation in New York, New York.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: August 31, 1982.

Robert G. Lineberry,

Deputy Associate Administrator for Investment.

[FR Doc. 82-24516 Filed 9-3-82; 8:45 am]

BILLING CODE 8025-01-M

[License No. 03-03-0152]

PNC Capital Corp.; Issuance of a Small Business Investment Company License

On March 8, 1982, a notice was published in the **Federal Register** (46 FR 35402) stating that an application has been filed by PNC Capital Corporation, Pittsburgh National Building, Fifth Avenue and Wood Street, Pittsburgh, Pennsylvania 15222 with the Small Business Administration (SBA) pursuant to Section 107.102 of the Regulations governing small business investment companies (13 CFR 107.102 (1982)) for a license as a small business investment company.

Interested parties were given until close of business March 23, 1982, to submit their comments to SBA. No comments were received.

Notice is hereby given that pursuant to Section 301(c) of the Small Business Investment Act of 1958, as amended, after having considered the application and all other pertinent information, SBA issued License No. 03-03-0152 on August 12, 1982, to PNC Capital Corporation to operate as a small business investment company.

Dated: August 31, 1982.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Robert G. Lineberry,

Deputy Associate Administrator for Investment.

[FR Doc. 82-24517 Filed 9-3-82; 8:45 am]

BILLING CODE 8025-01-M

[Declaration of Disaster Loan Area No. 2062]

Tennessee; Declaration of Disaster Loan Area

As a result of the President's major disaster declaration, I find that the counties of Hamilton, Marion, and Smith, Tennessee, constitute a disaster loan area as a result of damage resulting from severe storms and flooding beginning on August 16, 1982. Eligible persons, firms and organizations may file applications for loans for physical damage until the close of business on October 25, 1982, and for economic injury until the close of business on May 24, 1983, at the address listed below: U.S. Small Business Administration, Parkway Towers, Room 1012, 404 James Robertson Parkway, Nashville, Tennessee 37219 or other locally announced locations.

Interest rates for applicants filing for assistance are:

Homeowners with credit available elsewhere, 14¾%
Homeowners without credit available elsewhere, 7⅜%
Businesses with credit available elsewhere, 14%
Businesses without credit available elsewhere, 8%
Businesses (EIDL) without credit available elsewhere, 8%
Other (non-profit organizations including charitable and religious organizations), 11½%

It should be noted that assistance for agriculture enterprises is the primary responsibility of the Farmers Home Administration as specified in Pub. L. 96-302.

Dated: August 27, 1982.

Peter Terpeluk, Jr.,

Acting Administrator.

[FR Doc. 82-24518 Filed 9-3-82; 8:45 am]

BILLING CODE 8025-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Future Navigation Systems Planning—Economic Considerations Conference

A Future Navigation Systems Planning—Economic Considerations Conference is to be held at the Federal Aviation Administration Headquarters, Washington, D.C., 800 Independence Avenue, SW., on September 29, 1982.

This conference is a follow-up to the *Future Navigation Systems Planning Conference* held at FAA Headquarters on August 2-3, 1982. The purpose of the Conference is to present to the users and suppliers of navigation systems the results to date of FAA sponsored studies and technical evaluations of the economic considerations for future navigational systems. This will include a detailed description of the DOT Radionavigation Economic Analysis Model, the assumptions used and the model output, including the results of a sensitivity analysis of the basic Navigation System Scenarios. An opportunity will be provided for the navigation community to participate in a discussion of both the model results and the planned activities in this field.

A conference agenda of scheduled technical presentations will be available to the public on September 14.

This Conference is open to all interested individuals and organizations without prior notification by attendees. The Federal Aviation Administration contact for the Conference is Mr. Michael Zywokarte, APO-100, Telephone (202) 426-8733.

Issued in Washington, D.C., on August 26, 1982.

Donald R. Segner,

Associate Administrator for Policy and International Aviation.

[FR Doc. 82-24175 Filed 9-3-82; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF THE TREASURY

Comptroller of the Currency

[Docket No. 82-17]

Performance Review Board

AGENCY: Comptroller of the Currency, Treasury.

ACTION: Notice of change in membership of a senior executive service performance review board.

SUMMARY: This notice announces the new membership of the OCC Performance Review Board (PRB), pursuant to 5 U.S.C. 4314(c)(4).

DATE: September 7, 1982

FOR FURTHER INFORMATION CONTACT: Gary W. Norton, Director for Human Resources, Office of the Comptroller of the Currency, 490 L'Enfant Plaza, SW., Washington, D.C. 20219.

SUPPLEMENTARY INFORMATION: The membership of the OCC PRB which appeared in the **Federal Register**, Volume 46, No. 249, page 62994, Tuesday, December 29, 1981, has been changed. The current membership is as follows:

H. Joe Selby, Senior Deputy Comptroller for National Operations (Chairman)
Paul M. Homan, Senior Deputy Comptroller for Bank Supervision
Doyle L. Arnold, Senior Deputy Comptroller for Policy and Planning
Brian W. Smith, Chief Counsel
Martha B. Stephens, Deputy Comptroller for Human Resources (Non-voting Executive Secretary and Technical Advisor)

Gary W. Norton, Director for Human Resources (Non-voting Technical Advisor).

C. T. Conover,

Comptroller of the Currency.

[FR Doc. 82-24476 Filed 9-3-82; 8:45 am]

BILLING CODE 4810-33-M

Office of the Secretary

[Supp. to Dept. Circ. Public Debt Series—No. 22-82]

Series G-1987; Interest Rate

September 1, 1982.

The Secretary announced on August 31, 1982, that the interest rate on the notes designated Series G-1987, described in Department Circular—Public Debt Series—No. 22-82 dated August 25, 1982, will be 12⅞ percent. Interest on the notes will be payable at the rate of 12⅞ percent per annum.

Paul H. Taylor,

Fiscal Assistant Secretary.

[FR Doc. 82-24488 Filed 9-3-82; 8:45 am]

BILLING CODE 4810-40-M

Sunshine Act Meetings

Federal Register
Vol. 47, No. 173
Tuesday, September 7, 1982

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).

CONTENTS

	Items
Consumer Product Safety Commission	1–2
Federal Energy Regulatory Commission	3
Federal Home Loan Bank Board	4
Federal Mine Safety and Health Review Commission	5–6
Interstate Commerce Commission	7
Nuclear Regulatory Commission	8

1

CONSUMER PRODUCT SAFETY COMMISSION

TIME AND DATE: 10 a.m., Wednesday, September 8, 1982.

LOCATION: Third floor hearing room, 1111 18th Street, N.W., Washington, D.C.

STATUS: *Open to the public.*

MATTERS TO BE CONSIDERED:

1. *Over-the-counter Antihistamines*
   The Commission will consider the issue of whether to propose to require special packaging under the Posion Prevention Packaging Act for over-the-counter antihistamines.
2. *Final Crib Amendments*
   The Commission will consider amendments to the regulations for full-size baby cribs and non-full-size cribs. The amendments, which concern the strangulation hazard presented by crib cutouts, were proposed on December 16, 1980.
3. *Wood Products With Urea-Formaldehyde Resins*
   The staff will brief the Commission on the status of the project concerning pressed wood products manufactured with urea-formaldehyde resins.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Sheldon D. Butts, Deputy Secretary, Office of the Secretary, Suite 342, 5401 Westbard Avenue, Bethesda, MD 20207; telephone (301) 492–6800.

[S–1265–82 Filed 9–1–82; 4:45 pm]

BILLING CODE 6355–01–M

2

CONSUMER PRODUCT SAFETY COMMISSION

TIME AND DATE: 10 a.m., Thursday, September 9, 1982.

LOCATION: Third floor hearing room, 1111 18th Street, N.W., Washington, D.C.

STATUS: *Open to the public.*

MATTERS TO BE CONSIDERED:

1. *Section 6(b) CPSA Proposed Rules*
   The staff will brief the Commission on issues related to a proposed rule which would establish the Commission policy and procedure for the public disclosure of information under Section 6(b) of the Consumer Product Safety Act.

Closed to the public:

2. *Compliance Status Report*
   The staff will brief the Commission on the status of various compliance activities.
3. *Enforcement Matter OS# 2090*
   The Commission will consider issues related to enforcement matter OS# 2090

CONTACT PERSON FOR ADDITIONAL INFORMATION: Sheldon D. Butts, Deputy Secretary, Office of the Secretary, Suite 342, 5401 Westbard Avenue, Bethesda, MD 20207; telephone (301) 492–6800.

[S–1266–82 Filed 9–1–82; 4:46 pm]

BILLING CODE 6355–01–M

3

FEDERAL ENERGY REGULATORY COMMISSION

September 1, 1982.

TIME AND DATE: 9:30 a.m., September 3, 1982.

PLACE: Room 9306, 825 North Capitol Street, N.E., Washington, D.C. 20426.

STATUS: Closed.

MATTERS TO BE CONSIDERED: *Farmers Union Central Exchange* v. *FERC*, D.D.C. No. 82–2065.

CONTACT PERSON FOR MORE INFORMATION: Kenneth F. Plumb, Secretary; telephone (202) 357–8400.

Kenneth F. Plumb,

Secretary.

[S–1269–82 Filed 9–2–82; 11:13 am]

BILLING CODE 6717–01–M

4

FEDERAL HOME LOAN BANK BOARD

TIME AND DATE: 10 a.m., Thursday, Septembe 9, 1982.

PLACE: Board room, sixth floor, 1700 G Street N.W., Washington, D.C.

STATUS: Open meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Lockwood (202–377–6679).

MATTERS TO BE CONSIDERED:

Permission to Organize a New Federal Association—Kenneth W.P. Cheng. et al.
Application for limited Trust Powers—Western Heritage Federal Savings and Loan Association, Pendleton, Oregon
Branch Office Applications (4)—Texas Federal Savings and Loan Association (Stock), Dallas, Texas
Request for Approval of Additional Suretyship Authority—First Federal Savings and Loan Association, Warner Robins, Georgia
Application for Bank Membership and Insurance of Accounts—Sutter Buttes Savings and Loan Association, Yuba City, California (In Organization)
FSLIC Insurance Coverage of Prinicpal and Interest Collections Held by Loan Servicers
Branch Office Approval

[No. 59, September 2, 1982]

[S–1268–82 Filed 9–2–82; 11:13 am]

BILLING CODE 6720–01–M

5

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

August 31, 1982.

TIME AND DATE: 10 a.m., Wednesday, September 1, 1982.

PLACE: Room 600, 1730 K Street, N.W., Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED: In addition to the previously announced items, the Commission will also consider and act upon the following:

3. William Haro v. Magma Copper Company, Docket No. WEST 80–482–DM (Petition for Discretionary Review)

It was determined by a unanimous vote of Commissioners that Commission business required that a meeting be held on this item and that no earlier announcement of the meeting was possible.

CONTACT PERSON FOR MORE INFORMATION: Jean Ellen (202) 653–5632.

[S–1272–82 Filed 9–2–82; 3:42 pm]

BILLING CODE 6735–01–M

6

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

September 1, 1982.

TIME AND DATE: 10 a.m., September 8, 1982.

PLACE: Room 600, 1730 K Street, N.W., Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following:

1. Emery Mining Company, Docket Nos. WEST 82–48, WEST 82–80, WEST 81–400–R. (Petition for Discretionary Review filed by the Secretary of Labor and United Mine Workers of America). Issues include whether the ALJ erren in dismissing citations issued under 30 CFR 48.8(a), which deals with annual refresher training for miners.

CONTACT PERSON FOR MORE INFORMATION: Jean Ellen (202) 653–5632.

[S–1271–82 Filed 9–2–82; 3:42 pm]

BILLING CODE 6735–01–M

7

INTERSTATE COMMERCE COMMISSION

TIME AND DATE: 9 a.m., Monday, September 13, 1982.

PLACE: Room 4225, Interstate Commerce Commission Building, 12th and Constitution Avenue, N.W., Washington, D.C. 20423.

STATUS: Closed Special Conference.

This amends the notice served September 1, 1982, to show a change in time of conference from 1:30 p.m., to 9 a.m.

MATTER TO BE CONSIDERED: Finance Docket No. 30,000:

Union Pacific Corporation, Pacific Rail System, Inc., and Union Pacific Railroad Company—Control—Missouri Pacific Corporation and Missouri Pacific Railroad Company, et al.

CONTACT PERSON FOR MORE INFORMATION: Robert R. Dahlgren, Director, Office of Public Affairs; telephone (202) 275–7252.

[S–1270–82 Filed 9–2–82; 12:30 pm]

BILLING CODE 7035–01–M

8

NUCLEAR REGULATORY COMMISSION

DATE: Week of September 6, 1982.

PLACE: Commissioners' Conference Room, 1717 H Street, N.W., Washington, D.C.

STATUS: Open and closed.

MATTERS TO BE DISCUSSED: Tuesday, September 7:

10:00 a.m.:
- Briefing on Contested Issues in Summer—1 Full Power Operating License (Closed—Exemption 10) (*rescheduled* from September 2)

2:00 p.m.:
- Discussion of Order in Waste Confidence Proceeding (Closed—Exemption 10)

Wednesday, September 8:

2:00 p.m.:
- Discussion of Management—Organization and Internal Personnel Matters (Closed—Exemption 2 and 6) (*rescheduled* from September 1)

Thursday, September 9:

9:30 a.m.:
- Discussion of Severe Accidents—Policy Statement and Research Plan (Public Meeting) (*rescheduled* from September 2)

2:00 p.m.:
- Discussion of Staff Action on Emergency Planning at Indian Point (Public Meeting)

3:30 p.m.:
- Affirmation/Discussion and Vote (Public Meeting)
  - a. Amendment to Part 110—Exports of Australian-Origin Equipment and Material
  - b. Revision of ALAB–664 (In the Matter of Tennessee Authority)
  - c. Indian Point Special Proceeding—Order Responding to Licensing Board's Certified Questions (*rescheduled* from September 1)

Friday, September 10:

10:00 a.m.:
- Discussion of Contested Issues in TMI–1 Restart Proceeding (Closed—Exemption 10)

2:00 p.m.:
- Meeting with the ACRS (Public Meeting)

ADDITIONAL INFORMATION: Affirmation of S–3 Policy Statement scheduled for September 1—*cancelled.*

AUTOMATIC TELEPHONE ANSWERING SERVICE FOR SCHEDULE UPDATE: (202) 634–1498. Those planning to attend a meeting should reverify the status on the day of the meeting.

CONTACT PERSON FOR MORE INFORMATION: Walter Magee (202) 634–1410.

Walter Magee,

Office of the Secretary.

[S–1267–82 Filed 9–2–82; 10:11 am]

BILLING CODE 7590–01–M

federal register

Tuesday
September 7, 1982

Part II

Department of Commerce

International Trade Administration

Final Affirmative Countervailing Duty Determinations; Various Countries; and Suspension of Investigation; Brazil

DEPARTMENT OF COMMERCE

International Trade Administration

Final Affirmative Countervailing Duty Determinations; Certain Steel Products From Belgium

AGENCY: International Trade Administration, Commerce.

ACTION: Final Affirmative Countervailing Duty Determinations.

SUMMARY: We have determined that certain benefits which constitute subsidies within the meaning of the countervailing duty law are being provided to manufacturers, producers, or exporters in Belgium of certain steel products, as described in the "Scope of the Investigations" section of this notice. The estimated net subsidy for one company is *de minimis*. Therefore, all estimated countervailing duties shall be refunded and all appropriate bonds shall be released with respect to imports from the company for which we have determined *de minimis* estimated subsidies. However, we have not excluded that company from these determinations for reasons stated in the "Suspension of Liquidation" section. The estimated net subsidy for each firm and for each product is indicated under the "Suspension of Liquidation" section of this notice. The U.S. International Trade Commission (ITC) will determine within 45 days of the publication of this notice whether these imports are materially injuring, or threatening to materially injure, a U.S. industry.

EFFECTIVE DATE: September 7, 1982.

FOR FURTHER INFORMATION CONTACT: Michael J. Altier, Office of Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230, telephone: (202) 377–1785.

SUPPLEMENTARY INFORMATION:

Final Determinations

Based upon our investigations, we have determined that certain benefits which constitute subsidies within the meaning of section 701 of the Tariff Act of 1930, as amended (the Act), are being provided to manufacturers, producers, or exporters in Belgium of certain steel products, as described in the "Scope of the Investigations" section of this notice. For purposes of these investigations, the following programs are found to confer subsidies:

- Capital grants.
- Loan guarantees.
- Exemptions from real property tax.
- Exemptions from capital registration tax.
- Loans to uncreditworthy companies.
- Equity participation by the government of Belgium (GOB).
- Assumption of financing costs.
- Preferential loans.
- Industrial investment loans from the European Coal and Steel Community (ECSC).
- Reimbursement of worker training costs.
- Readaptation and retraining assistance.
- Funds for loss coverage.

We determine the estimated net subsidy to be the amount indicated for each firm and for each product in the "Suspension of Liquidation" section of this notice. Although the estimated net subsidy for one company is *de minimis*, we have not excluded that company from these investigations for reasons stated in the "Suspension of Liquidation" section.

Case History

In January 11, 1982, we received petitions for United States Steel Corporation; counsel for Bethlehem Steel Corporation; and counsel for Republic Steel Corporation, Inland Steel Company, Jones & Laughlin Steel, Inc., National Steel Corporation, and Cyclops Corporation (the Five), filed on behalf of the U.S. industry producing carbon steel structural shapes, hot-rolled carbon steel plate and hot-rolled carbon steel sheet and strip. The petitioners alleged that certain benefits which constitute subsidies within the meaning of section 701 of the Act are being provided, directly or indirectly, to the manufacturers, producers or exporters in Belgium of the steel products listed above. Counsel for Bethlehem Steel Corporation and counsel for the Five alleged that "critical circumstances" exist, as defined in section 703(e) of the Act. We found the petitions to contain sufficient grounds upon which to initiate countervailing duty investigations, and on February 1, 1982, we initiated countervailing duty investigations (47 FR 5744).

Since Belgium is a "country under the Agreement" within the meaning of section 701(b) of the Act, injury determinations are required for these investigations. Therefore, we notified the ITC of our initiations. On Februray 26, 1982, the ITC preliminarily determined that there is a reasonable indication that these imports are materially injuring, or threatening to materially injure, a U.S. industry.

We presented qestionnaires concerning the allegations to the Delegation of the Commission of the European Communities and to the government of Belgium (GOB) in Washington, D.C. On April 30, 1982, we received the responses to the questionnaires. Supplemental responses were received on May 17, 1982. On June 10, 1982, we issued our preliminary determinations in these investigations (47 FR 26300). They stated that the GOB was providing its manufacturers, products, or exporters of certain steel product with benefits which constitute subsidies. The programs preliminarily determined to bestow countervailable subsidies were:

- "Interest rebates".
- Capital grants.
- Loan guarantees.
- Exemptions from real property tax.
- Exemptions from capital registration tax.
- Loans to uncreditworthy companies.
- Equity participation by the GOB.
- Assumption of financing costs.
- Labor assistance.
- Preferential loans.
- Industrial investment loans from the ECSC (Article 54).
- Research and development aid.

Scope of the Investigations

The products covered by these investigations are:

- Carbon steel structural shapes.
- Hot-rolled carbon steel plate.
- Hot-rolled carbon steel sheet and strip.

The products are fully described in Appendix 1, which follows this notice. The product definition of hot-rolled carbon steel sheet and strip has been amended since the initiation of these investigations (47 FR 5739–40). The product definition of certain steel bar products was amended on two occasions (47 FR 28121, 34609), but these products are not involved in the proceedings on certain steel products from Belgium.

Cockerill Sambre (Cockerill), Siderurgie Maritime (Sidmar), Forges de Clabecq (Clabecq), Fabrique de Fer de Charleroi (Fabfer), and Usines Gustave Boel (Boel) are the only known producers and exporters in Belgium of the subject products which were exported to the United States.

Cockerill Sambre is a company which resulted from the merger in June 1981 of Cockerill, which itself is a merger of several steel mills, and Hainaut-Sambre. Hainaut-Sambre was composed of three major components: Carlam, a recently constructed flat products mill, which was mostly owned by Hainaut-Sambre; Thy-Marcinelle et Providence (TMP), which resulted from a merger of a Providence mill of the former Cockerill

company with Thy-Marcinelle et Monceau in 1979; and the old Hainaut-Sambre Company. TMP merged with Hainaut-Sambre in 1980.

The period for which we are measuring subsidization is the calendar year 1981, except in the cases of Fabfer and Clabecq, which both operate on a fiscal year which runs from July 1 to June 30. Therefore, the period for which we are measuring subsidization for Fabfer and Clabecq is July 1, 1980 to June 30, 1981. We received no response from Boel. Therefore, we are applying to Boel the highest subsidy rate found in Belgium for each product under these investigations.

Analysis of Programs

In their responses, the GOB and the Delegation of the Commission of the European Communities provided data for the applicable periods. Additionally, we received information from Cockerill, Sidmar, Clabecq and Fabfer. These companies produced and exported carbon steel structural shapes (Cockerill), hot-rolled carbon steel plate (Cockerill, Sidmar, Clabecq, and Fabfer), and hot-rolled carbon steel sheet and strip (Cockerill, Clabecq and Sidmar), which were exported to the United States during 1981. Since the preliminary determinations, product coverage for Clabecq was amended to included hot-rolled carbon steel sheet and strip (47 FR 35266).

Throughout this notice, general principles applied by the Department of Commerce to the facts of the current investigations concerning certain steel products are described in detail in Appendices 2–4, which follow this notice. Unless otherwise noted, one subsidy rate is calculated for each company for all products under investigation produced by that company. Where benefits were provided to specific products, they were allocated over the value of sales of only those products in calculating the subsidy rate. Based upon our analysis of the petitions, responses to our questionnaires, our verification and oral and written comments by interested parties, we determine the following.

Programs Determined To Confer Subsidies

We have determined subsidies are being provided under the programs listed below to manufacturers, producers, or exporters in Belgium of carbon steel structural shapes, hot-rolled carbon steel plate and hot-rolled carbon steel sheet and strip.

A. Programs Administered under the Laws of July 14, 1966 and December 30, 1970 on Economic Expansion. The laws of July 18, 1959 and July 14, 1966 (the 1966 law) were economic development laws providing regional assistance. They predated the Law of December 30, 1970 (the 1970 law), which applies to the same regions covered by the earlier laws. The 1970 law provided for regional assistance to companies located in certain development areas to promote activities which contribute to the establishment, expansion, conversion or modernization of industrial enterprises. The 1966 law provided for assistance for economic reconversion and development of coal-producing regions and certain other regions experiencing grave and urgent problems. We have determined that benefits were provided under both the 1966 and 1970 laws (items 1–4 below) and that these benefits are countervailable because they are targeted to companies in specific areas. Clabecq is located outside the development areas created by these laws and did not benefit from any of the programs under these laws.

1. Capital grants. This program provides assistance in financing capital investments made by companies. A grant may be given which totally or partially replaces an "interest rebate" for which the investment is otherwise eligible under both laws. The methodology for calculating the subsidy value of grants is described in Appendix 2. The benefits are allocated over the average useful life of steel assets, 15 years, and are applied to the value of sales of the appropriate products of the company.

Cockerill received several grants for less than $50 million. Where grants were directed to a particular mill, we allocated the benefits over the sales value of all products produced by Cockerill at that mill. Where grants were not tied to any particular mill or product, but benefited carbon steel production, we allocated the benefits over the total sales value of carbon steel products produced by Cockerill.

The grants received by Cockerill amounted to a subsidy rate of 0.208 percent *ad valorem* for hot-rolled carbon steel plate and hot-rolled carbon steel sheet and strip, and .112 percent *ad valorem* for carbon steel structural shapes. Sidmar received grants valued under $50 million and tied to plant and equipment. The subsidy rate for Sidmar is 0.410 percent *ad valorem*.

Balber received grants for less than $50 million. For Fabfer a separate subsidy exists in addition to its receipt of these grants. Fabfer is able to take advantage of a special provision of the 1970 law, which allows it a preferential deferral of payment of corporate income taxes on the receipt of these grants. The additional subsidy arises from the preferentiality of the tax treatment within the overall tax system. The combined subsidy rate for these two programs amounted to 2,042 percent *ad valorem*.

2. Loan guarantees. The Belgian government may guarantee total or partial repayment of loans and debentures under the 1966 and 1970 laws. When the loan or debenture is not granted by a public institution, the guarantee may not exceed 75 percent of the difference between the amount of the loan outstanding and the value of any collateral offered by the borrower. The company pays a one-time fee based upon the value and duration of the guaranteed loans.

Government loan guarantees have been obtained by companies on loans that we have determined to be countervailable. A loan guarantee by the government constitutes a subsidy to the extent the guarantee assures more favorable loan terms than for an unguaranteed loan. The subsidy amounts for these preferential loans are calculated in the sections of this notice titled "Loans to Uncreditworthy Companies," "Preferential Loans" and "Industrial Investment Loans from the ECSC (Article 54)." We calculated the benefits from loans subject to these guarantees by offsetting the guarantee fees against the benefit calculated for the loans. Such offsets are permissible pursuant to section 771(6) of the Act.

Cockerill and Sidmar received loan guarantees under this program. Because Cockerill did not demonstrate what fees it paid for these guarantees, we are not offsetting the guarantee fees for Cockerill. We did offset these fees for Sidmar. Fabfer received no loan guarantees.

3. Exemptions from Real Property Tax. Under the 1970 law, qualifying investments may be granted an exemption from the real property tax levied by the state, province, or local community on the estimated rental income from fixed assets. The exemption may be granted for a period of up to five years, depending on the degree to which the investment program achieves the objectives of the 1970 law. Exemptions received by companies were treated as grants that are normally expensed in the year received and applied to the value of the sales of the appropriate products of the company. Benefits received by a particular mill were allocated to the total sales value of all of the products produced by Cockerill at that mill.

The subsidy rate for Cockerill under this program is 0.148 percent *ad valorem*

for hot-rolled carbon steel plate and hot-rolled carbon steel sheet and strip; and 0.073 percent *ad valorem* for carbon steel structural shapes.

The subsidy rates calculated for Sidmar and Fabfer are 0.071 and 0.123 percent *ad valorem*, respectively.

4. Exemptions from Capital Registration Tax. Assets transferred to a company which makes investments pursuant to the 1970 law may be exempted from the one percent capital registration tax. We treated exemptions under this program as grants that are normally expensed in the year received. The entire amount of the benefit was allocated over the total sales value of all products of the company.

Cockerill received exemptions amounting to a subsidy rate of 0.40 percent *ad valorem*.

Sidmar and Fabfer did not receive exemptions from the capital registration tax in 1981.

B. Restructuring Plan Programs. The GOB has mandated a reorganization of the steel industry in Belgium under the following enactments and agreements:

- The Reorganization Plan of 1978 (Hanzinelle Agreement)
- Council of Ministers decision of November 23, 1978
- Royal Decree of December 15, 1978
- Council of Ministers decision of May 15, 1981
- Related and additional agreements between the government and the individual steel companies

These are intended to assist the modernization of the steel industry. Specific programs include loans to uncreditworthy companies, equity participation by the GOB and assumption of financing costs. We find these programs to provide countervailable benefits.

1. Loans to Uncreditworthy Companies. Petitioners allege that Cockerill, Hainaut-Sambre and TMP (now merged with Cockerill), Sidmar and Clabecq were uncreditworthy at the time that loans from government institutions were made to them.

We determine Cockerill to be uncreditworthy from 1978 through 1981. The company received a large, unguaranteed private loan (for which there is no evidence of government direction) during 1977 which establishes its creditworthiness despite negative indicators. Cockerill has been uncreditworthy since 1977 for several reasons. First, the company sustained losses ranging from 2.4 to 7.3 billion Belgian francs (BF) in each of the last four years prior to its merger with Hainaut-Sambre in 1981. Second, certain significant financial ratios for this company indicate an uncreditworthy situation, including successive years (1975 through 1981) of negative cash flow and low current ratios. Third, Cockerill apparently lost access to loans from independent commercial sources after 1977. Fourth, the government-directed moratorium on Cockerill's debt service is a further indication of uncreditworthiness, as is the amount, timing and nature of some of the government equity participation.

We determine Hainaut-Sambre to be uncreditworthy from 1977 through 1981. First, Hainaut-Sambre sustained losses ranging from 0.7 to 5.4 billion BF during the five years preceding its merger with Cockerill in 1981. Second, certain significant financial indicators for this company indicate an uncreditworthy situation, including successive years (1976 through 1980) of negative cash flow, except 1979, and very low current ratios. Third, the government-directed moratorium on this company's debt service is a further indication of uncreditworthiness, as is the amount, timing and nature of some of the government equity participation.

In our preliminary determinations, we made no decision concerning the uncreditworthiness of TMP because we lacked sufficient information to identify loans to the company. On the basis of information subsequently received we have identified separate loans made to TMP. It was therefore necessary to evaluate TMP's creditworthiness.

We determine TMP to be uncreditworthy from 1977 through 1981. First, the company sustained losses ranging from 0.5 to 1.8 billion BF in the 4 years prior to its merger with Hainaut-Sambre. Second, certain significant financial indicators for this company indicate an uncreditworthy situation, including successive years (1976 through 1978) of negative cash flow and very low current ratios. Third, the government-directed moratorium on this company's debt service is a further indication of uncreditworthiness, as is the amount, timing and nature of some of the government equity participation.

In our preliminary determinations we concluded that Clabecq was uncreditworthy from 1976 through 1981. However, after evaluation of additional information received concerning its loan experience, we determine Clabecq to be uncreditworthy from 1978 through 1981. This change from our preliminary determinations resulted from information that certain loans received in 1977 were from private sources and were given on terms consistent with commercial considerations. Consequently, we conclude that it was not until after 1977, when Clabecq lost access to loans from independent commercial sources, that Clabecq became uncreditworthy.

Several factors, in addition to loans received by Clabecq, contributed to our determination that Clabecq was uncreditworthy from 1978 through 1981. First, the company sustained losses ranging from 300 to 500 million BF between 1976 and 1981. Second, certain financial ratios for this company, particularly "times interest earned" and current ratios, indicate an uncreditworthy situation. Third, the government-directed moratorium on Clabecq's debt service is a further indication of uncreditworthiness.

In the preliminary determinations, the Department found Sidmar to be uncreditworthy from 1976 through 1981. At verification we obtained more detailed information on Sidmar's recent loan history. We were able to verify that, prior to the 1979 moratorium on outstanding long-term debt, Sidmar had been able to secure long-term loans under arm's-length conditions at market rates. Further analysis of Sidmar's use of government aid showed that it went to plant expansion and not to loss coverage. The company was also able to maintain positive cash flow for the years 1976 through 1981, and recorded net profits from 1978 through 1980. Consequently, we determine that Sidmar should not be treated as an uncreditworthy company.

Because we consider Cockerill (and before their acquisition, TMP and Hainaut-Sambre) and Clabecq to have been uncreditworthy, loans and loan guarantees issued by the GOB during the period of uncreditworthiness are treated essentially as equity investments. Under the equity methodology for loans to uncreditworthy companies as discussed in Appendix 2, we compared the national rate of return on equity in Belgium to the rate realized by Cockerill. To prevent countervailing a higher subsidy amount than if the loan had been an outright grant to the company, we limited the 1981 benefit under this methodology to the result that would be found if the loans were treated as grants under the grant methodology discussed in Appendix 2. The countervailable benefit from each loan was allocated over the total sales value of all steel production of the company. Loans actually converted to equity or convertible debentures are treated separately under the section entitled "Equity Participation by the GOB," which follows.

Clabecq received loans during the period for which we are measuring subsidization. However, using the

methodology discussed in Appendix 2, the benefit from these loans is not countervailable in the year of receipt. Since Clabecq did not receive such loans in the year prior to the period for which we are measuring subsidization, there is also no countervailable benefit to Clabecq in the period for which we are measuring subsidization. Any countervailable benefits flowing to Clabecq which occur outside the period for which we are measuring subsidization would be included in an annual review following the issuance of countervailing duty orders in these investigations.

The benefits to Cockerill under this program amounted to a subsidy rate of 1.075 percent *ad valorem.*

2. Equity Participation by the GOB. The GOB has purchased equity in certain steel companies and has converted "medium-" and long-term debt to equity. Equity infusions by the GOB took place as follows:

• Cockerill.

1979—Conversion of debt to equity and convertible debentures.

1981—Conversion of debt to equity and convertible debentures; purchase of equity to cover "cash drains".

• Hainaut-Sambre.

1979—Conversion of debt to equity and convertible debentures.

• TMP

1979—Conversion of debt to equity and convertible debentures.

Equity participation by the government is not a subsidy *per se.* Petitioners allege, however, that government infusions of equity in Belgian steel companies were made at a time when these infusions did not represent sound commercial investments. Under the methodology described in Appendix 2, the treatment of government equity in a company hinges essentially on an analysis of the soundness of the investment. If such an investment was not reasonably sound at the time it was made, we will consider it as giving rise to a potential subsidy.

As described *supra,* all the companies listed above recorded substantial and persistent losses over the last several years. Cockerill sustained loses from 1975 through 1981. Hainaut-Sambre sustained losses from 1975 through 1980, and TMP incurred losses from 1975 through 1979.

Under normal business or financial criteria, companies exhibiting a pattern of deep or significant continuing losses would not be regarded as sound investments. In view of these histories of losses and other factors already discussed in the preceding section entitled "Loans to Uncreditworthy Companies," we do not regard these Belgian steel companies as representing sound commercial investments at the time the GOB acquired equity positions in them. Therefore, we determine that the equity infusions were inconsistent with commercial considerations.

Since the stocks of Cockerill, Hainaut-Sambre and TMP were traded on Belgian markets during the time span covering the government's equity infusions, we look to the market and determined the value of the benefit by comparing the market value of these stocks at the beginning of the month in which the equity infusions were made to the actual price paid by the government. If the value paid by the GOB was greater than the market value, we treated the difference as a grant and allocated it over the average useful life of steel assets, 15 years, and over the total value of the company's sales.

In 1979 and 1981 the GOB entered into arrangements with Cockerill whereby it converted the company's debt into convertible debentures. Because these debentures will be repayable only at such time as the company makes sufficient profits to overcome its present heavy debt burden, we treated these conversions as tantamount to purchases of equity in amounts equal to the value of the debentures.

It was alleged by petitioners that Clabecq issued participating debentures to the GOB to cover interest payments. However, we have determined that the GOB did not purchase any convertible debentures from Clabecq. Sidmar and Fabfer did not participate in this program.

The benefit to Cockerill under this program amounted to a subsidy rate of 4.981 percent *ad valorem.*

3. Assumption of Financing Costs. The GOB, in addition to converting debt to debentures, has assumed all financing costs on "medium-" and long-term borrowing for Cockerill for the years 1979–83. This assumption took the form of issuance of convertible debentures in the amount of the interest charges and the postponement of principal repayments. The principal repayments were scheduled to resume in 1984. We treated the benefits from this program as grants to Cockerill and followed the methodology described in Appendix 2. Because the grants under this program were not tied to specific capital equipment, we allocated the benefits over the average useful life of steel assets, 15 years, and over the total sales value of steel products produced by Cockerill.

The benefit to Cockerill under this program amounted to a subsidy rate of 2.619 percent *ad valorem.*

For Sidmar and Clabecq, assumption of financing costs took a somewhat different form. The GOB assumed the costs in exchange for the companies' conditional promise of a future issuance to it of convertible debentures. Principal repayments were deferred until 1984. We treated the benefits from this program as grants and followed the methodology described in Appendix 2. Because the grants under this program were not tied to specific capital equipment, we allocated the benefits over the average useful life of steel assets, 15 years, and over the total sales value of steel products produced by the companies.

The benefits to Sidmar and Clabecq under this program amounted to a subsidy rate of 4.159 percent and 0.177 percent *ad valorem,* respectively.

Fabfer did not participate in this program.

C. Preferential Loans. The Societe Nationale de Credit a l'Industrie (SNCI) is a lending institution created by the GOB which sets the long-term interest rates generally adhered to by private banks in Belgium. Loans were provided to Cockerill and Clabecq (prior to the years in which we find those companies to be uncreditworthy) by SNCI or with SNCI participation at interest rates lower than those provided by the lenders to other customers. We treated these loans as preferential loans to the recipient companies.

Some of these preferential loans were guaranteed by the GOB (see the section of this notice titled "Loan Guarantees"). Fees paid by companies to obtain these guaranteed loans were treated as part of the cost of these loans. To calculate the benefit from these preferential loans, we followed the methodology outlined in Appendix 2.

Cockerill also received a short-termed loan from the GOB in 1981 that we have determined to be preferential. For short-term benchmark rates we used the representative money-market rates for Belgium for the month the loan was received. We found the difference between the interest rate provided by the GOB and our benchmark to represent an interest subsidy to Cockerill. We calculated the interest saved by Cockerill on that loan during the applicable period of 1981 and treated it as a grant expensed in the year received.

The subsidy rates to Cockerill and Clabecq for this program are 0.025 percent and 0.009 percent *ad valorem,* respectively.

Sidmar and Fabfer did not receive benefits from the program.

D. Industrial Investment Loans from the ECSC (Article 54). For the reasons described in Appendix 3, we have determined that ECSC industrial investment loans (pursuant to Article 54 of the Treaty of Paris) provide countervailable benefits. Cockerill received such loans between 1962 and 1976 and Sidmar received such loans between 1975 and 1979. We calculated the benefits from these loans made to Cockerill by using the methodology for loans to companies not considered uncreditworthy described in Appendix 2. We allocated the benefits of these loans over the sales value of carbon steel products of each company.

The benefits amounted to a subsidy rate of 0.036 percent *ad valorem* for Cockerill.

Clabecq and Fabfer did not receive such loans. Sidmar received these loans, but derived no countervailable benefit.

E. Reimbursement of Worker Training Costs. The National Employment Office in Belgium reimburses firms for various in-plant and outside professional training costs. Increased benefits are provided to enterprises located in development areas or in areas in which coal mine closings have adversely affected the economic or social situation in the area. We have determined that this program is countervailable because of its regional nature.

The benefit to Cockerill amounted to subsidy rates of 0.029 percent *ad valorem* for hot-rolled carbon steel plate and hot-rolled carbon steel sheet and strip, and 0.014 percent *ad valorem* for carbon steel structural shapes.

Sidmar, Clabecq and Fabfer did not participate in this program.

F. Readaptation and Retraining Assistance. The GOB finances a portion of readaptation and retraining assistance for laid-off employees under Article 56 of the ECSC Treaty (described in Appendix 3). The program provides for the assumption by the government of a portion of the training costs of the steel companies for the re-employment of laid-off workers. We have determined that laid-off workers are being retrained to assume jobs in the steel industry and that the assistance is, therefore, a subsidy to a participating steel company.

The benefits to Cockerill amounted to a subsidy rate of 0.045 percent *ad valorem.*

Sidmar, Clabecq and Fabfer did not participate in this program.

G. Funds for Loss Coverage. The GOB has provided equity infusions to Cockerill for "cash drains." These funds have been treated as grants used to cover operating deficits. Since these funds were for loss coverage, the benefits were used fully in the year received (see Appendix 2).

The benefits to Cockerill amounted to a subsidy rate of 3.841 percent *ad valorem.*

Sidmar and Fabfer did not receive benefits from this program.

II. Programs Determined Not To Confer Subsidies

We have determined that subsidies are not being provided under the following programs to manufacturers, producers, or exporters in Belgium of carbon steel structural shapes, hot-rolled carbon steel plate and hot-rolled carbon steel sheet and strip.

A. Environmental Incentives. The GOB provides funding for certain environmental projects. Certain Belgium steel companies received small grants under this program. We have reviewed the applicable laws and have found no provisions which limit aid for environmental projects to specific industries or regions. Since the grants are generally available and we have no evidence that the steel industry in Belgium is a major beneficiary, we have determined that this program does not provide subsidies to the steel industry.

B. Employment Premiums for New Workers and Trainees. The "De Wulf Plan" (Royal Decree of October 15, 1979) grants employment premiums of 62,500 BF per quarter to companies who reduce their work week and increase their labor force. Under another plan, 30,000 BF may be paid for each trainee in excess of a number equaling one percent of the workforce of a company in 1980 and 1981. Clabecq and Fabfer have received small grants under these programs. We have determined from examination of the applicable laws that these programs are not countervailable since the benefits of this program are generally available and we have no evidence that the steel industry is a major beneficiary.

C. Assistance to the Coal Industry. In our preliminary determinations, we found that subsidies to Belgian coal producers did not bestow a countervailable benefit upon the production, manufacture or export of Belgian steel.

Between the preliminary determinations and these final determinations, we have analyzed and verified aspects of the Belgian coal subsidy program as it applies to steel. Based upon the verified information in the records of these investigations, we find that this program does not confer a countervailable benefit on Beligum steel producers for the following reasons.

Benefits bestowed upon the manufacturer of an input do not flow down to the purchaser of that imput, if the sale is transacted at arm's length. In an arm's-length transaction the seller generally attempts to maximize its total revenue by charging as high a price and selling as large a volume as the market will bear.

These principles apply to Belgian coal sales as follows. With respect to sales of Belgium coal outside Belgium, the price charged for subsized Belgian coal certainly does not undercut the freely available market price. Therefore, non-Belgian purchasers of subsidized Belgian coal do not benefit from Belgian coal subsidies.

In support of this conclusion, we note that if non-Belgian steel producers did benefit from Belgian coal subsidies, they would attempt to purchase more Belgian coal rather than unsubsidized coal from the other sources, including the U.S. The fact that they purchase significant amounts of unsubsidized coal from other sources indicates that the subsidies on Belgian coal do not flow to non-Belgian coal consumers.

Moreover, it is extremely unlikely that the Belgian government would subsidize non-Belgian coal consumers unless compelled to do so by obligations with respect to the European Communities. Since there is no evidence of such obligation, we conclude that the Belgian government is not in fact subsidizing non-Belgian coal consumers.

With respect to sales of Belgian coal within Belgium—which account for the vast majority of all sales of Belgian coal—we likewise find that the price of Belgian coal does not undercut the market price. Absent special circumstances warranting a contrary conclusion, then, Belgian steel producers apparently do not benefit from Belgian coal subsidies as long as the price for Belgian coal does not undercut the market price.

Further consideration is warranted for two reasons. First, the major Belgian coal producer and Cockerill are both largely government-owned. The issue arises whether transactions between them are conducted on an arm's-length basis. We do not believe that government ownership *per se* confers a subsidy, or that common government ownership of separate companies necessarily precludes arm's-length transactions between them. To determine whether coal sales between Belgian government-owned coal and steel producers appear to have been consummated on arm's-length terms, we considered two factors: (1) whether the government-owned coal producer sold to the government-owned steel producer at the prevailing market price, and/or (2) whether the government-owned coal

producer sold coal at the same prices to steel producers not owned by the government (*e.g.*, Clabecq). We found that Belgian coal producers did charge the prevailing market prices, and that the same coal prices were charged regardless whether the purchaser was or was not Belgian government-owned. On this basis, we conclude that coal subsidies were not conferred on steel producers as a result of government ownership.

Second, we were told by one Belgian government official that all Belgian steel companies are pressured to purchase all coking coal produced by Belgian coal companies at the price established by the government, based upon market prices. This indicates that there are *de facto*, although not *de jure*, restrictions on the importation of coal into Belgium. However, the Belgian coal companies collectively produce only enough coking coal to satisfy less than 50% of the Belgian steel companies' requirements. Therefore, the market prices outside Belgium remain relevant, both directly for the coking coal purchased outside Belgium, and indirectly for the Belgian coking coal since the Beglian price is based on market prices outside Belgium.

Moreover, there is no evidence that the Belgian government would pressure Beglian steel producers to buy Belgian coal if the price for such coal were to rise significantly above the market price—a factor over which the Belgian government has control since it establishes prices.

Based upon the above considerations, we determine that Belgian coal subsidies do not confer upon Belgian steel producers a subsidy within the meaning of the Act.

Regarding the allegation that the Belgian steel industry benefits from German government assistance provided to the coal industry in the FRG, we do not consider such assistance to confer a countervailable benefit on the Belgian steel industry for the reasons outlined in Appendix 2.

The ECSC provides various production and marketing grants to ECSC coal and coke producers. However, we do not consider this assistance to confer a countervailable benefit on the Belgian steel industry for the reasons described in Appendix 3.

D. Programs contained in the Law of July 17, 1959 for Economic Expansion. The Law of July 17, 1959 for economic expansion (the 1959 law) contains programs which are designed to promote economic expanison and modernization. The 1959 law provides for interest rebates, grants for capital investments, government loan guarantees, exemptions from property taxes on investments approved under the law and grants for research and development (R&D). Cockerill and Clabecq received benefits under this law, but the benefits under this law are generally available and we have no evidence that the steel industry in Belgium is a major beneficiary. Thus, absent other evidence of preferentiality, the benefits under this law are not countervailable.

E. GOB Advances for R&D Under the Economic Expansion Laws. Interest-free advances can be provided under the 1959 law and the 1970 law up to a maximum of 80 percent of the expense incurred for the R&D of prototypes. the GOB responded that it has provided this type of aid under the economic expansion laws during 1980–81, but for the preliminary determinations we were unable to determine from the response that the aide was given under the 1959 law, which we have concluded does not confer countervailable benefits, as discussed above.

F. Supplier Credit. Subsequent to the preliminary determinations in these investigations, counsel for Bethlehem alleged that but for government assistance, the various steel companies found to be uncreditworthy by the Department would not have been able to obtain supplier credit. We have no information that would cause us to believe that the supplier credits are provided on terms inconsistent with commercial considerations. Since these credits have been provided by independent, private sources and we have no evidence that the GOB has influenced financial institutions in this regard, we have determined that this program does not provide subsidies to the steel industry. For further discussion of this program, see Appendix 2.

G. Maribel Program. Subsequent to the preliminary determinations in these investigations, counsel for Bethlehem alleged that Belgian steel produces benefited from a change in the social security system instituted on July 1, 1981. Under the "Maribel Program," contributions to social security programs by employers of manual workers were reduced by 6.17 percent. Counsel for Bethlehem maintains that since the program is restricted to manual workers, ti provides benefits to a specific industry or group of industries and is, therefor , countervailable. We have decided that assistance to virtually all manual workers does not create a program targeted to steel or to a specific enterprise or industry or group of enterprises or industries. Therefore, we determine that the program does not confer countervailable subsidies to the steel industry.

H. Labor Assistance (Prepension program). The government-mandated restructuring of the steel industry included provisions for the early retirement of certain workers. The government assumed responsibility for funding costs for which the company would not normally be obliged. We have determined that this government assistance does not confer countervailable benefits to the companies because it is really assistance to the workers passed through the companies.

I. Research and Development (R&D) from the GOB. The GOB provides R&D funds to a wide range of disciplines through the Institute for Scientific Research in Industry and Agriculture (IRSIA). Funding is provided for projects which "ensure the progress" of industry and agriculture. IRSIA is administered by a board of directors which has representation from various sectors of industry and agriculture, trade unions and educational institutions.

In the preliminary determinations the Department considered that this program conferred countervailable benefits to Cockerill, because of direct grants to Cockerill, and to Clabecq through its participation in projects with the Center for Metallurgical Research (CRM), which were partially funded by IRSIA. Because of the broad scope and administration of the IRSIA program, we have determined that the program is not countervailable since there is no evidence of targeting funds for an industry under investigation. In the 1980–81 research cycle, approximately 11 percent of IRSIA's budget went to the entire metallurgical sector for research involving steel and non-ferrous metals.

III. Programs Determined Not To Be Used

We have determined that the following programs which were listed in the notice of "Initiation of Countervailing Duty Investigations" were not used by the manufacturers, producers, or exporters in Belgium of carbon steel structural shapes, hot-rolled carbon steel plate and hot-rolled carbon steel sheet and strip.

A. Accelerated Depreciation. Companies that receive investment benefits provided for by the 1970 law may take twice the normal annual straight-line depreciation for assets acquired as the result of the investment. The benefit from the program is reduced taxable income. With the exception of Fabfer, the Belgian steel companies had losses, during the period for which we are measuring subsidization, greater than the amounts that would have been

saved by use of accelerated depreciation. After examination of its depreciation schedules, we determined that Fabfer depreciated its assets at normal rates and, in effect, made no use of the program.

b. Employment Premiums. Article 14 of the 1970 law provides for employment premiums for investments that create new jobs. The assistance may be given for new enterprises or for the expansion of existing enterprises. Nonrepayable premiums may be paid for as long as five years depending on the rate at which new jobs are created and filled. We have found no evidence that the companies under these investigations participated in this program. Employment has dropped approximately 30 percent as the result of actions taken under the steel industry restructuring plan.

C. Contractual Aid. The 1970 law provides for aid in realizing specific objectives related to certain long-term, large scale investments. The government and an enterprise negotiate the specific terms of the program and enter into a "progress contract." The GOB has stated that this provision of the 1970 law has not been applied. Companies may also receive aid for reorganizations. Under "management contracts," the government may grant interest-free aid, to be repaid within three years, for up to 75 percent of management advisory fees. The GOB stated that of the twelve management contracts it has entered into, none were with steel companies.

D. Export Assistance. Certain export assistance programs, such as export financing and commercial risk guarantees, are provided by the Office National du Ducroire. We have found no evidence that the companies under investigation have received assistance under this program.

E. The European Regional Development Fund (ERDF). On the basis of our investigations we have concluded that no company under investigation in Belgium receives ERDF funds (see Appendix 3).

F. European Investment Bank (EIB).We have determined that no company under investigation in Belgium carried loans from the EIB in 1981 (see Appendix 3).

G. Loan Guarantees from the ECSC. We have determined that no company under investigation in Belgium received loan guarantees from the ECSC. For further discussion of this issue, see Appendix 3.

H. "Interest Rebates". "Interest rebate" programs are administered by the Ministry of Economic Affairs. The rebates may be given on investment loans for tangible and intangible assets. The law also provides for "interest rebates" on interest payable by the companies to holders of bonds and convertible debentures. Rebates are variable depending upon the degree to which the investment projects meet the objectives of the 1970 law.

Upon verification we discovered that Cockerill, Fabfer, Clabecq and Sidmar did not receive "interest rebates" during the period for which we are measuring subsidization.

I. ECSC Interest Rebates and R & D Grants. We have determined the companies under investigation received no benefits from this program. For our treatment of these programs in general, see Appendix 3.

J. Reduction of Capital Gains Tax. Capital gains on the sales of tangible property may be exempt from corporate taxes if receipts are reinvested in Belgium in the development areas of the 1970 law within one year of the end of the tax period. We have determined that the companies under investigation did not receive any benefits under this program.

Petitioners' Comments

Comment 1

Counsel for petitioners argue the Department should alter its methodology for calculating the benefit from equity infusions to uncreditworthy companies, because the current methodology understates the value of such infusions.

DOC Position

For reasons set forth in Appendix 2, the Department has not changed its methodology. Furthermore, in the case of Cockerill, the availability of a market price against which to compare the price paid by the government provides an independent, disinterested measure of the true value of the company's stock.

Since our methodology, as applied in this case, uses the market price as the basis for determining the value of equity infusions to Cockerill, we believe it is the most appropriate approach.

Comment 2

Petitioner argues that Sidmar's financial condition demonstrates that it is uncreditworthy.

DOC Position

We find Sidmar to have been creditworthy for the reasons described under the section of this notice titled "Loans to Uncreditworthy Companies." For further discussion of our standards for determining uncreditworthiness, see Appendix 2.

Comment 3

We calculated the value of loans to companies found to be uncreditworthy by using the methodology outlined in Appendix B (Loans to Uncreditworthy Companies). Counsel for petitioners argue that, since the cost of equity must always be higher than the cost of debt, a risk premium should be added to the rate of return for profitable enterprises against which the rate of return of the government is compared in order to ensure that the cost of equity comes out to be higher than the cost of debt. They suggest various methods for estimating this risk premium.

DOC Position

Our comparison rate for return on equity is based on a national average. As such, it reflects annual rates of return to both successful and unsuccessful investors. In our view, use of this average is a better measure of a reasonable expectation of return than a rate which reflects only the experience of successful investors. For further discussion of our methodology, see Appendix 2.

Comment 4

Counsel for petitioners argue that programs contained in the Law of July 17, 1959 for economic expansion are countervailable. They state that the July 17, 1959 law is the "template" for the 1970 regional law which was found to be countervailable and has become a *de facto* regional development vehicle.

DOC Position

Two laws were passed in July, 1959. Programs under the Law of July 18, 1959 are countervailable on the basis of regional preferentiality. Programs under the Law of July 17, 1959 are not countervailable because they are available to companies in all regions and are not directed to a specific enterprise or industry or group of enterprises or industries. See Appendix 4 for a discussion of the Department's interpretation of preferentiality under section 771(5) of the Act.

Comment 5

Counsel for petitioners argue the Department should assess the entire amount of R&D advances by the GOB against each company. They note that the GOB stated it advanced R&D money to the steel industry under the 1970 regional law, yet no steel company admitted receipt. Therefore, they argue, the Department should countervail the entire amount against all companies. They also noted additional instances of R&D funding through IRSIA.

DOC Position

Although the GOB informed us it had advanced R&D funds to "a steel company," we found the aid was given under the July 17, 1959 law for economic expansion, which we determined is not countervailable, and not under the 1970 law, as assumed by the petitioner. We also determined that IRSIA funding is generally available on equal terms to industries in Belgium and does not confer a subsidy on the steel industry.

Comment 6

Petitioners argue that, since 80 percent of Belgian coal is used in coke ovens, the coal subsidies are targeted to the steel industry. They argue further that transactions between Belgian coal and steel producers are unlikely to be conducted at arm's length since both buyer and seller are government-owned.

DOC Position

In our preliminary determinations, one reason cited for concluding that Belgian subsidization of its coal industry does not indirectly subsidize its steel industry is that Belgian governmental assistance is provided to producers of all types of coal, not just coking coal. On this basis, we preliminarily determined that assistance provided by the GOB to Belgian coal producers does not indirectly subsidize ". . . a specific enterprise or industry or group of enterprises or industries."

Upon verification, we determined that the great majority of subsidized Belgian coal is coking coal, which is used primarily by the steel industry (although the Belgian steel industry acquires 55–60 percent of its coking coal from foreign sources, including the U.S.). In these final determinations, therefore, we are basing our determinations on a different basis, as indicated *supra*.

Also as explained *supra*, we do not believe that government ownership of separate companies necessarily precludes them from conducting some transactions on an arm's-length basis. Since the major Belgian coal producer and Cockerill are both largely government-owned, we consider whether (1) the coal prices charged to Cockerill were at the prevailing market rates; and (2) whether the same prices were charged to Cockerill and to other steel producers not owned by the Belgian government. Since we reached affirmative determinations in both cases, we concluded that it is reasonable to assume that coal transactions between the Belgian government's coal producer and Cockerill were conducted on an arm's-length basis.

Comment 7

Petitioners claim that there are implicit restrictions on the amount of coal Belgian steel companies can buy from abroad.

DOC Position

An indicated *supra*, and in the Department's verification report concerning the GOB, there is some evidence that Belgian steel companies are pressured by the Belgian government to purchase the entire output of Belgian coal companies. (There is no evidence that there are any *de jure* restrictions on the importation of coal.) However, Belgian coal producers at best can satisfy less than 50 percent of the requirements of Belgian steel producers. Therefore, market prices outside Belgium remain relevant in determining whether Belgian steel producers benefit from assistance to Belgian coal producers for the following reasons. First, the price for Belgian coal established by the Belgian government is based upon that market price, which is thus indirectly relevant. Second, over 50 percent of the Belgian steel companies' requirements for coking coal are satisfied through coking coal imports. Their prices are, therefore, directly relevant. Moreover, there is no evidence that the Belgian government would continue to pressure its steel producers to buy Belgian coal if the price for Belgian coal rose significantly above market price. We, therefore, determine that, even if there are *de facto* restrictions on the importation of coking coal into Belgium, the Belgian steel producers nonetheless received no countervailable benefits from subsidization by the GOB of its coal industry.

Comment 8

Counsel for petitioners argue that ECSC subsidies to coal benefit Belgian steel companies and thus are countervailable.

DOC Position

For reasons set forth in Appendix 3, we have determined that ECSC aid to the European coal industry does not confer countervailable benefits to the steel industry.

Comment 9

Counsel for petitioner argues that, in the absence of GOB subsidies, the steel companies would not have been able to obtain supplier credits. Thus, supplier credits represent countervailable subsidies.

DOC Position

The Department examined supplier credits extended to Belgian steel companies. We have found that these credits have been provided by independent, private sources and we have no evidence that the GOB has influenced financial institutions in this regard. Therefore, we conclude these credits confer no subsidies to the companies under investigation.

Comment 10

Counsel for petitioner argues that the Maribel program provides countervailable benefits because it applies only to manual workers and excludes certain employees.

DOC Position

The Department has determined that benefits under the Maribel program are provided to virtually all companies which employ manual laborers and, consequently, are not provided to a specific enterprise or industry or group of enterprises or industries. We found that the sectors specifically excluded were only certain utility industries and certain white collar sectors such as banking and insurance. Consequently, the benefits are not countervailable.

Comment 11

Counsel for petitioners argue that the added burden imposed on the steel industry by the GOB as a result of requirements to pay "prepension" (early retirement) benefits under the steel restructuring plan is an offset not permissible under the Act. They further argue that this plan allowed companies to reduce their workforces more cheaply than the unions would have otherwise allowed.

DOC Position

The effect of this program was to impose the burden of paying extraordinary severance benefits on the steel companies. In assuming a portion of these benefits the government did no more than reduce extraordinary costs in excess of what the steel companies would have had to pay had their obligations remained the same as for any other Belgian industry. In addition, the benefits went to workers and not to the steel companies. This is distinguishable from the situation in which the government acts to relieve a specific industry of obligations normally also imposed on other industries. The government's shutdown requirement and the government's payment of the extraordinary costs must be taken together—the company is merely a conduit for the flow of funds from the

government to the workers, and there is no gross subsidy against which an offset could be made. In these circumstances, we do not find any preferential benefit to the steel industry.

Comment 12

Counsel for petitioners argue that the Department should countervail all funds received by steel companies for readaptation and retraining assistance under Article 56 of the ECSC Treaty.

DOC Position

As discussed in the section of this notice titled "Readaptation and Retraining," the Department has determined that ECSC readaptation and retraining assistance which benefits the production of steel is countervailable to the extent such assistance is funded by the governments. The portion funded by producer levies is not countervailable (see comment 13 listed below).

Comment 13

Counsel for petitioners argue that the portion of ECSC assistance funded by producer levies is countervailable.

DOC Position

For reasons set forth in Appendix 3, we determine that the portion of ECSC assistance funded by producer levies is not countervailable.

Comment 14

Counsel for petitioners argue that Fabfer took advantage of an exemption from income tax on a 1981 grant. Fabfer, the only known profit-making steel company in Belgium, was in a position to take advantage of a provision in the 1970 economic expansion law allowing this exemption.

DOC Position

Based upon verified information, we have determined that Fabfer did take advantage of the tax exemption for grants received under the 1966 and 1970 laws.

Comment 15

Counsel for petitioners argue that "critical circumstances" exist because the proper period of time to measure a surge of imports is prior to the filing of the petition. They further argue that the cumulative effects of imported merchandise should be considered.

DOC Position

For a discussion of this issue, see Appendix 4.

Respondent's Comments

Comment 1

Counsel for respondents argue that the Department adopted new methodologies for the calculation of subsidy rates without the normal regulatory notice and comment procedures. They stated that the concept of "creditworthiness" and the methodologies described in Appendix B of the preliminary determinations have no basis in law.

DOC Position

For a discussion of this issue, refer to Appendix 4.

Comment 2

Respondents argue that the Department erred in certain determinations concerning the purchase of equity by the GOB.

A. Counsel for Cockerill argues that the stock market price used by the Department does not represent an adequate basis for comparison with the price paid by the GOB because it does not include the added value of a premium for gaining control of the company. In addition, they state the prices paid by the GOB were below book value and were comparable to those paid by purchasers of stock in other European steel mills.

DOC Position

The Department believes that the price set by the market for Cockerill's stock is the most appropriate measure of the true value of its equity. For further discussion of this issue, see Appendix 2.

B. Counsel for Sidmar claims the DOC erred in finding that a purchase of Sidmar stock by the GOB in 1979 resulted in a countervailable benefit.

DOC Position

The Department has reversed its determination regarding this purchase. It was established at verification that this was a purchase of pre-existing stock on the market and not of a new stock issue. It also was confirmed that proceeds from the GOB purchase did not flow back to Sidmar but remained with the seller, Acieries Reunies de Burbach-Eich-Dudelange S.A.

Comment 3

Counsel for respondents argue that the Department erred in certain determinations concerning creditworthiness.

A. Counsel for Cockerill argues that the Department's creditworthiness decision concerning Cockerill is incorrect. They assert that Cockerill and Hainaut-Sambre have received substantial private lending in the form of short-term loans. They further argue that the GOB does not implicity stand behind Cockerill to help it get private credit because the GOB has let several companies it owns go bankrupt. Thus, they argue, Cockerill is creditworthy independent of the backing of the GOB.

DOC Position

Respondent argues that Cockerill is creditworthy because it has received short-term credit from private sources. We determine, however, that such lending, which is largely backed by receivables, does not imply a judgment of creditworthiness.

We determine Cockerill to be uncreditworthy from 1978 through 1981. For each of those years, various financial indicators pointed to the uncreditworthiness of the company. For further discussion of this issue, see the section titled "Loans to Uncreditworthy Companies."

B. Counsel for Sidmar argues that the Department erred in determining that Sidmar was an uncreditworthy company.

DOC Position

In the preliminary determinations the Department found Sidmar to be uncreditworthy from 1976 through 1981. At verification, we were able to verify that prior to the 1979 moratorium on outstanding long-term debt, Sidmar was able to secure long-term loans under arm's-length conditions at market rates. We have, therefore, determined that for the years 1976 through 1978, Sidmar will not be treated as an uncreditworthy company. We have further determined that Sidmar should not be considered as an uncreditworthy company from 1979 through 1981. The reversal of our preliminary determination of Sidmar's uncreditworthiness is based on the following factors:

- Verification of private long-term loans prior to 1979.
- Positive cash flow in all of the six years between 1976 and 1981.
- Further analysis of Sidmar's use of government aid which showed that aid went to plant expansion and not to loss coverage.
- Net profits in 1978, 1979 and 1980.

C. Counsel of Clabecq argues that Clabecq should be deemed creditworthy. They state that Clabecq is well managed, efficient and shows "every sign of recovery and renewed profitability." Clabecq, they further argue, received private lending after the year we considered them uncreditworthy in the preliminary determinations.

DOC Position

We determine that Clabecq has been uncreditworthy from 1978 through 1981. The company did receive long-term private lending on commercial terms in 1977. Subsequent to that time, however, Clabecq has lost access to similar lending. Further, the company's history of significant losses and the weakness of certain significant financial ratios for the company still point to its uncreditworthiness from 1978 through 1981. For further information on this issue, see the section titled "Loans to Uncreditworthy Companies."

Comment 4

Counsel for respondents argue that programs under the law of December 30, 1970, are not contervailable for the following reasons:

- The law is regional but not targeted to specific industries.
- The 1970 law is similar to the general law of July 17, 1959.

DOC Position

The 1970 law provides benefits only to companies in certain regions. Consequently, these benefits are provided to a specific group of enterprises or industries and are countervailable under section 771(5) of the Tariff Act of 1930. Further, past administrative practice, judicial decisions, and the legislative history of the Trade Agreements Act of 1979 make it clear that regional benefits are countervailable.

Comment 5

Respondents argue that since the 1970 law, which provides benefits only to certain regions, provides only marginally higher benefits than would be available under the July 17, 1959 law, only the incremental benefit should be countervailed.

DOC Position

The benefits to which respondents refer were provided under the 1970 law. The Department would have to ignore the facts in the record to treat benefits provided under the 1970 law as if they were provided under the July 17, 1959 law.

Comment 6

Counsel for Cockerill argues that the benefits from the capital registration tax resulted from a corporate reorganization and that similar tax exemptions exist in the United States. They state that there would have been no such benefit if the funds received from the GOB were grants rather than equity.

DOC Position

Regardless of the circumstances of the increase in capital, this exemption from a statutory obligation, provided under the regional incentive law of December 30, 1970, confers a countervailable benefit on Cockerill.

Comment 7

Counsel for Cockerill and Clabecq argue that the GOB "prepension" benefits are not countervailable subsidies. They argue that, but for these provisions, the company would have had to pay 3–6 months of severance pay to retiring workers, which is less than the obligations under the "prepension" program. They state that under the restructuring plan the government mandated these extraordinary benefits to retirees and at the same time helped the companies to pay for them.

DOC Position

The Department has determined that since the government mandated these payments to the workers as part of the steel restructuring plan, the company is merely a conduit for the flow of funds from the government to the workers, and the government's contribution is not countervailable. See additional discussions of this issue at petitioner's comment on the "prepension program" and the section of this notice title "Labor Assistance (Prepension Program)."

Comment 8

Counsel for Cockerill argues that the largest instance of research and development funding to Cockerill was made available under the general incentive law of July 17, 1959.

DOC Position

The Department verified that this benefit was granted specifically under the law of July 17, 1959 and determined that it is not a countervailable benefit to Cockerill.

Comment 9

Counsel for Clabecq argues that funds received by Clabecq from the Center for Metallurgical Research (CRM) are not countervailable. They state that the funds were reimbursements for work performed, not grants or loans.

DOC Position

We preliminarily determined that Clabecq received countervailable benefits through membership in the CRM. A portion of the projects carried out at the CRM are funded by grants from the Belgian government, through IRSIA. The company shares in the funding of the projects through the payment of dues and the performance of work for the CRM. If the value of the work performed by Clabecq exceeds the dues owed, it may be reimbursed for its expenses. We do not consider the funding of a portion of the research by the company or the reimbursement for work performed to be a subsidy. Further, we have determined that the funding of research by the GOB through IRSIA is not countervailable because of the broad scope of the IRSIA program. For further discussion of this issue, see the position of this notice titled "Research and Development Advances by the GOB."

Comment 10

Counsel for Clabecq and Fabfer argue that the Department's methodology for the determination of subsidy rates resulting from grants is incorrect for the following two reasons.

A. The "present value" methodology results in countervailing an amount greater than the face value of the grant.

DOC Position

The Department has determined that this "present value" methodology is the most appropriate for measuring the benefit of grants to recipient companies. For further discussion of this issue, see Appendices 2 and 4.

B. Counsel for Fabfer believes that grant amounts should be offset by taxes paid by the company on the grants.

DOC Position

The Department finds that this offset is not allowed under section 771(6) of the Act.

Comment 11

Counsel for Clabecq maintains that the creditworthiness standard was not applied consistently by the Department. They claim that the Department's methodology treated loans as debt when calculating the debt/equity ratio; however, once a company was determined to be uncreditworthy, the loans were treated as equity.

DOC Position

Because these loans were not truly equity, they were counted as debt in our creditworthiness analysis. The best method to calculate the benefit to recipient companies from these loans given to uncreditworthy companies is to treat them as similar to equity infusions for reasons set out in Appendix 2. We are not considering them as equity *per se*.

Comment 12

Counsel for Clabecq maintains that subsidy rates for preferential loans and loan guarantees to creditworthy companies were calculated incorrectly. They argue that the present value methodology incorrectly overstates the amount of the subsidy.

DOC Position

The Department has determined that this methodology is the most appropriate for measuring the benefit of loans and loan guarantees to recipient companies. For further discussion of this issue, see Appendices 2 and 4.

Comment 13

Counsel for Clabecq maintains that the Department's methodology for calculation of subsidy rates for loans and loan guarantees to companies considered uncreditworthy is incorrect.

They cite the following points:

- The use of an average rate of return on equity for a country is unfair when trying to measure the rate of a cyclical industry like steel.
- The Department's assumption that the government should not make an equity infusion in a company having a rate of return below the national average is unjust. This evaluation is based upon hindsight; we must examine the situation at the the time the loan was made.
- The use of a company's rate of return as a benchmark is not accurate since a company may suffer from temporary operating losses.
- The present value methodology produces results which greatly exceed the amounts actually received.

DOC Position

The Department has determined that the methodology utilized is most appropriate for valuing the benefits related to each of the above points raised by counsel. For further discussion of these issues, see Appendices 2 and 4.

Comment 14

Counsel for Clabecq argues that forgiveness of debt is not countervailable in all cases. They state that, in the commercial world, forgiveness of debt is frequently granted.

DOC Position

Debt forgiveness by the government is an assumption of a company's cost of doing business and, as such, is countervailable.

Comment 15

Counsel for Clabecq maintains in general that a government loan financed by government borrowing on international capital markets does not confer a subsidy so long as the loan funds are relent at rates sufficient to cover the costs to the government. In particular, they maintain that the Department's rejection of this principle with respect to R&D loans was incorrect. They argue that the Department is unreasonably applying a stricter standard for domestic subsidies than those established for export subsidies.

DOC Position

For discussion of these issues, see Appendix 4.

Comment 16

Counsel for Clabecq maintains that the Department's standard for determining the countervailability of labor programs is incorrect. They argue that the Department's method relies on a determination of whether programs benefit employees or employers. They claim the determination should be based upon whether these programs actually benefit the production of the products under investigation.

DOC Position

The Department's determinations were not based solely on whether these programs benefit the employer, since the benefits, if any, are allocated only to the products under investigation. Where an employer receives these benefits, but does not produce any product under investigation, we do not include in our calculations the benefits to that employer or that employer's sales.

Comment 17

Counsel for Clabecq maintains that the Department erred in its calculations. They argue that the total value of steel production should be used as the denominator in subsidy calculations. This would include slab products and all interest and depreciation, which, when added, would produce a "fully absorbed" cost.

DOC Position

We will use an ex-factory sales value for all steel production (including slab) rather than a cost model for subsidies to Clabecq that were untied and benefited all steel production. For further discussion of our methodology, see Appendix 2.

Comment 18

Counel for Clabecq argues that the Department's loan computations should be adjusted to give credit for interest and guarantee fees, and also that they should be made on an accrual basis. Similarly, counsel for Cockerill argues that an adjustment should be made for loans treated as equity that were received late in 1981.

DOC Position

We will take account of all interest and guarantee fees paid when calculating the subsidy, pursuant to section 771(6) of Act.

We will continue to calculate loan subsidies for the entire year regardless of when the loan was given. However, we start measuring the benefit from these loans the year after they are received. For further discussion of our methodology, see Appendix 2.

Comment 19

Counsel for Clabecq maintains that the calculation of benefits to Clabecq resulting from loans to uncreditworthy companies should be adjusted to take account of guarantee fees required by the general law of 1959.

DOC Position

As discussed in the section of this notice title "Loan Guarantees," where applicable, we have made allowance for payment of these fees in our calculations.

Comment 20

Counsel for Sidmar disputes the petitioners' claim that GOB and ECSC subsidies to coal confer an indirect subsidy on Belgian steel production.

DOC Position

The Department agrees with the respondents' position. For further discussion of this issue, see Appendix 3 and the section of this notice titled "Assistance to the Coal Industry," *supra*.

Negative Determination of Critical Circumstances

Bethlehem Steel Corporation and the Five alleged that imports of carbon steel structural shapes, hot-rolled carbon steel plate and hot-rolled carbon steel sheet and strip under investigation present "critical circumstances." Under §§355.29 and 355.33(b) of the Department's regulations, critical circumstances exist when the alleged subsidies include an export subsidy inconsistent with the Agreement and there have been massive imports of the class or kind of merchandise which is the subject of the investigation over a relatively short period.

We have not found any export subsidy in these investigations. Therefore, "critical circumstances" do not exist in these investigations for carbon steel structural shapes, hot-

rolled carbon steel plate and hot-rolled carbon steel sheet and strip.

Verification

In accordance with section 776(a) of the Act, we verified the data used in making our final determinations. During this verification, we followed normal procedures, including inspection of documents, discussions with government officials and on-site inspection of manufacturers' operations and records.

Administrative Procedures

The Department has afforded interested parties an opportunity to present oral views in accordance with its regulations (19 CFR 355.35). A public hearing was held on July 13, 1982. In accordance with the Department's regulations (19 CFR 355.34 (a)), written views have been received and considered.

Suspension of Liquidation

The suspension of liquidation ordered in our preliminary affirmative countervailing duty determinations shall remain in effect until further notice. the estimated net subsidy for each firm and for each product is as follows:

Manufacturer/producer/exporter	Ad valorem rate (percent)
Name:	
Cockerill Sambre:	
Carbon steel structural shapes	13.225
Hot-rolled carbon steel plate	13.411
Hot-rolled carbon steel sheet and strip	13.411
Siderurgie Maritime:	
Hot-rolled carbon steel plate	4.640
Hot-rolled carbon steel sheet and strip	4.640
Fabrique de Fer de Charleroi: Hot-rolled carbon steel plate	2.165
Forges de Clabecq:	
Hot-rolled carbon steel plate	0.000
Hot-rolled carbon steel sheet and strip	0.000

As explained above, we have determined that a subsidy is being provided to Clabecq. The amount of the estimated net subsidy during the period for which we are measuring subsidization is 0.348 percent *ad valorem* which is *de minimis*. Therefore, all estimated countervailing duties deposited subsequent to the preliminary determinations on entries of merchandise manufactured by Clabecq shall be refunded and the appropriate bonds released. However, because of additional subsidies which may flow from certain loans received during this period, as described in the section of this notice titled "Loans to Uncreditworthy Companies," Clabecq is not being excluded from these final affirmative countervailing duty determinations.

All other manufacturers/producers/exporters:	(percent)
Carbon steel structural shapes	13.225
Hot-rolled carbon steel plate	13.411
Hot-rolled carbon steel sheet and strip	13.411

We are directing the U.S. Customs Service to require a cash deposit or bond in the amount indicated above for each entry of the subject merchandise entered on or after the date of the publication of this notice in the **Federal Register**. Where the manufacturer is not the exporter, and the manufacturer is known, the rate for that manufacturer shall be used in determining the cash deposit or bond. If the manufacturer is unknown, the rate for all other manufacturers/producers/exporters shall be used. Where a company specifically listed above has not exported a particular product under investigation during the period for which we are measuring subsidization, the cash deposit or bond amount shall be based on the highest rate for products that were exported by that company.

ITC Notifications

In accordance with section 705(d) of the Act, we will notify the ITC of our determinations. In addition, we are making available to the ITC all non-privileged and non-confidential information relating to these investigations. We will allow the ITC access to all privileged and confidential information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order, without the written consent of the Deputy Assistant Secretary for Import Administration. The ITC will determine within 45 days of the publication of this notice whether imports of carbon steel structural shapes, hot-rolled carbon steel plate and hot-rolled carbon steel sheet and strip are materially injuring, or threatening to materially injure, a U.S. industry. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated and all securities posted as a result of the suspension of liquidation will be refunded or cancelled. If, however, the ITC determines that such injury does exist, within 7 days of notification by the ITC of that determination, we will issue a countervailing duty order, directing Customs officers to assess a countervailing duty on certain steel products from Belgium entered, or withdrawn from warehouse, for consumption after the suspension of liquidation, equal to the net subsidy determined or estimated to exist as a result of the annual review prescribed by section 751 of the Act. The provisions of section 707(a) of the Act will apply to the first directive for assessment.

This notice is published pursuant to section 705(d) of the Act and section 355.33 of the Department of Commerce Regulations (19 CFR 355.33).

Dated: August 24, 1982.

Gary N. Horlick,

Acting Assistant Secretary for Trade Administration.

Appendix 1.—Description of Products

For purposes of these investigations:

1. The term *"carbon steel structural shapes"* covers hot-rolled, forged, extruded, or drawn, or cold-formed or cold-finished carbon steel angles, shapes, or sections, not drilled, not punched, and not otherwise advanced, and not conforming completely to the specifications given in the headnotes to Schedule 6, Part 2 of the *Tariff Schedules of the United States Annotated ("TSUSA")*, for blooms, billets, slabs, sheet bars, bars, wire rods, plates, sheets, strip, wire, rails, joint bars, tie plates, or any tubular products set forth in the *TSUSA*, having a maximum cross-sectional dimension of 3 inches or more, as currently provided for in items 609.8005, 609.8015, 609.8035, 609.8041, or 609.8045 of the *TSUSA*. Such products are generally referred to as structural shapes.

2. The term *"hot-rolled carbon steel plate"* covers hot-rolled carbon steel products, whether or not corrugated or crimped; not pickled; not cold-rolled; not in coils; not cut, not pressed, and not stamped to non-rectangular shape; 0.1875 inch or more in thickness and over 8 inches in width; as currently provided for in items 607.6615, or 607.94, of the *Tariff Schedules of the United States Annotated ("TSUSA");* and hot- or cold-rolled carbon steel plate which has been coated or plated with zinc including any material which has been painted or otherwise covered after having been coated or plated with zinc, as currently provided for in items 608.0710 or 608.11 of the *TSUSA*. Semifinished products of solid rectangular cross section with a width at least four times the thickness in the as cast condition or processed only through primary mill hot rolling are not included.

3. The term *"hot-rolled carbon steel sheet and strip"* covers the following hot-rolled carbon steel products. Hot-rolled carbon steel sheet is a hot-rolled carbon steel product, whether or not corrugated or crimped and whether or not pickled; not cold-rolled; not cut, not pressed, and not stamped to non-rectangular shape; not coated or plated with metal; over 8 inches [1] in width and in coils or if not in coils under 0.1875 inch in thickness and over 12 inches in width; [2] as currently provided for in items 607.6610, 607.6700, 607.8320, 607.8342, or 607.9400 of the *Tariff Schedules of the United States Annotated ("TSUSA"). PLEASE NOTE THAT THE DEFINITION OF HOT-ROLLED CARBON STEEL SHEET INCLUDES SOME PRODUCTS CLASSIFIED AS "PLATE" IN*

[1] Amended from 12 inches in the initiation notice.

[2] Initiation notice amended by adding after thickness "and over 12 inches in width."

THE TSUSA (ITEMS 607.8610 AND 607.8320). Hot-rolled carbon steel strip is a flat-rolled steel product, whether or not corrugated or crimped and whether or not pickled; not cold-rolled, not cut, not pressed, and not stamped to non-rectangular shape under 0.1875 inch in thickness and not over 12 inches in width; as currently provided for in items 608.1920, 608.2120, or 608.2320 of the *TSUSA*. Hot-rolled carbon steel strip originally rolled less than 12 inches in width and containing over 0.25 percent carbon is not included.

4. The term *"cold-rolled carbon steel sheet and strip"* covers the following cold-rolled carbon steel products. Cold-rolled carbon steel sheet is a cold-rolled carbon steel product, whether or not corrugated or crimped and whether or not pickled; not cut, not pressed, and not stamped to non-rectangular shape; not coated or plated with metal; over 12 inches in width and in coils or if not in coils under 0.1875 inch in thickness; as currently provided for in items 607.8320 or 607.8344 of the *Tariff Schedules of the United States Annotated ("TSUSA") PLEASE NOTE THAT THE DEFINITION OF COLD-ROLLED CARBON STEEL SHEET INCLUDES SOME PRODUCTS CLASSIFIED AS "PLATE" IN THE TSUSA (ITEM 607.8320).* Cold-rolled carbon steel strip is a flat-rolled carbon steel product; cold-rolled, whether or not corrugated or crimped and whether or not pickled; not cut, not pressed, and not stamped to non-rectangular shape; under 0.1875 inch in thickness and over 0.50 inch in width but not over 12 inches in width; as currently provided for in items 606.1940, 608.2140, or 608.2340 of the *TSUSA*. Cold-rolled carbon steel strip originally rolled less than 12 inches in width and containing over 0.25 percent carbon is not included.

5. The term *"galvanized carbon steel sheet"* covers hot- or cold-rolled carbon steel sheet which has been coated or plated with zinc including any material which has been painted or otherwise covered after having been coated or plated with zinc, as currently provided for in items 608.0710, 608.0730, 608.11 or 608.13 of the *Tariff Schedules of the United States Annotated ("TSUSA"). NOTE THAT THE DEFINITION OF GALVANIZED CARBON STEEL SHEET INCLUDES SOME PRODUCTS CLASSIFIED AS "PLATE" IN THE TSUSA (ITEMS 608.0710 and 608.11).* Hot- or cold-rolled carbon steel sheet which has been coated or plated with metal other than zinc is not included.

6. The term *"hot-rolled carbon steel bars"* covers hot-rolled carbon steel products of solid section which have cross sections in the shape of circles, segments of circles, ovals, triangles, rectangles, hexagons, or octagons, not cold-formed, and not coated or plated with metal, as currently provided for in items 606.8310, 606.8330, or 606.8350 of the *Tariff Schedules of the United States Annotated.*

7. The term *"hot-rolled alloy steel bars"* covers hot-rolled alloy steel products, other than those of stainless or tool steel, of solid section which have cross sections in the shape of circles, segments of circles, ovals, triangles, rectangles, hexagons, or octagons, not cold-formed,[3] as currently provided for in term 606.97 of the *Tariff Schedules of the United States.*

8. The term *"cold-formed carbon steel bars"* covers cold-formed carbon steel products of solid section which have cross sections in the shape of circles, segments of circles, ovals, triangles, rectangles, hexagons, or octagons,[3] as currently provided for in items 606.8805 or 606.8815 of the *Tariff Schedules of the United States Annotated.*

9. The term *"cold-formed alloy steel bars"* covers cold-formed alloy steel products, other than those of stainless or tool steel, of solid section which have cross sections in the shape of circles, segments of circles, ovals, triangles, rectangles, hexagons, or octagons,[3] as currently provided for in item 606.99 of the *Tariff Schedules of the United States.*

[3] Initiation notice amended by deleting after octagons "and not coated or plated with metal."

Appendix 2.—Methodology

Several basic issues are common to many of the countervailing duty investigations of certain steel products, initiated by the Department of Commerce ("the Department") on February 1, 1982; *e.g.*, government assistance through grants, loans, equity infusions, loss coverage, research and development projects and labor programs. This appendix describes in some detail the general principles applied by the Department when dealing with these issues as they arise within the factual contexts of these cases. This appendix, although substantially the same as Appendix B to the preliminary determinations (see "Preliminary Affirmative Countervailing Duty Determinations, Certain Steel Products from Belgium (47 FR 26300)), does describe some changes in methodology. These changes are principally in the areas of the discount rate value, funds for loss coverage, and preferential loans with deferred principal payment.

Grants

Petitions alleged that respondent foreign steel companies have received numerous grants for various purposes. Under section 771(5)(B) of the Tariff Act of 1930, as amended (the Act) (19 U.S.C. 1677(5)(B)), domestic subsidies are countervailable where they are "provided or required by government action to a *specific* enterprise or industry, or group of enterprises or industries" (emphasis added).

The legislative history of Title VII of the Act states that where a grant is "tied" to—that is, bestowed specifically to purchase—costly pieces of capital equipment, the benefit flowing from the grant should be allocated in relation to the useful life of that equipment. A subsidy for capital equipment should also be "front loaded" in these circumstances; that is, it should be allocated more heavily to the earlier years of the equipment's useful life, reflecting its greater commercial impact and benefit in those years.

Prior to these cases on certain steel products, the Department allocated the face value of the grant, in equal increments, over the appropriate time period. For large capital equipment, we used a period of half the useful life of the equipment purchased with the grant. In each year we countervailed only that year's allocated portion of the total grant. For example, a hypothetical grant of $100 million used to purchase a machine with a 20-year life would have been countervailed at a rate of $10 million per year (allocated over the appropriate produce group) for 10 years, beginning in the year of receipt.

This allocation technique has been criticized for not capturing the entire subsidy because it ignores the fact that money has a changing value as it moves through time. It has been argued that $100 million today is much more valuable to a grant recipient than $10 million per year for the next 10 years, since the present value (the value in the initial year of receipt) of the series of payments is considerably less than the amount if initially given as a lump sum. We agree with this position and, as indicated in the preliminary determinations, have now changed our methodology of grant subsidy calculation to reflect this agreement. As long as the present value (in the year of grant receipt) of the amounts allocated over time does not exceed the face value of the grant, we are consistent with both our domestic law and international obligations in that the amount countervailed will not exceed the total net subsidy.

The present value of any series of payments is calculated using a discount rate. As indicated in the preliminary determinations, we considered using each company's weighted cost of capital at the time of the grant receipt as the appropriate measure of the time value of its funds. However, we lacked sufficient information to do so for the preliminary determinations, and instead used the national cost of long-term corporate debt as a substitute measure of a company's discount rate.

Between the preliminary and final determinations we reviewed the comments and suggestions of various interested parties, principally contained in the pre- and post-hearing briefs. In addition, we sought the advice of an outside counsultant with experience in the field of international investment banking.

On the basis of those discussions and that advice, we determine that the most appropriate discount rate for our

purposes is the "risk-free" rate as indicated by the secondary market rate for long-term government debt (in the home country of the company under investigation). The basic function of the "present value" exercise is to allocate money received in one year to other years. Domestic interest rates perform this function within the context of an economy. The foundation of a country's interest rate structure is usually its government debt interest rate (the risk-free rate). All other borrowings incorporate this risk-free rate and add interest overlays reflecting the riskiness of the funded investment.

When we allocate a subsidy over a number of years it is not the intention of the Department to comment on nor judge the riskiness of the project undertaken with the subsidized funds nor to evaluate the riskiness of the company as a whole. Nor do we intend to speculate how a project would have been financed absent government involvement in the provision of funds. Rather, we simply need a financial mechanism to move money through time so as to accurately reflect the benefit the company receives. We believe that the best discount rate for our purposes is one which is risk free and applicable to all commercial actors in the country. Therefore we have used in these final determinations long-term government debt rates (as reflected in the secondary market) as our discount rates.

For costly pieces of capital equipment, we believe that the appropriate time period over which to allocate the subsidy is its entire useful life. In the past, we allocated the subsidy over only half the useful life in order to "front load" the countervailing duties, thereby complying with the legislative intent of the Act. However, so long as we allocate the subsidy the equal nominal increments over the entire useful life, it will still be effectively front loanded in real terms (as long as a positive discount rate is used) since money tomorrow is less valuable than money today.

For these steel investigations we have allocated a grant over the useful life of equipment purchased with it when the value of that grant was large (in these investigations, greater than $50 million) and specifically tied to pieces of capital equipment. Where the grant was small (generally less than 1 percent of the company's gross revenues and tied to items generally expensed in the year purchased, such as wages or purchases of materials), we have allocated the subsidy solely to the year of the grant receipt. We consture that a grant is "tied" when the intended use is known to the subsidy giver and so acknowledged prior to or concurrent with the bestowal of the subsidy. All other grants—the vast majority of those involved in these investigations—are allocated over 15 years, a period of time reflecting the average life of capital assets in integrated steel mills. The 15-year figure is based on Internal Revenue Service studies of actual experience in integrated mills in the U.S. Furthermore, we understand that a 15-year period is a common useful life adopted in some of the countries involved in these investigations for steel capital equipment. We are using this time period because we sought a uniform period of time for these allocations and this was the best available estimate of the average steel asset life worldwide. We could not calculate the average life of capital assets on a company-by-company basis, since different acounting principles, extraordinary write-offs, and corporate reorganizations yield extremely inconsistent results.

Funds To Cover Losses

In the preliminary determinations we did not distinguish funds (either in the form of untied grants or equity infusions) which were available for loss coverage from other grants or equity infusions. We stated that since grants used for loss coverage often have the effect of helping keep the firm in business, we allocated the benefit over 15 years when the funds were in the form of a grant or used the appropriate equity methodology when the loss coverage funds were in the form of equity.

Between the preliminary and final determinations we reviewed the comments and suggestions of various interested parties principally contained in the pre- and post-hearing briefs. In addition, we sought the advice of the Department's accountants and outside consultants on the issue of the appropriate treatment of funds for loss coverage. Based on the above, we have decided not to allocate the subsidy benefit of these funds over time but rather to allocate them to the year of receipt.

We have done so on the advice of these accounting experts in order to reflect the nature of the liabilities giving rise to the loss. These liabilities are generally the basic costs of operations (*e.g.*, wages, materials, certain overhead expenses)—items generally expensed in the year incurred.

We calculated the magnitude of the loss from a company's financial statements beginning with net earnings and working back to a cash based measure of loss. We allocated to loss coverage only those grants and equity infusions which were truly cash inflows into the company and were actually available to cover losses.

In any instances in which infusions were specifically tied to loss coverage, we allocated such infusions accordingly. If infusions were not so tied, we concluded that general, untied grants were a more logical source of loss coverage assistance than general infusions of equity. Accordingly, in making these allocations we treated funds available from grants as the primary source of monies available for loss coverage. We allocated funds available from equity infusions to loss coverage only in the absence of grants or after available grant funds had been exhausted.

We generally treated such cash inflows as covering the losses incurred in the previous fiscal year and allocated the subsidy benefit flowing from such funds to the year of their receipt. An exception was made where losses were continually covered by a special arrangement with the government (as through the use of a special reserve account). In these cases, since the funds for loss coverage were accessible as the losses arose, we allocated the benefit flowing from these funds to the period in which the losses occurred.

Loans and Loan Guarantees for Companies Considered Creditworthy

In these investigations, various loan activities give rise to subsidies. The most common practices are the extension of a loan at a preferential interest rate where the government is either the actual lender or directs a private lender to make funds available at a preferential rate, or where the government guarantees the repayment of the loan made by a private lender. The subsidy is computed by comparing what a company would pay a normal commercial lender in principal and interest in any given year with what the company actually pays on the preferential loan in that year. We determine what a company would pay a normal commercial lender by constructing a comparable commercial loan at the appropriate market rate (the benchmark) reflecting standard commercial terms. If the preferential loan is part of a broad, national lending program, we use a national average commercial interest rate as our benchmark. If the loan program is not generally available—like most large loans to respondent steel companies—the benchmark used instead, where available, is the company's actual commercial credit experience (*e.g.*, a

contemporaneous loan to a company from a private commercial lender). If there were no similar loans, the national commercial loan rate is used as a substitute rate. Finally, where a national loan-based interest rate was not available, an average industrial bond rate was used as best evidence.

For loans denominated in a currency other than the currency of the country concerned in an investigation, the benchmark is selected from interest rates (either national or company-specific, as appropriate) applicable to loans denominated in the same currency as the loan under consideration (where possible rates on loans in that currency in the country where the loan was obtained; otherwise, loans in that currency in other countries, as best evidence). The appropriate discount rate remains the risk-free rate as indicated by the secondary market rate for long-term debt obligations of the company's home country government. The subsidy for each year is calculated in the foreign currency and converted at an exchange rate applicable for each year.

After calculating the payment differential in each year of the loan, we then calculated the present value of this stream of benefits in the year the loan was made, using the risk-free rate (as described in the grants section of this appendix) as the discount rate. In other words, we determined the subsidy value of a preferential loan as if the benefits had been bestowed as a lump-sum grant in the year the loan was given. This amount was then allocated evenly over the life of the loan to yield the annual subsidy amounts. We did so with one exception: where the loan was given expressly for the purchase of a costly piece of capital equipment, the present value of the payment differential was allocated over the useful life of the capital equipment concerned.

For loans not tied to capital equipment with mortgage-type repayment schedules, this methodology results in annual subsidies equivalent to those calculated under the methodology previously employed by the Department whereby we considered the difference in total repayments in each year of a loan's lifetime to be the subsidy *in that year.* For loans with constant principal repayments (*i.e.,* declining total repayments), loans with deferral of repayments, and loans for costly capital equipment, the present value method results in even allocations of the subsidy over the relevant period. This effectively front loads countervailing duties on these loan benefits in the same manner as grants are front loaded.

A loan guarantee by the government constitutes a subsidy to the extent the guarantee assures more favorable loan terms than for an unguaranteed loan. The subsidy amount is quantified in the same manner as for a preferential loan.

If a borrowing company preferentially received a payment holiday from a government lending institution or from a private lender at government direction, an additional subsidy arises that is separate from and in addition to the preferential interest rate benefit. The subsidy value of the payment holiday is measured in the same manner as for preferential loans, by comparing what the company pays versus what it would pay on a normal commercial loan in any given year. A payment holiday early in the life of a loan can result in such large loan payments near the end of its term that, during the final years, the loan recipient's annual payments on the subsidized loan may be greater than they would have been on an unsubsidized loan. By reallocating the benefit over the entire life of the loan through the present value methodology described above, we avoid imposing countervailing duties in excess of the net subsidy. Where we have sufficient evidence that deferral of principal is a normal and/or customary lending practice in the country under consideration, then such deferral has not been considered as conferring an additional subsidy.

Loans and Loan Guarantees for Companies Considered Uncreditworthy

In a number of cases petitioners have alleged that certain respondent steel companies were uncreditworthy for purposes of these investigations at the time they received preferential loans or guarantees, and that they could not have obtained any commercial loan without government intervention.

Where the company under investigation has a history of deep or significant continuing losses, and diminishing (if any) access to private lenders, we generally agree with petitioners. This does not mean that such a company is totally uncreditworthy for all purposes. Virtually all companies can obtain limited credit, such as short-term supplier credits, no matter how precarious their financial situation. Our use of the term uncreditworthy means simply that the company in question in question would not, in our view, have been able to obtain comparable loans in the absence of government intervention. Accordingly, in these situations neither national nor company-specific market interest rates provide an appropriate benchmark since, by definition, an uncreditworthy company could not receive loans on these or any terms without government intervention. Nor have we been able to find any reasonable and practical basis for selecting a risk premium to be added to a national interest rate in order to establish an appropriate interest benchmark for companies considered uncreditworthy. Therefore, we continue to treat loans to an uncreditworthy company as an equity infusion by or at the direction of the government. We believe this treatment is justified by the great risk, very junior status, and low probability of repayment of these loans absent government intervention or direction. To the extent that principal and/or interest is actually paid on these loans, we have adjusted our subsidy calculation (which is performed using our equity methodology, *infra*) to reflect this. We have applied the rate of return shortfall (the amount by which the corporate rate of return on equity was lower than the national average rate of return on equity) only to the outstanding principal in the year which we are measuring subsidization. From this amount, we additionally subtract any interest and fees paid in that year. Moreover, in no case do we countervail a loan subsidy to a creditworthy or uncreditworthy company more than if the government gave the principal as an outright grant.

Short-Term Credits

In all our cases, even the most financially troubled companies regularly receive short-term supplier credits. We find this type of debt different and easily distinguishable from the loans previously discussed. Where a company receives private-sourced supplier credits we have found this countervailable only where they were at preferential rates because of explicit government direction.

Where supplier credits were not given at a preferential rate directed by the government, we found no subsidy. Furthermore, since the risk involved and basis for giving supplier credits is qualitatively different than for long-term loans, we did not interpret the presence of supplier credits as an indication of creditworthiness.

Equity

Petitioners allege that government purchases of equity in respondent steel companies confer a subsidy equal to the entire amount of the equity purchased. Many respondents claim that such equity purchases are investments on commercial terms, and thus do not confer subsidies on these companies.

It is well settled that neither government equity ownership *per se,* nor

any secondary benefit to the company reflecting the private market's reaction to government ownership, confers a subsidy. Government ownership confers a subsidy only when it is on terms inconsistent with commercial considerations. An equity subsidy potentially arises when the government makes equity infusions into a company which is sustaining deep or significant continuing losses and for which there does not appear to be any reasonable indication of a rapid recovery. If such losses have been incurred, then we consider from whom the equity was purchased and at what price, or, absent a market value for the equity, we examine the rate of return on the company's equity and compare it to the national average rate of return on equity.

If the government buys previously issued shares on a market or directly from shareholders rather than from the company, there is no subsidy to the company. This is true no matter what price the government pays, since any overpayment benefits only the prior shareholders and not the company.

If the government buys shares directly from the company (either a new issue or corporate treasury stock) and similar shares are traded in a market, a subsidy arises if the government pays more than the prevailing market price. The Department has a strong preference for measuring the subsidy by reference to a market price. This price, we believe, rightly incoporates private investors' perceptions of the company's future earning potential and worth. To avoid any effect on the market price resulting from the government's purchase or speculation in anticipation of such purchase, we used for comparison a market price on a date sufficiently preceding the government's action. Any amount of overpayment is treated as a grant to the company.

It is more difficult to judge the possible subsidy effects of direct government infusions of equity where there is no market price for the shares (as where, for example, the government is already sole owner of the company). Government equity participation can be a legitimate commercial venture. Often, however, as in many of these steel cases, equity infusions follow massive or continuing losses and are part of national government programs to sustain or rationalize an industry which otherwise would not be competitive. We respect the government's characterization of its infusion as equity in a commercial venture. However, to the extent in any year that the government realizes a rate of return on its equity investment in a particular company which is less than the average rate of return on equity investment for the country as a whole (thus including returns on both successful and unsuccessful investments), its equity infusion is considered to confer a subsidy. This "rate of return shortfall" (the difference between the company's rate of return on equity and the national average rate of return on equity) is multiplied by the original equity infusion (less any loss coverage to which the equity funds were applied) to yield the annual subsidy amount. Under no circumstances do we countervail in any year an amount greater than that which is calculated treating the government's equity infusion as an outright grant.

Foregiveness of Debt

Where we have found that the government has forgiven an outstanding debt obligation, we have treated this as a grant to the company equal to the outstanding principal at the time of foregiveness. Where outstanding debt has been converted into equity (*i.e.*, the government receives shares in the company in return for eliminating debt obligations of the company), a subsidy may result. The existence and extent of such subsidies are determined by treating the conversions as an equity infusion in the amount of the remaining principal of the debt. We then calculate the value of the subsidy by using our equity methodology, *supra*.

Coal Assistance

As explained in detail in our notice of "Final Affirmative Countervailing Duty Determinations: Certain Steel Products from the Federal Republic of Germany" in this issue of the **Federal Register**, we have analyzed and verified aspects of the German coal subsidy program as it applies to steel. Based upon the verified information in the records of these investigations, we have determined that this particular program does not confer a countervailable benefit on either non-German or German steel producers.

As we stated in some of the preliminary determinations reached on June 10 (47 Fed. Reg. 26309), benefits bestowed upon the manufacturer of an input do not flow down to the purchaser of that input if the sale is transacted at arm's length. In an arm's length transaction, the seller generally attempts to maximize its total revenue by charging as high a price and selling as large a volume as the market will bear.

The application of these principles to sales of German coal outside Germany is as follows. The records of these transactions show that the prices charged for subsidized German coal outside Germany certainly do not undercut the freely available market prices. Therefore, non-German purchasers of subsidized German coal do not benefit from German coal subsidies.

In support of this conclusion, we note that if non-German steel producers did benefit from German coal subsidies, they would attempt to purchase German coal rather than unsubsidized coal from other sources including the U.S., since there are no restrictions on their ability to do so. The fact that they purchase significant amounts of unsubsidized U.S. coal indicates that the subsidies on German coal do not flow to non-German coal consumers.

Moreover, it is extremely unlikely that the German government would significantly subsidize non-German coal consumers unless compelled to do so by obligations with respect to the European Communities. Since there is no evidence of such obligation, we conclude that the German government is not in fact subsidizing non-German coal consumers.

For these reasons, we determine that non-German steel producers do not benefit from subsidization of German coal.

Research and Development Grants and Loans

Grants and preferential loans awarded by a government to finance research that has broad application and yields results which are made publicly available do not confer subsidies. Programs of organizations or institutions established to finance research on problems affecting only a particular industry or group of industries (*e.g.*, metallurgical testing to find ways to make cold-rolled sheet easier to galvanize) and which yield results that are available only to producers in that country (or in a limited number of countries) confer a subsidy on the products which benefit from the results of the research and development (R&D). On the other hand, programs which provide funds for R&D in a wide range of industries are not countervailable even when a portion of the funds is provided to the steel sector.

Once we determine that a particular program is countervailable, we calculate the value of the subsidy by reference to the form in which the R&D was funded. An R&D grant is treated as a "united" grant; a loan for R&D is treated as any other preferential loan.

Labor Subsidies

To be countervailable, a benefit program for workers must give

preferential benefits to workers in a particular industry or in a particular targeted region. Whether the program preferentially benefits some workers as opposed to others is determined by looking at both program eligibility and participation. Even where provided to workers in specific industries, social welfare programs are countervailable only to the extent that they relieve the firm of costs it would ordinarily incur—for example, a government's assumption of a firm's normal obligation partially to fund worker pensions.

Labor-related subsidies are generally conferred in the form of grants and are treated as united grants for purposes of subsidy calculation. Where they are small and expensed by the company in the year received, we likewise allocated them only to the year of receipt. However, where they were more than one percent of gross revenues we allocated them over a longer period of time generally reflecting the program duration.

Comments by Parties to the Proceeding

• *Grants.*

Comment 1

Respondents claim that the present value methodology used in these investigations does not provide a "real" value and that it is based on assumptions which do not reflect the realities of the manufacture of the products under investigation.

DOC Position

The present value concept is a widely recognized tool of financial and economic analysis. Its utility and necessity derive from the fact that money has a time value. For example, as stated above, $100 million today is considerably more valuable to a grant recipient than $10 million per year for the next ten years. To move a sum of money through time without adjusting the nominal amount would seriously understate the value of the money. So long as the present value (in the year of grant receipt) of the amounts allocated over time does not exceed the face value of the grant, the amount countervailed will not exceed the total net subsidy.

Comment 2

Petitioners argue that grants and preferential loans awarded expressly for the benefit of products not under investigation should also be considered countervailable benefits for the product(s) under investigation. They base their argument on the contention that aid thus received is fungible.

DOC Position

We have not viewed all aid received for any purpose by companies under investigation as fungible, and thus equally beneficial to all products made by the company in question. While the law clearly envisions reaching subsidies which benefit the product under investigation indirectly, as well as directly, it would distort and be inconsistent with the clear intent of the statute, as reflected in its legislative history, to allocate to products under investigation any portion of benefits clearly tied to products not under investigation. This is particularly true since we are compelled to allocate fully to the products actually being investigated any subsidies directly tied to them. To allocate tied subsidies fully to the products to which they are tied and simultaneously to allocate any part of the same subsidies to other products would result in double-counting, which would be inconsistent with both the Act and the Subsidies Code.

• *Loans and Loan Guarantees for Companies Considered Creditworthy.*

Comment 3

Petitioners allege that the Department has improperly applied offsets to preferential loan benefits by subtracting principal and interest paid on the loans in 1981 and by the use of a "grant cap".

DOC Position

In calculating the subsidy flowing from a loan to a creditworthy company, we must take account of principal and interest paid because, by definition, the subsidy is equal to the difference between what the company actually paid and what it should have paid as expressed by our benchmark loan.

When calculating the subsidy arising from a loan to an uncreditworthy company, for purposes of these final determinations, we recognize the effect on the subsidy of principal and interest repayments. We believe it is appropriate to apply the rate of return shortfall only to the outstanding principal in 1981, recognizing that prior year paybacks of principal are equivalent to disinvestment of equity. We then subtract interest paid in 1981 not because it is an offset but because it is a legitimate payment on their debt. These funds, therefore, are not available to benefit the company and should not be included in the gross subsidy amount.

We apply a "grant cap" (the amount of subsidy allocated to the year of review if the original principal had been received as a grant rather than a loan) because a loan cannot be worth more to a company than an outright grant of the same amount. This capping by the grant amount is not distortive, nor does it lead to an understatement of the subsidy because the grant methodology incorporates in it the time value of money.

Comment 4

Petitioner argues that respondent steel companies, absent government backing, would not have been able to borrow at "average" or "national" rates and that our use of these rates as benchmarks understates the subsidy.

DOC Position

When the Department is measuring the subsidy flowing from a preferential loan, the benchmark rate (our choice of rate which we believe reflects the unsubsidized cost of debt to which this firm has access) of first choice is one which reflects loans of similar magnitude and duration actually received by the firm in a private transaction without government influence. In those situations where comparable private loans were not available, this benchmark rate had to be estimated. We chose a national average rate since we had no evidence a given firm was perceived as more or less risky than the "average" firm by lenders at the time the preferential loan was received.

• *Loans and Loan Guarantees for Companies Considered Uncreditworthy.*

Comment 5

Respondents argue that the Department's method of determining uncreditworthiness was unfair in that it was based in hindsight which was not available to a lender at the time it made a decision whether or not to provide funds to a company.

DOC Position

As outlined in each of these notices in which uncreditworthiness was found, all determinations as to the creditworthiness of firms were based upon information reasonably available to a potential lender *at the time a loan was given.* For instance, although British Steel Corporation's financial results for the fiscal year 1976/77 were a major factor pointing to uncreditworthiness, in our final determinations we found it uncreditworthy beginning in fiscal year 1977/78, when the lending community could reasonably have known of the weakness of the firm's financial position in the preceding year. This approach allows the potential lender time to evaluate its behavior in light of the changed circumstances of the firm.

Comment 6

Petitioners state that to the extent that the Department calculates the benefit from a loan to an uncreditworthy company as if it were a grant, failure to use a discount rate to reflect the greater risk of providing credit to uncreditworthy firms which could not borrow at any average or national rate leads to an understatement of the true value of the subsidy received.

DOC Position

We disagree. Although we used the average national debt rate as the discount rate in the preliminary determinations, we did not intend this to imply that the choice of the discount rate reflected our speculation as to the riskiness of the company or the cost of alternative financing. As discussed in the *Grants* section of this appendix, we view the discount rate as simply a financial tool to move money through time. It is not our intention to embed in this rate any project-specific risk or company risk. For this reason we are changing the discount rate used in these final determinations to the risk-free rate, a rate equally accessible to all companies (including very risky ones) country-wide.

Comment 7

Petitioners allege that the provision of supplier credit to an uncreditworthy company constitutes a subsidy because once the firm becomes uncreditworthy, absent government support, suppliers would require cash payments instead of extending credit.

DOC Position

Government subsidization of a company does not convey benefits over and above the actual subsidy (whose measurement is described earlier in this appendix). Private supplier credits are countervailable only where they are at a preferential rate due to government guarantees or direction. There is no benefit from rates and terms the petitioner may argue to be preferential resulting from the private sector's commercial reaction to government ownership.

Regarding the presence of supplier credits as it affects the Department's evaluation of creditworthiness, since the risk involved and the basis for giving supplier credits is qualitatively different than for long-term loans, we did not interpret the presence of supplier credits to be an indication of creditworthiness.

Comment 8

Petitioners argue that the Department should have used the methods for calculating benefits to uncreditworthy firms which they proposed in their petitions. U.S. Steel had proposed the "Sossin method" and counsel for the Five proposed a "creditworthiness proxy".

DOC Position

The Sossin method, developed by Howard B. Sossin of the Columbia University Business School, represents an attempt to adapt the Option Pricing Model for use in valuing loan guarantees. This model has applications in analysis of a number of complex financial transactions, such as measuring the effects of risk on the value of corporate debt, the effect of mergers, acquisitions, scale-expansions and spin-offs on the relative values of debt and equity claims on a firm, and the value of commodity options, forward contracts and futures contracts.

The Department decided not to use the Sossin method for several reasons. First, the model itself contains numerous simplifying assumptions which cast doubt on its applicability and non-arbitrariness for these investigations. In addition, we would have had to adapt the method greatly to make it applicable on a firm-specific basis, posing an immense administrative burden given the information and technical expertise necessary to calculate the benefits.

The "creditworthiness proxy" method proposed by counsel for the Five would use the cash-to-debt-service ratio for each firm. If a firm under investigation for possible subsidization is granted a loan when its ratio is less than 2:1, the amount by which its income is below twice the debt payments would be considered to be a subsidy in that year.

This method also poses several serious problems. First, as there is no direct relationship in this formula between specific benefits and the calculation of subsidies, its use by the Department would place it in violation of both the Act and the GATT Subsidies Code. Second, the ratio chosen is arbitrary and does not represent a reasonable benchmark for uncreditworthiness across companies. While a 2:1 ratio may indeed be a common "rule of thumb" popular in American banking circles, we have no compelling evidence indicating its applicability and general use in each of the nine countries examined in these cases. We cannot and do not intend to impose American standards of banking practice upon foreign firms.

• *Equity.*

Comment 9

Respondents claim that our determination whether government infusions of equity into a steel company are consistent with commercial considerations must take into account the fact that private stockholders or creditors of companies in financial trouble often inject additional capital into the company in the hopes of recouping as much of their original investment as possible.

DOC Position

We agree that government ownership of a company does not confer a subsidy *per se*, and that the government may act based upon commercial considerations with respect to decisions whether to increase its equity ownership in a firm. Our determination whether such action is in fact on terms consistent with commercial considerations necessarily depends upon the facts of each individual case. In our investigations of certain steel products from Luxembourg, for example, we found an instance in which private persons as well as the government invested equity in MMR–A, a Luxembourg steel company which arguably was in financial trouble. In view of the participation of those private persons, we considered the government's action not to confer a subsidy because it was consistent with commercial considerations as evidenced by the private purchasers' behavior. In other situations, however, we think that, based upon the facts presented, no stockholder, governmental or private, would have injected further equity into the company based upon commercial considerations.

Comment 10

Respondents argue that the use of an average rate of return on equity in a country sets an unfair standard for measuring the rate of a cyclical industry like steel, because such a standard by definition will indicate subsidization in the troughs of the cycles.

DOC Position

The Department's methodology does not penalize firms simply because they are in the trough of a cycle. A subsidy only arises when an original equity investment is unsound, *i.e.* inconsistent with commerical considerations.

We recognize that steel is a cyclical industry, but neither the Act nor the GATT Subsidies Code immunize subsidies to a company in the bottom of its cycle from countervailing duties. Unsubsidized companies in cyclical industries survive by using revenues from the peak of a cycle to offset the years in the cycle's trough.

Comment 11

Respondents argue that premiums paid over market value of stock are common in takeovers where the objective is to gain control of a firm, and that therefore such a payment should not be considered a subsidy.

DOC Position

Payment of a premium over market value for stock (including where the objective is to gain control) is a special commercial circumstance which occurs under fairly unique conditions. Payment of such a premium for stock in a firm in weak or distressed financial condition is unlikely, for as a firm approaches near-bankruptcy, its market price of equity falls to the liquidation value range. Furthermore, it is highly unlikely for a control premium to be warranted when the government is the sole bidder for the troubled firm. Therefore in the absence of compelling evidence that a premium payment by a government was warranted and motivated by commercial conditions (as evidenced, for example, by similar competing private bids), the Department has a strong preference for measuring a subsidy by the difference between the market price of the stock and the stock price paid by the government. We believe that this market price correctly incorporates private investors' perceptions of the worth of the stock.

- *Coal Assistance.*

Comment 12

Petitioners reject the Department's view that a party receiving a benefit on the production of its merchandise is not assumed to share that benefit with an unrelated purchaser. They maintain that a party may market its products at a lower price than it would be able to charge absent the subsidy in order to secure or hold on to a larger share of the market, and thus to increase its profitability by realizing lower unit costs and increased unit sales.

DOC Position

We agree that there is more than one way to seek to achieve maximum profitability. In these investigations, in fact, assistance to coal has been provided to enable some coal companies to sell below their cost of production. However, the German coal companies do not sell below the prices of coal as sold in Europe and elsewhere. In fact, German steel producers are required to pay a slight but significant premium for German coal. Under these circumstances, we disagree with petitioners' argument that German steel companies are indirectly subsidized through German coal subsidies.

Comment 13

Petitioners argue that the Department should have considered German coal subsidies to subsidize all steel companies purchasing that coal, both German and non-German, because the intent of the coal subsidies is to stabilize coal supplies to the ECSC steel industry and to insure that industry against the risk of adverse price developments on the world market. Petitioners claim that without this subsidized coal, the ECSC steel companies would have had to pay higher world market prices.

DOC Position

For the reasons indicated *supra*, we believe that it is too speculative to consider possible effects on world prices for coal in the hypothetical absence of German subsidization of its coal industry. However, if coal prices would rise in that event, we believe that they would rise throughout the world. We do not believe that prices would rise more for European purchasers of coal rather than non-Europeans.

As also indicated in detail *supra*, we believe that the real economic effect of German subsidies is to penalize, not to assist, German steel companies. As a result of the German coal policy, German steel companies are required to pay a slight premium above the world market price for their coal purchases. Non-German purchasers of subsidized German coal similarly receive no demonstrable price advantage.

Comment 14

Petitioners argue that the ECSC and the FRG government, through an "intense program of coordinated subsidy financing," have assisted the German coal and steel industries in order to sustain production at cost efficient levels, in significant part by producing for export.

DOC Position

Although the arguments seem ambiguous, we believe that petitioners mean to imply that the German and ECSC coal assistance programs constitute an export subsidy for steel. If so, then we disagree, since in both cases coal assistance is provided without the establishment of any condition concerning the exportation of steel produced using that coal.

Comment 15

Petitioners object to the Department's alleged requirement that a subsidy on an input be demonstrated to confer an unfair competitive advantage. Petitioners imply that in so doing, the Department is usurping the jurisdiction of the International Trade Commission which is authorized to determine injury.

DOC Position

Under the Act, the Department is required to determine whether respondents have received subsidies within the meaning of the Act. To do so, the Department seeks to determine whether or not respondents have received directly or indirectly an economic benefit. Whereas this is relatively easy in the case of the direct bestowal of a grant, it is quite difficult with regard to indirect subsidies allegedly conferred through the subsidization of inputs used in a final product. In this more complex area, we believe it is required for the Department to consider whether there is an economic benefit to foreign manufacturers of the final product of subsidies bestowed on manufacturers of an individual input. This is quite distinct from the ITC's determination whether imports of the final product into the United States injure a U.S. industry. The Department therefore disagrees with petitioners on this issue.

Comment 16

Respondents argue that they pay more for their coal than would otherwise be the case if the FRG coal assistance program and import restrictions were not in effect.

DOC Position

As indicated in detail *supra*, we agree. Largely on this basis we have determined that FRG assistance to its coal producers does not indirectly subsidize either FRG steel producers or non-German steel producers.

Comment 17

Respondents argue even that if Germany entered the world market for coal and world coal prices were driven up, they would be the same to all purchasers.

DOC Position

We have no firm basis upon which to predict possible effects on world coal prices by cessation of German subsidization of its coal industry.

- *Labor Subsidies.*

Comment 18

Respondents argue that the Department's treatment of labor programs is not related to possible benefits to the production of the products under investigation, but rather

is based on whether programs benefit employees or employers.

DOC Position

Labor programs are countervailable only to the extent that they relieve the company of some or all of its labor-related obligations. Direct assumption of a cost of production, such as absorption in whole or part of the wage bill, is indeed a subsidy on the products produced by the company.

Appendix 3.—Programs Administered by Organizations of the European Communities

I. The ECSC

On April 8, 1965, the three separate European communities—the European Coal and Steel Community ("ECSC"), the European Economic Community ("EEC"), and the European Atomic Energy Community—signed a treaty to merge into the European Communities ("EC"). Article 9 of the merger treaty established the Commission of the European Communities to take the place of the High Authority of each of the formerly independent institutions. The merger became effective in 1967.

The ECSC itself was established by the Treaty of Paris in 1851 to modernize production, improve quality, and assure a supply of coal and steel to the member countries. The Treaty of Paris governs all programs intended directly to affect the steel industry. Funds for these programs flow from two sources: (1) ECSC borrowings on international capital markets, and (2) the ECSC budget.

A. *ECSC Programs Determined To Be Subsidies.* 1. *ECSC Loan Guarantees.* Under Article 54 of the Treaty of Paris, the ECSC is authorized to guarantee loans from commercial lenders to coal and steel companies. Since these guarantees are intended specifically for the steel industry, we find the resulting benefits to be countervailable. The countervailable benefit is the difference between the interest rate charged by private lenders to commercial customers in the ordinary course of business and the rates available with an ECSC loan guarantee.

2. *Programs Funded through ECSC Borrowings.* Because of its quasi-governmental nature, the ECSC is able to raise funds at interest rates lower than those which would be available on commercial terms to European steel companies. When the ECSC relends these borrowed funds to a company without increasing the interest rate, any difference between the lower interest rate passed on and the rate otherwise available to the steel company in the commercial financial market (the "benchmark") is a benefit to the company. For this reason, we determine that ECSC loans raised through capital market funding are countervailable insofar as they offer preferential interest rates (*i.e.*, rates which would not be available on commercial terms) to steel companies. Consequently, any loan to a steel company involving ECSC funds borrowed on international capital markets, provided under an ECSC assistance program, confers countervailable benefits to the extent that the loan is made at a preferential interest rate.

a. *ECSC Industrial Investment Loans.* Article 54 of the Treaty of Paris authorizes the ECSC to provide loans to steel companies in member countries for reducing production costs, increasing production, or facilitating product marketing. Loans provided under this program are funded exclusively from ECSC borrowings on world capital markets. For the reasons discussed above, we reaffirm our preliminary determination that this program confers countervailable benefits to loan recipients to the extent that the interest rates are preferential.

b. *ECSC Industrial Reconversion Loans.* Under Article 56 of the Treaty of Paris, the ECSC provides loans to companies or public authorities for investments in new non-steel ventures in regions of declining steel industry activity. The goal of the loan program is to provide employment for former steel workers in new industries. In our preliminary determinations, we concluded that this program did not appear to benefit steel companies. Therefore, we preliminarly determined that it does not confer subsidies on steel.

However, since our preliminary determinations, we verified that some industrial reconversion loans have been made for use in the iron and steel industry. Therefore, to the extent that such loans were made for steel production, they confer benefits on steel production generally if the loans were untied, and on steel production generally or possibly on particular types of steel products if the loans were tied. Since this program is funded exclusively from ECSC borrowings on world capital markets, we determine, for the reasons discussed above, that these loans to steel producers confer subsidies on steel to the extent that the interest rates are preferential.

3. *Programs Funded Through the ECSC Budget.* With respect to programs funded by the ECSC budget, we preliminarily determined that they do not confer countervailable benefits because for 1971–1980 (the last year for which complete data were available) their total amount did not exceed total levies collected from coal and steel producers within the ECSC member states.

Since our preliminary determinations were made we have verified the following facts about the composition of the ECSC budget:

—From 1952 through 1956, the ECSC budget was financed exclusively through producer-generated levies.

—From 1971 through 1977, the ECSC budget was financed exclusively through producer-generated levies, funds generated from unexpended levies, and other relatively small amounts obtained from steel companies (*e.g.*, fines and late payment fees).

—Since 1978, the ECSC budget has been financed by member state contributions to the following extent: 1978, 18.80%; 1979, 16.27%; 1980, 16.22%; and 1981, 20.05%.

—Beginning in 1982, the member state contribution is to be used exclusively to fund one particular program, rehabilitation aid provided under Article 56 of the Treaty of Paris.

We continue to believe that programs funded by the ECSC budget through 1977 do not confer countervailable benefits.

However, since 1978 member state contributions have constituted a portion of the ECSC budget. Upon consideration of this newly available information, for the years 1978–1981 we believe it is more reasonable to assume that programs funded by the ECSC budget are subsidized to the extent that the budget derives from member state contributions. To assume to the contrary (i.e., that *all* program assistance derives from levies and levy-generated funds, and that member state contributions are used *exclusively* for expenses other than program assistance) is inappropriate unless member state contributions are expressly earmarked for particular programs. Accordingly, we have treated as a subsidy in 1981 a proportion of the benefits received under programs funded by the ECSC budget.

Although not relevant to the subsidies being determined and measured in these investigations, we note that for 1982, member state contributions have been so earmarked for one particular program, rehabilitation aid provided under Article 56 of the Treaty of Paris. If all member state contributions are expended in funding that program, other programs would then be funded by levies and levy-generated funds, not from member state contributions.

a. *ECSC Labor Assistance and Rehabilitation Aids.* Under Article 56 of the Treaty of Paris, the ECSC provides matching grants to member states for programs that assist former steelworkers currently unemployed or in training for a new trade. In our preliminary determinations, we implied that this assistance may confer a subsidy on the industries for which workers are newly trained, but decided that it does not confer a subsidy on steel. However, upon verification we learned that some, though not all of this assistance has been provided to retrain workers for other jobs *within* the *same* industry; and to cover worker unemployment and early retirement expenses, for some of which the employing companies may have been legally responsible. If such assistance has been provided to retrain steel workers for new steel jobs, and/or to cover unemployment and early retirement expenses which steel companies would normally be required to pay, then it benefits the steel industry. To that extent, it is considered a subsidy in these investigations.

This program is funded from the ECSC budget. In view of the relatively small amounts concerned, we are expensing this assistance in the year it was received. Therefore, for purposes of these investigations, we are capturing only assistance provided in the period for which we are measuring subsidies (generally 1981). In 1981, member state contributions accounted for 20.05% of the ECSC budget. Therefore, for the reasons discussed above, 20.05% of the assistance under Article 56 provided to steel companies for programs benefitting steel production in 1981 constitutes a subsidy on the manufacture or production of steel.

b. *ECSC Interest Rebates.* (1) Certain Article 54 industrial investment loans qualify for further interest reductions depending on whether they are for environmental projects, removal of industrial bottlenecks, promotion of steel industry competitiveness, or stabilization of coal production. The rebates generally reduce the interest expense for the first five years of the loan repayment schedule by three percentage points. The interest rebates are paid out of the ECSC budget. Therefore, we preliminarily determined that this program does not confer countervailable benefits.

(2) Certain Article 56 industrial recoversion loans qualify for further interest reductions. Like the interest rebates on Article 54 industrial investment loans, these rebates are paid out of the ECSC budget. In a few instances the underlying loans made under Article 56 benefit the products under investigation. (Most Article 56 loans were given to non-steel ventures.)

For the reasons discussed above, we have now determined that both these programs described under (1) and (2) above confer countervailable benefits to the extent that the ESCS budget in the year concerned is financed by member state cotributions. In view of the relatively small amounts concerned, we are expensing this assistance in the year it was received. Therefore, for purposes of these investigations, we are capturing only assistance provided in the period for which we are measuring subsidies (generally 1981). In 1981 member state contributions accounted for 20.05% of the ECSC budget. Therefore, for the reasons discussed above, 20.05% of the assistance provided in 1981 constitutes a subsidy on the manufacture or production of steel.

c. *ECSC Coal and Coke Aids.* Petitioners have alleged that ECSC assistance to coal producers in EC countries constitutes an indirect benefit to steel producers purchasing that coal. In our preliminary determinations, we did not consider this program to confer countervailable benefits on steel. The basis for this conclusion was our understanding at that time that the ECSC coal aids are bestowed on all types of coal, used widely throughout many industries. Therefore, we reasoned, the ECSC aids on coal cannot be intended to benefit, and do not benefit, the steel industry in particular; consequently, under section 771(5)(B) of the Act, there is no subsidy to steel in these circumstances, even though steel producers in ECSC countries purchase some ECSC coal.

However, we have verified that, in fact, certain ECSC coal aids are bestowed exclusively on coking coal, which is used primarily by the iron and steel industry. Nonetheless, we continue to believe, for other reasons, that the ECSC coking coal aids do not confer a countervailable benefit on the manufacture or production of steel. We have no evidence that ECSC-assisted coking coal is sold to ECSC steel companies at prices less than the prices for other freely available coking coal produced in ECSC member countries but not assisted by the ECSC, or for freely available coking coal produced outside ECSC member countries. To the contrary, we have verified information that some coking coal is sold in Europe at prices below the prices of ECSC-assisted coking coal. This indicates that the coking coal subsidies to coal producers are not being passed along, in whole or in part, to steel producers purchasing that coal in arm's length transactions.

Where a subsidized coal producer and a steel producer are related companies, it is reasonable to question whether, in fact, the transfer price for coking coal is established on an arm's length basis. In general, our tests for whether the prices for coking coal charged to a related company were established on an arm's length basis include: (1) Whether the coal producer sold to its related steel producer at the prevailing price, and/or (2) whether the coal producers sold to its related steel producers and all other purchasers of coking coal at the same price.

B. *ECSC Programs Determined Not to Confer Subsidies.* 1. *ECSC Housing Loans for Workers.* Article 54(2) of the Treaty of Paris authorizes the ECSC to provide loans for residential housing for steel workers. In some cases these loan funds are provided directly to steel companies which relend them to their workers. In other cases, they are administered through financial institutions or housing authorities. These loans for the construction or purchase of homes are at highly concessionary one percent interest rates.

The preferential ECSC housing loans provide substantial benefits directly to steel workers. In our preliminary determinations, we assumed that they also indirectly benefit the employer steel companies by relieving them of certain labor wage costs. However, we have been unable to substantiate and verify this assumption. To the contrary, in many of the countries concerned there is a high rate of unemployment, which reduces upward pressure on wages. Moreover, we found no instance in which wage rates varied—depending upon the presence or absence of these mortgage loans to steel workers—either within a steel company or between steel companies. Since we have no firm basis for determining that the wage demands of steel workers would be responsive to the (non)availability of this mortgage subsidy, we conclude that the hypothetical benefits to their employer steel companies are too remote to be considered subsidies to these companies.

2. *ECSC R&D Grants and Loans.* a. Article 55 of the Treaty of Paris provides funding in the form of grants for up to 60 percent of an R&D project's cost. The projects must be for improvements in the production and use of coal and steel. On the ground that these grants are funded exclusively from the ECSC budget, we preliminarily determined

that this program does not confer countervailable benefits.

For the reasons discussed above, we have decided to consider ECSC budget-funded programs as countervailable to the extent that the ECSC budget for the year concerned is financed by member state contributions. Nevertheless, because we have evidence that the results of the R&D are made publicly available, we have determined that this program does not confer countervailable benefits.

b. With respect to ECSC R&D loans—also made under Article 55 of the Treaty of Paris—we preliminarily determined that additional information was necessary: *i.e.*, information as to how widely available the results of research are, and from which source the funds derive. Upon verification, we learned that the results of the research are made publicly available. Therefore, we determine that ECSC R&D loans do not confer countervailable benefits.

II. The European Investment Bank

The European Investment Bank ("EIB") was created by the Treaty of Rome establishing the EEC to fund projects that serve regional needs in Europe. Article 130 of the Treaty of Rome authorizes the EIB to make loans and guarantee financial projects in all sectors of the economy. These projects include the provision of funds to further the development of low income regions. Funds are drawn from debt instruments floated on world capital markets and from investment earnings. Because EIB loans are designed by charter to serve regional needs, we find them to be countervailable where the interest rate is less than the rate which would have been available commercially from a private lender without government intervention.

The EIB also provides loan guarantees to companies in EC member countries. Again, because this guarantee was available in some but not all regions, it is regarded as a countervailable benefit. These determinations remain unchanged from our treatment of this issue in our preliminary determinations.

III. European Regional Development Fund

The European Regional Development Fund was established by the EEC to provide funding in the form of low-interest loans for industrial projects designed to correct regional imbalances within the EEC. The fund also awards interest subsidies on EIB oans.

We preliminarily determined that this program is not used by any of the manufacturers, producers or exporters for any of the products from countries under investigation. We confirmed this determination through our verification, so it remains unchanged.

Comments Received From Parties to the Proceeding

Comment 1

Petitioners argue that persistent ECSC subsidization of its coal industry has resulted in severe trade distortions.

DOC Position

Perhaps ECSC subsidization of coal has distorted trade in coal. However, we do not believe that it has distorted trade in steel.

Comment 2

Petitioners argue that subsidization of European coal industries, both by the ECSC and member governments, prolongs the operation of uneconomic European coal producers. They maintain that if the subsidies were discontinued, the coal industries would collapse, and that coal prices would rise around the world unevenly depending upon which industries had captive sources of coking coal.

DOC Position

Even assuming *arguendo* that subsidization of the European coal industry by the ECSC and member states does significantly depress world market prices, we can only speculate that cessation of this subsidization would have similar price effects in that the price of *all* coal would rise. We are not sure whether and to what extent these price effects would differ depending upon which industries had captive sources of coking coal. We note that in addition to the existence of captive sources, another key factor would be the potential entrance into world commerce of alternate suppliers of coal and their effect on market prices.

Comment 3

Petitioners argue that the Department did not correctly interpret the term "subsidy" and did not countervail ECSC assistance programs to the extent that funds for these programs were derived from the ECSC budget.

DOC Position

As explained in detail *supra*, the Department has determined that ECSC budget-funded assistance is potentially countervailable to the extent that the ECSC budget for the year concerned is financed by Member State contributions.

Whether or not we found particular ECSC budget-funded assistance to confer a subsidy on the products subject to these investigations depended on other factors as well. For example, we found that the results of ECSC funded research and development projects were made publicly available, and therefore did not confer subsidies.

Comment 4

Petitioners argue that ECSC budget-funded assistance programs confer subsidies on ECSC steel producers despite levy financing of the budget, because the ECSC must borrow massively to supplement the levies.

DOC Position

As indicated in detail *supra*, to the extent that the ECSC budget in a given year is funded by Member State contributions, we consider any assistance funded generally from the budget in that year to be partially countervailable. Also as explained *supra*, to the extent that ECSC loans financed by ECSC borrowings on world capital markets are made to steel companies at preferential interest rates, we believe that they are countervailable.

Comment 5

Petitioners maintain that ECSC budget-funded programs confer subsidies even when financed through levy funding; that the ECSC borrows to finance its programs, and there is no delineation between the programs funded by the levy and the programs funded by debt.

DOC Position

As explained in detail *supra*, we agree that many (though not all ECSC) budget-funded programs confer some countervailable benefit if the assistance was provided in a a year in which the ECSC budget was derived partially from Member State contributions. Where it can be shown that ECSC budget-funded assistance derives exclusively from levies and levy-generated funds ultimately derived from steel producers, no countervailable benefit is conferred upon steel producers by the return to them of their own funds. However, for the period of investigation we did not find that any program's funding derived could be shown to derive exclusively from a levy financing.

Comment 6

Petitioners argue that all ECSC readaptation and retraining assistance to steel producers confers a subsidy. They argue that the steel companies did not supply sufficient information regarding their obligations to employees who received this assistance, and that

the Department preliminarily allowed an offset not permitted by law.

DOC Position

With respect to ECSC assistance for readaptation and retraining of workers provided under Article 56, we have verified whether (and the extent to which) this assistance relieved recipient steel companies of expenses that they would otherwise have been obliged to incur, and whether the retraining was for jobs related to steel production. Based upon verified information, we have concluded that most ECSC assistance provided under Article 56 does not confer countervailable benefits in these investigations. In the view instances where it does (either because assistance was provided for retraining for jobs related to steel production or because the companies were relieved thereby of an obligation they otherwise would have been required to fulfill), we have found subsidies.

Comment 7

Respondents argued that the ECSC's credit rating is based not upon its quasi-governmental nature, but on an ECSC reserve fund financed by levies and levy-generated funds, and by the fact that the ECSC represents the financial resources of the steel industry in ECSC Member States. Since the ECSC credit rating is based upon the levy, ECSC loans to steel companies at rates below those which an individual firm could obtain represent solely a partial return to the company of its levies.

DOC Position

For the reasons indicated *supra*, we agree that a program benefitting the steel industry which is financed exclusively by ECSC levies and levy-generated funds does not confer a countervailable benefit on steel production since it merely returns to companies funds which they originally paid in. However, based upon our examination and analysis of the ECSC budget, we are unable to conclude that the reserve fund is composed exclusively of levies and levy-generated funds. In any event, we do not agree that the ECSC's credit rating is based solely upon its reserve fund, or upon the implied backing of European steel industries. We think its credit rating necessarily reflects, at least in part, its quasi-governmental nature. Therefore, we disagree with the arguments tendered by respondents on this issue.

Comment 8

Respondents claim that ECSC worker rehabilitation programs, such as retraining or early retirement payments, do not confer a subsidy on steel because the benefits go to workers no longer employed in steel production. Even if those benefits are funnelled through a steel company, that company simply serves as a conduit of funds and receives no benefits from them.

DOC Position

For the reasons indicated *supra*, we agree that retraining assistance does not confer a benefit on a steel company so long as the job for which a worker is being retrained is a non-steel job. Likewise the payment of early retirement benefits does not confer a subsidy on a steel company unless it is thereby relieved of a cost that it would otherwise be required to assume. As indicated *supra*, the facts in these cases in some instances require, in applying the above principle, that a subsidy be found to exist.

Comment 9

Respondents claim that the ECSC and Member State production and marketing aids for the coal industry do not subsidize steel because the prices for European coal paid by the steel industry are not below world market prices. Thus, these aids do not affect steel trade and do not distort normal conditions of competition.

DOC Position

Comment 10

Respondents claim that ECSC aid to coal under Articles 54 and 56 does not confer subsidies on steel because the aid is given through ECSC loans made on commercial terms or grants financed from levy-generated funds.

DOC Position

We agree that ECSC assistance to coal companies in Member States does not subsidize steel companies in Member States, but for other reasons set forth *supra*. In general, we note that where ECSC assistance can be satisfactorily shown to be exclusively financed by levy-generated funds, the Department would agree that it is not countervailable. Likewise, any ECSC loans which were made on truly commercial terms would not include a preferential interest rate, and therefore not confer a subsidy.

Comment 11

Respondents argued that ECSC budget-funded programs are financed exclusively from producer levies and levy-generated funds, and not from Member State contributions which allegedly are used exclusively for non-steel purposes.

DOC Position

In our preliminary determinations, we did not consider ECSC budget-funded assistance to confer subsidies on steel production in view of our conclusion that total ECSC levies and levy-generated funds historically have exceeded all ECSC assistance provided to steel companies. However, in these final determinations, based upon verification and more thorough understanding of the ECSC budget, we have determined that it cannot be shown that ECSC budget-funded assistance derives exclusively from levies or levy-generated funds. Although such funding accounts for the vast majority of ECSC budget-funded assistance (79.95% in 1981), a portion of this assistance (20.05% in 1981) derives from Member State contributions. As explained *supra*, where it can be shown that Member State contributions are clearly earmarked for particular programs and that Member State contributions are fully expended in such programs, then we agree that the other programs are fully funded by levies on steel production and thus not countervailable. For example, we noted that beginning with 1982, all Member State contributions appear earmarked for one particular ECSC program, industrial investment assistance. Provided that verification during the annual review process confirms this, then for 1982 we would not consider ECSC budget-funded assistance—other than this one program—to confer subsidies on steel.

Comment 12

Respondents claim that certain rehabilitation measures by the European Communities and Member States do not subsidize steel because the aid is used to promote sectors other than steel.

DOC Position

To the extent that assistance is provided to sectors other than steel, we agree. For example, with respect to ECSC industrial reconversion loans, we have found that for the most part, they do not provide subsidies for steel production. Likewise with respect to certain ECSC labor assistance programs, for the most part we found that this assistance benefitted industrial sectors other than steel; *e.g.*, a grant bestowed and used to train former steel workers to assume new jobs unrelated to the steel sector, even if the training program is administered by a steel company.

Comment 13

Respondents claim that measures adopted by the European Communities

and Member States under the Community Steel Policy to restructure the steel industry within Europe do not subsidize steel because they are bestowed for the purpose of reducing the manufacture, production and export of steel in Europe.

DOC Position

Where a restructuring program involves subsidies to steel products and the U.S. industry is injured by the import of such products, we are required by our domestic law, and authorized by the Subsidies Code, to impose appropriate countervailing duties. All subsidies are indisputedly subject to countervailing duties under Part I of the Subsidies Code, provided only that injury is determined and that procedural requirements are satisfied. The provisions of Article 11 of Part II of the Code—stating that the Code "does not intend to restrict the right of any signatory to use (domestic) subsidies to achieve . . . policy objectives (including) to facilitate the restructuring, under socially accepted conditions, of certain sectors"—do not preclude the United States from imposing countervailing duties in appropriate cases. Part II of the Code, including Article 11, merely establishes that domestic subsidies for restructuring are not precluded by the Code. A code member retains the right under Part I to impose countervailing duties on imports, injurious to its industry, which benefit from domestic subsidies aimed at restructuring. Further, while restructuring aids may be devoted in part to reducing production capacity, such aids, by making the recipient steel companies more efficient and relieving them of significant financial burden, are of unquestioned benefit to the continuing production of steel aid, and, as such, confer subsidies.

Comment 14

Respondents argued that the Department's preliminary determinations to countervail ECSC housing loans were based on supposition rather than on evidence in the record.

DOC Position

We agree. For the reasons set forth in detail *supra*, we were not able to find sufficient evidence that the provision of ECSC housing loans to steel workers had any measurable effect upon the steel companies by whom such workers were employed. Therefore, in these final determinations, we have decided not to consider ECSC housing loans as conferring a countervailable benefit on steel companies.

Comment 15

Some petitioners have claimed that ECSC assistance funded by producer levies confers subsidies wherever an individual producer receives assistance in excess of levies paid by that producer.

DOC Position

As explained elsewhere in this Appendix and in Appendix 4, we do not consider ECSC budget-funded programs to confer subsidies on steel producers to the extent such programs are funded by producer levies. Our view is not affected by the degree to which individual producers which have contributed levies do not participate in or receive benefits from these programs. The producers probably should be viewed as pooling their resources, for their mutual benefit, to create and maintain certain programs which are available to all the producers. Over the relatively short period for which we are measuring subsidies, certain producers have more frequent occasion to use certain programs than other producers. In principle, this is not different from other types of cooperative behavior, such as jointly funded risk insurance, under which not all participants will have identical claims although all contribute equal premiums. Accordingly, insofar as producer levies are directly funding the programs, no subsidies can be said to arise from any apparent short-term disparity of benefits received.

Comment 16

Some petitioners have challenged our preliminary determinations that benefits received under certain ECSC programs funded by ECSC coal and steel producers levies were not subsidies. They assert that, in reaching such a determination, we have allowed offsets from subsidies in a manner contrary to law.

DOC Position

We disagree with petitioners' characterization of the determination on this issue. To the extent that we have viewed benefits received under ECSC programs as attributable or allocable to producer levies, we find that no gross subsidy exists. No "offset" or reduction in subsidy amount is made, because the recipients of the program benefits are directly funding those benefits themselves and thus the ECSC is not creating a subsidy. This is not analogous to governmental benefits funded by general tax revenues, for the levies in question are—and since the inception of the levy system have been—strictly earmarked for the ECSC budget-funded programs for which they are, in fact, used. In reality, the ECSC acts as no more than the administrator and distributor of levies collected, and does so under such tight restrictions as to preclude the conclusion that the return of levy funds to the producers gives rise to a gross subsidy.

Comment 17

Petitioners reject the Department's view that a party receiving a benefit on the production of its merchandise is not assumed to share that benefit with an unrelated purchaser. They maintain that a party may market its products at a lower price than it would be able to charge absent the subsidy in order to secure or hold on to a larger share of the market, and thus to increase its profitability by realizing lower unit costs and increased unit sales.

DOC Postition

We agree that there is more than one way to seek to achieve maximum profitability. In these investigations, in fact, assistance to coal has been provided to enable some coal companies to sell below their cost of production. However, the German coal companies do not sell below the prices of coal as sold in Europe and elsewhere. In fact, German steel producers are required to pay a slight but significant premium for German coal. Under these circumstances, we disagree with pertitioners' argument that German steel companies are indirectly subsidized through German coal subsidies.

Comment 18

Petitioners argue that the ECSC and the FRG government, through an "intense program of coordinated subsidy financing," have assisted the German coal and steel industries in order to sustain production at cost efficient levels, in significant part by producing for export.

DOC Position

Although the arguments seem ambiguous, we believe that petitioners mean to imply that the German and ECSC coal assistance programs constitute an export subsidy for steel. If so then we disagree, since in both cases coal assistance is provided without the establishment of any condition concerning the exportation of steel produced using that coal.

Comment 19

Respondents argue that even if Germany entered the world market for coal and world coal prices were driven

up, they would be the same to all purchasers.

DOC Position

We have no firm basis upon which to predict possible effects on world coal prices by cessation of German subsidization of its coal industry.

Comment 20

Petitioners object to the Department's alleged requirement that a subsidy on an input be demonstrated to confer an unfair competitive advantage. Petitioners imply that in so doing, the Department is usurping the jurisdiction of the International Trade Commission which is authorized to determine injury.

DOC Position

Under the Act, the Department is required to determine whether respondents have received subsidies within the meaning of the Act. To do so, the Department seeks to determine whether or not respondents have received directly or indirectly an economic benefit. Whereas this is relatively easy in the case of the direct bestowal of a grant, it is quite difficult with regard to indirect subsidies allegedly conferred through the subsidization of inputs used in a final product. In this more complex area, we believe it is required for the Department to consider whether there is an economic benefit to foreign manufacturers of the final product of subsidies bestowed on manufacturers of an individual input. This is quite distinct from the ITC's determination whether imports of the final product into the United States injure a U.S. industry. The Department therefore disagrees with petitioners on this issue.

Appendix 4.—General and Gatt-Related Issues

- *General Issues.*

Comment 1

Some of the petitioners contend that many of the conclusions in our preliminary determinations were erroneous insofar as they found that particular programs of general applicability and availability within a country do not give rise to domestic subsidies. They assert that subsidies must be found to exist from any governmental programs providing benefits, regardless whether those programs are generally available.

DOC Position

Section 771(5) of the Act, in describing governmental benefits which should be viewed as domestic subsidies under the law, clearly limits such subsidies to those provided "to a specific enterprise or industry, or group of enterprises or industries." We have followed this statutory standard consistently, finding countervailable only the benefits from those programs which are applicable and available only to one company or industry, a limited group of companies or industries, or companies or industries located within a limited region or regions within a country. This standard for domestic subsidies is clearly distinguishable from that for export subsidies, which are countervailable regardless of their availability within the country of exportation. We view the word "specific" in the statutory definition as necessarily modifying both "enterprise or industry" and "group of enterprises or industries". If Congress had intended programs of general applicability to be countervailable, this language would be superfluous and different language easily could and would have been used. All governments operate programs of benefit to all industries, such as internal transportation facilities or generally applicable tax rules. We do not believe that the Congress intended us to countervail such programs. Further, our conclusion is supported by the clear Congressional intent that "subsidy" be given the same meaning as "bounty or grant" under section 303 of the Act. Never in the history of the administration of this law or section 303 of the Act has a generally available program providing benefits to all production of a product, regardless whether it is exported, been considered to give rise to a subsidy or a bounty or grant. In enacting the Trade Agreements Act of 1979, Congress specifically endorsed that interpretation of section 303. Finally, the fact that the list of subsidies in section 771(5) is not an exclusive one in no way compels the conclusion that domestic benefits of general availability must or can be considered subsidies. Indeed, in view of the statute and its legislative and administrative history, we doubt that we are free to treat such generally available benefits of domestic programs as subsidies; certainly we are not compelled to do so.

Comment 2

Petitioners contend that our preliminary negative determinations regarding critical circumstances were erroneous. They allege that, in determining whether imports were "massive" within the meaning of section 703(e) of the Act, we acted inconsistently with the law and past practice by examining imports in the period subsequent, rather than prior, to initiation of these cases, thereby denying petitioners the ability to provide adequate documentation to support their allegations. They also disagree with our characterization of the import levels as not being massive.

DOC Position

This issue is moot. Under section 703(e) of the Act, in order to determine that critical circumstances exist, we must determine that "(A) the alleged subsidy is inconsistent with the Agreement, and (B) there have been massive imports of the class or kind of merchandise which is the subject of the investigation over a relatively short period." Section 355.29(e) of the Commerce Regulations (19 C.F.R. 355.29(e)) on critical circumstances provides, *inter alia*, that we will determine "whether the alleged subsidy is an *export* subsidy inconsistent with the Agreement" (emphasis added). For purposes of this law, then, under existing regulations, a subsidy may be viewed as inconsistent with the Agreement only if it is an export subsidy. Since all of the subsidies determined to exist in the cases in which we are issuing final determinations in these notices are domestic, rather than export, subsidies, we are precluded from determining that critical circumstances exist in any of these cases.

Comment 3

Some respondents claim that our adoption in the preliminary determinations of a number of new methodologies for the ascertainment and calculation of subsidies was procedurally deficient as a matter of law. They assert that these new methodologies conflict with past practice and, therefore, cannot be implemented in any case before rulemaking procedures have been completed, which procedures would have to provide published notice of proposed changes and opportunity to comment.

DOC Position

We do not agree that the methodologies employed in these cases have to be the subject of rulemaking procedures or that such methodologies could not be employed until such procedures have been completed. The adoption of these methodologies is neither rulemaking nor adjudication within the meaning of the Administrative Procedure Act. Some of the methodologies employed cannot be said to be in conflict with any past practice under sections 701 or 303 of the

act, for they address issues and factual situations which, to the best of our knowledge, have not previously been encountered. Others, such as the present value methodology of valuing money over time, do represent a departure from past methods for determining the existence or size of subsidies. However, the prior practice, with which the methodology used in these cases has been alleged to be inconsistent has never been prescribed in the Commerce Regulations or, before that, the Customs Regulations.

Decisions as to the use of such methodologies are not matters requiring rulemaking procedures, but are questions of policy left to the judgment and discretion of the Department and decided on a case-by-case basis, applying the law, as we understand its requirements and intent, to the facts of each case. While the Department could prescribe such methodologies in its regulations, we have not chosen to do so. Unless and until that occurs, no rulemaking procedures can be considered necessary before changing prior methodologies. At the outset of these investigations, respondents may have anticipated that certain prior methodologies would be employed in place of ones actually used, but they have no legal right to the maintenance of such prior practices.

Further, our preliminary determinations and subsequent disclosures to all interested parties fully explained these methodologies and each respondent took advantage of its opportunity to comment upon them, both orally and in writing. We took all of these comments fully into account in reaching our final determinations. As such, each respondent fully participated in the decision-making process to the extent of its legal rights, and cannot properly be viewed as having been denied any such rights. Moreover, there is no substantial evidence in the record in any of these cases which would support a conclusion that the respondent governments, when establishing or administering the program investigated, relied to their detriment on prior methodologies. Indeed, it would be difficult to conclude that these governments in any way considered the possible consequences under the U.S. countervailing duty law before taking the actions which resulted in countervailable benefits to the products under investigation.

Comment 4

Some respondents contend that many of the benefits received by the steel companies investigated, such as aids for restructuring, are directly analogous to procedures and benefits common to bankruptcy proceedings. As such, they are consistent with normal commercial considerations and should not be considered subsidies.

DOC Position

No respondent has furnished us any evidence that it has been subject to formal bankruptcy proceedings, or that its restructuring or other procedures actually employed remotely resembled normal bankruptcy procedure in its country. In the absence of any such evidence the contention of respondents is entirely too speculative a basis upon which to base a determination in these cases.

Comment 5

Respondents allege that the use of the present value methodology is inconsistent with U.S. law.

DOC Position

The use of the present value concept is fully consistent with the countervailing duty law. Section 701(a) states that where the Department determines there to be subsidization and, where appropriate, the ITC determines there to be injury, " . . . then there shall be imposed upon such merchandise a countervailing duty . . . equal to the amount of the net subsidy." So long as the present value (in the year of grant receipt) of the amounts allocated over time does not exceed the face value of the grant, the amount countervailed will not exceed the total net subsidy.

• *GATT-Related Issues.*

Comment 6

The European Communities (EC) assert that in order for a countervailable subsidy to exist under the GATT, there must be a charge on the public account. In support of this contention, the EC cites in particular item (1) of the Illustrative List of Export Subsidies (the List), included as an annex to the agreement on Interpretation and Application of Articles VI, XVI and XXIII of the General Agreement on Tariffs and Trade (the code). Item (1) of the List defines as an export subsidy, "Any other charge on the public account constituting an export subsidy in the sense of Article XVI of the General Agreement."

DOC Position

Item (1) does not limit the definition of subsidy to a charge on the public account, but rather makes clear that such a charge is included in the universe of subsidies which constitute on their face prohibited export subsidies. Items (c) and (d) of the List show that preferential treatment for exports, without regard to a charge on the public account, can also constitute a subsidy on its face. These items define as subsidies:

(c) Internal transport and freight charges on export shipments, provided or mandated by governments, on terms more favorable than for domestic shipments.

(d) The delivery by governments or their agencies of imported or domestic products or services for use in the production of exported goods, on terms or conditions more favorable than for delivery of like or directly competitive products or services for use in the production of goods for domestic consumption, if (in the case of products) such terms or conditions are more favorable than those commercially available on world markets to their exporters.

Item (1), cited by the EC, derives from the original illustrative list of subsidies of 1960, which represented an agreed interpretation of Article XVI:4 of the GATT. However, the Department notes that this list also includes items (c) and (d) of the current List. Since the negotiation of Article XVI:4 in the 1950's, there has never been a consensus on an interpretation such as that advanced by the EC. Rather, it has been generally accepted that the range of activities covered by the term subsidy as used in the GATT is quite broad, including charges on the public account as well as certain activities which do not necessarily involve such a charge.

Comment 7

The EC argues that subsidies other than export subsidies cannot be considered countervailable under the Code unless such subsidies "(a)dversely affect the conditions of normal competition. In the absence of any such distortion, subsidies, other than export subsidies, are recognized as important instruments for the promotion of social and economic policy objectives against which no action is envisaged by the Code." The EC further argues that the Department considered regional aids countervailable "(w)ithout taking into consideration any disadvantages incurred by companies having to operate in economically retarded and remote areas. . . . This approach does not take into account, that under GATT and the Code countervailable subsidies are only those, which adversely affect the conditions of normal competition." In support of this contention, the EC cities Article 11 of the Code, "Subsidies other than export subsidies".

DOC Position

The language of Article of Article 11 does not prejudice the right of any signatory to the code to countervail against non-export subsidies. The language of the Article is the result of compromise between the United States and the EC at the time of the negotiation of the Code; the United States proposed to include an illustrative list of domestic subsidies, while the EC position was that such subsidies should not be considered countervailable. The Department notes that, while no list of domestic subsidies was incorporated *per se* in the Code, examples of such subsidies are included in Article 11. in contrast, the position of the EC was not adopted, as no such prohibition regarding the countervailability of domestic subsidies appears in the Code. The fact that certain subsidies are not prohibited by the Code is not relevant to a determination as to whether such subsidies confer a countervailable benefit in a specific case.

In addition, the Department notes that Article 11:3 of the Code states, "(t)he above form of (non-export) subsidies are normally granted either regionally or by sector." Article 11:2 states:

> Signatories recognize, however, that subsidies other than expoet subsidies . . . may cause or threaten to cause injury to a domestic industry or another signatory or serious prejudice to the interests of another signatory or may nullify or impair benefits accruing to another signatory under the General Agreement, in particular where such subsidies would adversely affect the conditions of normal competition. Signatories shall therefore seek to avoid causing such effects through the use of subsidies. In particular, signatories when drawing up their policies and practices in this field, in addition to evaluating the essential internal objectives to be achieved, shall also weigh, as far as practicable, possible adverse effects on trade. They shall also consider the conditions of world trade, production (e.g. price, capacity utilization etc.) and supply in the product concerned.

While there is no agreed definition of the term "normal competition" in the context of the GATT, the term can reasonably be constured to include comparative advantage, a concept about which little, if any, serious dispute exists among economists. The argument of the EC flows against the logic of comparative advantage. Subsidies used to alter the comparative advantage of certain regions with respect to the production of a certain product or products are by definition distortive of trade and the allocation of resources, and, therefore, must affect normal competition, including competition with producers in the market of the importing country. There is no evidence that the governments of the countries in question, with regard to most of the programs and benefits under consideration, specifically sought to avoid causing injury to the domestic industries of other Code signatories, or even considered possible adverse effects on trade, as required by Article 11:2.

Finally the Department notes that Article 4 of the Code, "Imposition of countervailing duties", makes no distinction between domestic and export subsidies.

Comment 8

In objecting to the methodology used by the Department to calculate the subsidies found to exist by virtue grants, preferential loans and loan guarantees (*See* Appendix 2, Methodology), the EC argues that "Article VI of the GATT provides that a countervailing duty may not exceed the amount of subsidy 'determined to have been *granted*'. The use of the word 'granted' rather than 'received' and the absence of of any reference to 'value' or 'benefit' indicates clearly that the countervailable amount is the financial contribution of the government rather than the much more nebulous benefit to the recipient." (Emphasis in the EC brief).

DOC Position

The position of the Department with respect to the need for a specific financial contribution of the government is discussed above. With respect to the calculation of the amount of the subsidy, the Department believes that the use of the word "granted" in Article VI:3 does not control the question of calculation of the amount of a subsidy, but merely refers to the existence of the subsidy. In fact, as the EC itself notes, Footnote 15 to the Code states, "An understanding among signatories should be developed setting out the criteria for the calculation of the amount of subsidy." Were the amount of subsidy always equal to a charge on the public account, such an understanding would be unnecessary.

Article 4:2 of the Code states, "No countervailing duty shall be levied on any important product in excess of the amount of the subsidy found to exist * * *" The position of the Department is that the subsidy is the benefit received by the producer or exporter. In no way does the language of Article 4 of the Code or Article VI of the GATT mandate a methodology to be used by signatories in the calculation of a subsidy as long as no consensus to the contrary exists (as referred to in Footnote 15). As a matter of general interpretation of the Code and the GATT, the omission of language dealing with a specific issue must be seen as a purposeful decision on the part of the signatories to leave the question open. (*See* Comment 9 and DOC Position, below.)

Comment 9

The EC has criticized the Department for making unilateral interpretations of various provisions of the Code, in particular with respect to determinations as to whether certain specific practices are subsidies and with respect to the methodologies employed in calculating the value of a subsidy.

DOC Position

The Department will follow, as far as U.S. law permits, the mandatory provisions of the Code, as well as any interpretations on which a consensus exists among all Code signatories including the United States. However, the Code does *not* require inaction by signatories with regard to areas not clearly covered by the Code or by agreed interpretations of the Code. Such a requirement would be inconsistent with practice under the GATT as it has developed since its inception in 1947. The fact that the Code is silent with respect to whether a specific practice constitutes a subsidy does not mean that no signatory may make a determination with respect to that practice in the course of a proceeding. The fact that the signatories have not agreed on a methodology for the calculation of the amount of a subsidy does not mean that no signatory may adopt a methodology in the absence of such agreements, since the inability to calculate the amount of the subsidy found to exist would clearly frustrate the intent of the Code and the GATT.

Comment 10

The EC objects to the Department's use of average return on investment as a measure of the commercial reasonableness of a government infusion of equity in the absence of a market price for shares. The EC argues that "It follows from the GATT that the decisive criterion is the cost to the Government and therefore the investment should be treated as a long-term loan by the Government and the long-term return should be measured against the rate at which the Government borrowed money to make the investment."

DOC Position

The Code notes in Article 11:3 that possible forms of non-export subsidies include "(g)overnment subscription to, or provisin of, equity capital." However,

the Code and the GATT are silent on the question of precisely when such activity does constitute a subsidy and, where found, how such a subsidy should be calculated. The position of the EC with respect to this issue turns on defining a subsidy as the cost to the government. As discussed above in the response to Comment 6, the Department rejects this position. In any event, the equity infusions in question were not long-term and had no provisions for repayment. Accordingly, it is not possible to conclude that the decision of the Department is inconsistent with the GATT or the Code. (*See* Appendix 2 for a discussion of the methodology employed by the Department with respect to equity infusions.)

Comment 11

The EC avers that "This distinction (between creditworthy and uncreditworthy companies) is a complete innovation and is not provided for anywhere in the GATT. Since the GATT criterion for the determination of a subsidy is the financial contribution of the government, the creditworthiness of the companies is irrelevant."

DOC Position

The fact that the GATT dos not address this issue specifically does not preclude consideration of the issue where it arises in the course of a proceeding. As discussed above, the Department does not agree that the only criterion for the determination of the existence of a subsidy under the GATT is the financial contribution of the government. Therefore, the question of the creditworthiness of a borrower is relevant because a loan to a company unable otherwise to obtain credit is a greater benefit to that company than a comparable loan to a company which is able to obtain financing on its own.

Comment 13

The EC argues that the Code must be interpreted in its entirety, and that the various provisions must be considered in relation to each other. In particular, the EC emphasizes that the List prescribes by implication the manner in which subsidies must be determined to exist and must be calculated.

DOC Position

The Department agrees that the Code must be interpreted as a whole. This includes the Code's distinction between subsidies which are prohibited *per se* and subsidies which are prohibited only under certain circumstances. The subsidies which are enumerated in the List are prohibited *per se* under Article 9, and, hence, actionable under "Track II", as provided for under Articles 12, 13, 17 and 18. As its title implies, the List is *illustrative* of the types of practices which constitute grounds for the invocation of Track II dispute settlement procedures. The list is thus descriptive of *prohibited* practices, not dispositive of the calculation of the value of any subsidy conferred under any particular practice. Thus there is no inconsistency between the Department's calculation of benefits conferred by export subsidies compared with benefits conferred under domestic programs, since the Department employs uniform methodologies without regard to any distinction between the two types of subsidies.

Comment 14

The EC states that "Appendix B (of the Preliminary Determinations) contains a disturbing assertion: 'In the absence of special circumstances, a party receiving a benefit on the production of its merchandise *is not assumed to share a benefit with an unrelated purchaser.*' (47 FR 26307, 26309 (1982) emphasis supplied) The implication is that the existence of a countervailable subsidy, i.e., 'benefit' can be assumed in certain circumstances * * *" The EC asserts that the Code requires that the elements necessary for the imposition of countervailing duties be established by positive factual evidence. Further, the EC adds that "The only instance in which Title VII permits a presumption is under section 771(7)(E)(i) * * *"

DOC Position

The Department agrees that determinations as to the existence of a subsidy should be based on verified facts. However, this is possible only insofar as the facts are made available to the Department during the course of a proceeding. As a matter of normal procedure, the Department request information from all interested parties, including the foreign government involved, in order to establish the facts upon which its determinations may be based. The Department followed this procedure in the instant cases. In those instances where the Department has been forced to make a determination on the basis of incomplete information, the responsibility rests with the interested parties who, despite the requests of the Department, failed to provide such information to the Department in a timely manner.

Where incomplete information has formed the basis of decisions of the Department in particular cases, there is no contravention of the obligations of the Department with respect to the Code or the statute. Article 2:9 of the Code provides:

In cases in which any interested party or signatory refuses access to, or otherwise does not provide, necessary information within a reasonable period or significantly impedes the investigation, preliminary and final findings, affirmative or negative, may be made on the basis of the facts available.

Furthermore, Section 776(b) of the Act provides:

In making their determinations under this title, the administering authority and the Commission shall, whenever a party or any other person refuses or is unable to produce information requested in a timely manner and in the form required, or otherwise significantly impedes an investigation, use the best information otherwise available.

[FR Doc. 82-23883 Filed 8-31-82; 8:45 am]

BILLING CODE 3510-25-M

Certain Steel Products From Belgium; Amendment To Notice of Final Affirmative Countervailing Duty Determinations

AGENCY: International Trade Administration, Commerce.

ACTION: Notice of amendment to notice of final affirmative countervailing duty determinations.

SUMMARY: On August 24, 1982, the Department of Commerce signed the final affirmative countervailing duty determinations on certain steel products from Belgium.

Due to a clerical error involving the total value of sales for Siderurgie Maritime (Sidmar), the notice incorrectly stated that the net subsidies from capital grants, exemptions from real property tax and assumption of financing costs to Sidmar were, respectively, 0.410 percent *ad valorem*, 0.071 percent *ad valorem* and 4.159 percent *ad valorem* for each of the two products under investigation. The correct figures are, repectively, 0.243 percent *ad valorem*, 0.041 percent *ad valorem* and 2.487 percent *ad valorem*.

Due to another clerical error, the notice incorrectly stated that the net subsidy for Forges De Clabecq (Clabecq) from the assumption of financing costs was 0.177 percent *ad valorem*. In calculating this subsidy rate, only one year's benefits were included rather than benefits for each year since 1979 when the government of Belgium assumed certain financing costs. The correct subsidy rate for Clabecq for this program is 0.449 percent *ad valorem*.

The notice also incorrectly stated that the net subsidy for Clabecq for the period which we are measuring subsidization was 0.348 percent *ad valorem* which is *de minimis*. The correct estimated net subsidy rate is 0.458 percent *ad valorem* which is still *de minimis*.

Therefore, the estimated net subsidy rate in the "Suspension of Liquidation" section should read as follows:

Manufacturer/producer/exporter	Ad valorem rate (percent)
Siderurgie Maritime (Sidmar):	
Hot-rolled carbon steel plate	2.771
Hot-rolled carbon steel sheet and strip	2.771

This amendment does not imply that the Department will not issue a more general amendment of the estimated countervailing duty rates in this and the other Final Determinations on Certain Steel Products published in this issue of the **Federal Register** after we have reexamined all our calculations for possible clerical errors.

EFFECTIVE DATE: September 7, 1982.

FOR FURTHER INFORMATION CONTACT: Michael J. Altier, Office of Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone (202) 377–1785.

William T. Archey,

Acting Assistant Secretary for Trade Aministration.

September 2, 1982.

[FR Doc. 82-24645 Filed 9-3-82; 8:45 am]

BILLING CODE 3510-25-M

Final Affirmative Countervailing Duty Determinations; Certain Steel Products From France

AGENCY: International Trade Administration, Commerce.

ACTION: Final affirmative countervailing duty determinations; certain steel products from France.

SUMMARY: We have determined that certain benefits which constitute subsidies within the meaning of the countervailing duty law are being provided to manufacturers, producers, or exporters in France of certain steel products, as described in the "Scope of the Investigations" section of this notice. The estimated net subsidy for each firm and for each product is indicated under the "Suspension of Liquidation" section of this notice., The U.S. International Trade Commission (ITC) will determine within 45 days of the publication of this notice whether these imports are materially injuring, or threatening to materially injure, a U.S. industry.

EFFECTIVE DATE: September 7, 1982.

FOR FURTHER INFORMATION CONTACT: Nicholas C. Tolerico, Office of Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230, telephone: (202) 377–4036.

SUPPLEMENTARY INFORMATION:

Final Determinations

Based upon our investigations, we have determined that certain benefits which constitute subsidies within the meaning of section 701 of the Tariff Act of 1930, as amended (the Act), are being provided to manufacturers, producers, or exporters in France of certain steel products, a described in the "Scope of Investigations" section of this notice. The following programs are found to confer subsidies:

- Preferential financing including equity infusions.
- Certain labor-related aid.
- Assistance for plant operating expenses.
- Research and development.

We determine the estimated net subsidy to be the amount indicated for each firm and for each product in the "Suspension of Liquidation" section of this notice.

Case History

On January 11, 1982, we received petitions from United Steel Corporation; counsel for Bethlehem Steel Corporation; and counsel for Republic Steel Corporation, Inland Steel Company, Vones & Laughlin Steel, Inc., National Steel Corporation, and Cyclops Corporation (the Five), filed on behalf of the U.S. industry producing carbon steel structural shaped, hot-rolled carbon steel sheet and strip, and cold-rolled carbon steel sheet and strip. The petitioners alleged that certain benefits which constitute subsidies within the meaning of section 701 of the Act are being provided, directly or indirectly, to the manufacturers, producers, or exporters in France of the steel products listed above. Counsel for Bethlehem Steel Corporation and counsel for the Five alleged that "critical circumstances"; exist, as defined in section 703(e) of the Act. We found the petitions to contain sufficient grounds upon which to initiate countervailing duty investigations, and on February 1, 1982, we initiated countervailing duty investigations (47 FR 5739).

Since France is a "country under the Agreement" within the meaning of section 701(b) of the Act, injury determinations are required for these investigations. Therefore, we notified the ITC of our initiations. On February 26, 1982, the ITC determined that there is a reasonable indication that imports of carbon steel structural shapes, hot-rolled carbon steel sheet and strip, and cold-rolled carbon steel sheet and strip from France are materially injuring, or threatening to materially injure, a U.S. industry.

We presented questionnaires concerning the allegations to the Delegation of the Commission of the European Communities and to the government of France in Washington, D.C. On April 28 and 30, 1982, we received the responses to the questionnaires. Supplemental responses were received on May 14 and 17, 1982. On June 10, 1982, we issued our preliminary determinations in these investigations (47 FR 26315). These stated that the government of France was providing its manufacturers, producers, or exporters of certain steel products with benefits which constitute subsidies. The programs preliminarily determined to bestow countervailable benefits were:

- Export credit insurance.
- Preferential financing including equity infusions.
- Regional development incentives.
- Certain labor-related aid.
- Assistance for plant operating expenses.
- Research and development.

Scope of the Investigations

The products covered by these investigations are:

- Carbon steel structural shapes.
- Hot-rolled carbon steel sheet and strip.
- Cold-rolled carbon steel sheet and strip.

The products are fully described in Appendix 1 which appears with the notice of "Final Affirmative Countervailing Duty Determinations: Certain Steel Products from Belgium," in this issue of the **Federal Register**. The product definition of hot-rolled carbon steel sheet and strip has been amended since the initiation of these investigations (47 FR 5739).

Société Anonyme des Forges et Aciéries de Dilling (Dilling), Société des Aciéries et Laminoirs de Lorraine (Sacilor), Société Métallurgique de Normandie (Normandie), and Union Sidérurgique du Nord et de l'Est de la

France (Usinor) are the only known producers and exporters in France of the subject products which were exported to the United States.

The period for which we are measuring subsidization is the calendar year 1981. Dilling, Sacilor and Usinor operate on a calendar year basis.

Analysis of Programs

In their responses, the government of France and the Delegation of the Commission of the European Communities provided data for the applicable periods. Additionally, we received information from Dilling, Sacilor, and Usinor. Sacilor and Usinor produced and exported carbon steel structural shapes, hot-rolled carbon steel sheet and strip, and cold-rolled carbon steel sheet and strip.

Dilling produced and exported hot-rolled carbon steel sheet and strip, and cold-rolled carbon steel sheet and strip. Because we received no response from Normandie, we are applying to it the highest subsidy rate found in France for each product under investigation.

Dilling, also known as AG der Dillinger Hüttenwerke (Dillinger), is an integrated steel producer located at Dillingen in the Saar area of the Federal Republic of Germany. There is a substantial French interest in Dilling, as Sacilor owns 40.7 percent of Dilling's capital stock and Marine-Wendel, Sacilor's former holding company, also owns an unspecified amount of Dilling stock. Although Dilling is incorporated in Germany, we included that portion of Dilling's output produced in France. Details of this arrangement are outlined below.

Sacilor and Dilling both own substantial amounts of shares in Société Lorraine de Laminage Continu (Sollac), which produces hot-rolled carbon steel and sheet and cold-rolled carbon steel sheet and strip. The capital ownership of Sollac is as follows:

	Percent
Sacilor	64.29
Dilling	25.09
Forges de Gueugnon	8.01
Carnaud/Basse-Indre	2.61
Sollac	100.00

Sollac, in turn, owns 50 percent of Société Lorraine et Méridionale de Laminage Continu (Solmer), which produces hot-rolled steel sheet and strip. The capital ownership of Solmer is as follows:

	Percent
Sollac	47.50
Usinor	47.50
Thyssen	5.00
Solmer	100.00

Sollac and Solmer are run on a cooperative, non-profit basis on behalf of their respective shareholders. Neither Sollac nor Solmer sell their steel products in the marketplace; instead, each shareholder in Sollac and Solmer buys, at cost, a quantity of finished steel proportionate to its share of ownership, which it then resells under its own name.

For purposes of these determinations, we are treating Sollac as a joint production facility of its owners. Therefore, we are allocating Sollac's production and countervailable benefits to Dilling and Sacilor, in proportion to their holdings in Sollac (25.09 and 64.29 percent, respectively).

Likewise, we are treating Solmer as a joint production facility of its owners, and allocating Solmer's production and countervailable benefits to Usinor, Sacilor, and Dilling in proportion to their holdings in Solmer. We are not allocating any of Solmer's production and countervailable benefits to Thyssen, because Thyssen has not taken its share of production for several years. Thyssen has been negotiating to divest itself of its holding in Solmer, and the issue of Thyssen's participation in Solmer is currently under arbitration. Dilling thus receives 12.55 percent, and Usinor 50.0 percent of Solmer's production and countervailable benefits.

Since we do not consider Sollac and Solmer to be independent companies, any discussion in the body of this notice of programs used by Dilling, Sacilor, and Usinor, must be understood to cover the respondents' direct and indirect holdings in Sollac and Solmer.

Throughout this notice, general principles and conclusions of law applied by the Department of Commerce to the facts of the current investigations concernng certain steel products are described in detail in Appendices 2–4, which appear with the notice of "Final Affirmative Countervailing Duty Determinations: Certain Steel Porducts from Belgium," in this issue of the **Federal Register.** Unless otherwise noted, we allocated each company's countervailable benefits as follows:

Where benefits were provided to all steel production, they were allocated over the value of all steel sales of the company receiving the benefit;

Where benefits were provided to specific facilities producing hot-rolled carbon steel sheet and strip, or hot-rolled and cold-rolled carbon steel sheet and strip, we determined the value of the benefit for thse products as follows:

We allocated the benefit to each company in proportion to its share of ownership in the facility;

Each company's benefit was then multiplied by the percentage that the sales value of those products made at that facility represented of the total sales value of all products from that facility received by each company;

This amount was then divided by the total value of each company's sales of those products.

Based upon our analysis of the petitions, responses to our questionnaires, our verification and oral and written comments by interested parties, we determine the following.

I. Programs Determined To Confer Subsidies

We have determined that subsidies are being provided under the programs listed below to manufacturers, producers, or exporters in France of carbon steel structural shapes, hot-rolled cabon steel sheet and strip, and cold-rolled carbon steel sheet and strip.

A. *Preferential Financing Including Equity Infusions.* Petitioners alleged preferential financing in the form of low-interest loans and loan guarantees, and the conversion of accumulated debt.

1. *Loans and Loan Guarantees.* A number of organizations of the French government and of the European Community (EC) have issued loans and/or loan guarantees to the French steel industry. The majority of these loans were provided by the following institutions:

Fonds de Développement Economique et Social (FDES). Created by the French Parliament in 1955, FDES is a fund which provides loans to businesses and corporations in order to further the French government's economic, social, industrial, and regional development objectives. The fund, which is actually a line item in the French government budget, is approved every year by Parliament.

As FDES is not an organization but rather a budgetary item, it is administered by the Ministry of Finance. Loan applications are filed with the Ministry of Finance, but the decision to issue a loan rests with the FDES Board, which is composed of government ministers and career civil servants whose agencies are involved in economic policy.

A semi-public financial institution, Crédit National, disburses FDES funds to recipients approved by the Ministry of Finance (see discussion on Crédit National below).

FDES loans are always part of a global financial package, as other lenders such as government credit institutions and public and private banks participate in the funding of a

project (an FDES loan never covers the entire cost of a project). Usually, loans are secured by a mortgage or a pledge. We were advised by the government of France that FDES lending rates were consistently lower than commercial rates.

There is some evidence which suggests that FDES loans are available to all industries and regions. At verification, we requested French government authorities to provide sample FDES loan applications and agreements, and to specify the criteria on which these loans were actually granted. The French government did not provide this information. In light of this refusal, we cannot conclude that these loans are generally available. Therefore, we consider these loans to confer subsidies within the meaning of the countervailing duty law to the extent that they were provided at preferential, below-market rates.

Crédit National (CN). Crédit National is a semi-public credit institution, with special legal status, which issues medium- and long-term loans to French industry, including the steel industry. Loan funds are raised by offering bonds in the public marketplace. These bonds are guaranteed by the government of France.

Crédit National acted as the conduit through which FDES loans were granted to the steel industry. The French government, either directly or through Crédit National, also guarantees some loans to the steel companies. In addition, Crédit National has participated in bank loans to the steel industry through such means as assuring the banks that they can rediscount the loans with Crédit National, which in effect constitutes a guarantee.

In most cases, Crédit National acts only as part of a loan syndicate. The terms of any loans Crédit National makes on behalf of the French government are set by the French government. We verified that CN loans to the French steel industry were made with government backing and that Crédit National's operating budget is financed by the French government.

There is some evidence suggesting that CN loans are available to all industries and regions. At verification, we requested French government authorities to arrange a meeting with CN officials, to provide sample loan applications, and to specify the criteria on which these loans were actually granted. Since these requests were refused, we were unable to establish that these loans were not given at the direction of the government of France, or that CN loans are generally available. Therefore, we consider these loans to confer subsidies within the meaning of the countervailing duty law, to the exent that they were provided at preferential, below-market rates. Similarly, we find the bank loans in which Crédit National participated to confer subsidies within the meaning of the countervailing duty law to the extent that they were provided at preferential, below-market rates.

Caisse des Dépôts et Consignations (CDC). CDC is a government institution that invests funds deposited in the Caisses d'Epargne (the French savings banks), pension funds, and insurance company deposits. CDC makes both short- and long-term loans to various industries, including steel. At verification, we requested an interview with CDC from French government officials, in order to determine whether CDC loans were generally available. This request was refused. Therefore, we were unable to estalish that CDC loans to the steel industry were not given at the specific direction of the government, or that CDC loans are generally available. Therefore, we consider these loans to confer subsidies within the meaning of the countervailing duty law to the extent that they were provided at preferential, below-market rates.

European Coal and Steel Community (ECSC) and European Investment Bank (EIB) Loans, Loan Guarantees and Interest Rebates. For the reasons discussed in Appendix 3, ECSC industrial investment loans and guarantees and EIB loans and loan guarantees confer countervailable benefits to the extent that the loan was made at a preferential interest rate, or that the guarantee enabled the loan recipient to obtain a preferential interest rate.

Interest rebates on ECSC loans were provided to Dilling, Sacilor, and Usinor. For the reasons outlined in Appendix 3, we consider that portion of the rebates that was not financed by producer-generated funds to confer a countervailable benefit.

Groupement de l'Industrie Sidérurgique (GIS). GIS was founded in 1946 as a corporation whose sole shareholders were 45 steel companies. The purpose of GIS was to raise money for capital projects of the steel companies. By floating debt instruments in the public marketplace, GIS raised monies to lend to the companies at a rate equal to the rate being paid on bonds issued to the public, plus operating expenses. Five percent of the funds received were left on deposit with GIS to cover individual steel company defaults. Funds were raised in France, other EC countries, and abroad. GIS bonds are backed by unconditional guarantees of the companies, with each company being liable to the bondholders for the sums loaned to it by GIS. No loans have been issued by GIS since 1978, and no principal from previous loans remained outstanding on the steel companies' books in 1981.

Specialized Financial Institutions. A number of private, cooperative financial institutions emerged after World War II to raise capital for various sectors of French industry. By floating bond issues, these cooperative institutions raised capital and made loans to their member companies, including steel companies. Since 1978, none of these institutions has floated bonds or loaned funds to the steel industry. These institutions include:

—Groupement Interprofessionnel Financier Antipollution (GIFIAP): environmental protection;

—Groupement pour le Financement de la Région de Fos (GIFOS): development of the Fos area near Marseille;

—Groupement des Industries de Matériaux de Construction (GIMAT): construction materials;

—Groupement pour le Financement des Economies d'Energie (GENERCO): energy conservation;

—Groupement d'Equipement pour le Traitement des Minerais de Fer (GETRAFER): processing of iron ore.

Since these are private, cooperative institutions that issued loans at non-preferential rates, we find that those loans issued prior to 1978 with principal still outstanding in 1981 do not confer any countervailable benefits.

Our treatment of loans and loan guarantees that were provided at perferential rates from FDES, Crédit National, bank syndicates in which Chédit National participated, CDC, the ECSC and the EIB is outlined in section 5 (a) through (c) below. Our treatment of ECSC interest rebates is described in section 5(d). Since loans from the GIS and other specialized financial institutions were not issued after 1978, we did not find them countervailable except when they were converted into Loans of Special Characteristics ("Prêts à Caractéristiques Spéciales" or PACS), as outlined in section 5(c).

The 1978 Rescue Plan. By 1978, the French steel industry had been experiencing severe financial difficulties for a number of years. Usinor and Sacilor were unable to pay their debts. In September 1978, the government of France instituted a major recapitalization and restructuring program for the steel industry, hereinafter referred to as the "Rescue Plan."

A primary financial goal of the restructuring was the reduction of the companies' debt service bruden. This was accomplished in three ways.

First, the banks refunded a certain amount of interest to Sacilor and Usinor over a five-year period beginning in 1978. Since these refunds were provided under the government-directed Rescue Plan, and are grants to specific enterprises, we determine that they confer countervailable benefits. For our treatment of these refunds, refer to section 5(d).

Second, the private holding companies, Marine-Wendel for Sacilor and Denain Nord-Est Longwy (DNEL) for Usinor, cancelled a portion of Sacilor's and Usinor's debt. Since this forgiveness of debt was provided at the direction of the government as part of the Rescue Plan, we determine that it confers countervailable benefits. For our treatment of this debt, see section 5(e).

Third, the loans from Crédit National, FDES, the Caisse des Dépôts et Consignations, the GIS, and the other specialized financial institutions, were converted into PACS. Marine-Wendel and DNEL also converted a portion of their loans to Sacilor and Usinor into PACS. The PACS bear an interest rate or 0.1 percent until 1983, when they are scheduled to be renegotiated. Principal repayments are suspended until 1983 or whenever the companies return to profitability, whichever is sooner. In addition to the initial 1978 conversions, PACS were also issued between 1978 and 1981.

Under the Rescue Plan, the steel companies included in these investigations service both the PAACS and other debt owed to Marine-Wendel, DNEL, CDC, and the FDES. The French government created two institutions to service the debt, including PACS, owed to the remaining lenders. These institutions are the Caisse d'Amortissement pour l'Acier (CAPA), and the Groupement des Emprunts Collectifs de la Sidérugie (GECS).

CAPA was created to service the debt owed to Crédit National, the GIS, and the other specialized financial institutions. CAPA was initially funded by the French government, state-owned institutional investors, and the Caisse des Dépôts et Consignations. CAPA services the debt through interest payments on PACS, loans from the French Treasury, and borrowings on the financial markets, which are guaranteed by the French government.

The GECS was created because the French government determined that the holders of bonds issued by the GIS and the other specialized financial institutions should be protected from losses. CAPA reimburses the GECS with the funds it has raised as described above. The GECS then makes principal and interest payments to the bondholders.

Because the PACS were created under the government-directed Rescue Plan and are specific to the steel companies, we find that they confer countervailable benefits. Our treatment of these PACS is outlined in section 5(c).

3. *Equity Infusions.* Two equity infusions were made in Sacilor and Usinor through which the French government became a shareholder in both companies. The first infusion was made in 1979 under the Rescue Plan, when funds were provided in exchange for stock by CDC, the banks, GIS, FDES, and Crédit National. The second infusion was made in 1981, when PACS held by FEDES were cancelled in exchange for stock.

Equity participation by the government is not a subsidy *per se.* Petitioners alleged, however, that government infusions of equity into the French steel companies were made at a time when these infusions were not consistent with commercial considerations. We concluded that these infusions were made on terms inconsistent with commercial considerations, because of the critical financial condition of the companies at the time the infusions occurred (as described in the "Creditworthiness Issue" section below). Therefore, a subsidy potentially exists.

Since the providers of the infusions received stock in exchange for cash, we calculated average stock prices for the period preceding the infusions. We then compared the market value of the new stock issued with the actual value to the company of the equity infusion. Since the actual value was greater than the market value, we determine that the equity infusions conferred a countervailable benefit. The difference is considered to be a grant and is allocated over 15 years, the average useful life of capital assets in steel mills (see grants section in Appendix 2). For our treatment of equity infusions, refer to section 5 (d) and (e) below.

4. *Creditworthiness Issue.* Petitioners alleged that both Sacilor and Usinor are uncreditworthy. In our preliminary determinations, we found that, for purposes of these investigations, Sacilor and Usinor became uncreditworthy by the end of 1975. Upon further examination of the relevant data, we determined that, although Sacilor and Usinor had deteriorating financial situations through 1977, they were still in a position to obtain credit from private lenders on terms consistent with commercial considerations without government involvement.

Based on further analysis, we now find, for purposes of these determinations, that both Sacilor and Usinor became uncreditworthy in 1978 and remained so through 1981 (for additional information on the creditworthiness issue, see Appendix 2).

a. *Sacilor.* Our analysis of Sacilor's financial statements revealed a pattern of significant operating losses every year beginning in 1975 (from a low of FF 1.1 billion in 1979 to a high of FF 2.6 billion in 1981). Sacilor has had consistently high debt/equity ratios in every year beginning in 1975. By 1978, Sacilor's financial situation had become so critical that the government of France intervened with the Rescue Plan described above, under which most of Sacilor's debt was converted into PACS. These carry an interest rate of 0.1 percent and no obligation to repay principal until the company returns to profitability. In light of Sacilor's inability by 1978 to raise funds without the French government's heavy involvement in the company, and the continuing deterioration of the company's financial position (as indicated by certain financial ratios such as the current ratio, the debt/equity ratio, the finance charges to sales ratio, and the operating loss to sales ratio), we consider Sacilor to have been uncreditworthy since 1978.

b. *Usinor.* Our analysis of Usinor's financial statements revealed a pattern of significant operating losses every year beginning in 1975 (from a low of FF 833 million in 1979 to a high of FF 3 billion in 1981). Usinor has had consistently high debt/equity ratios in every year beginning in 1975. By 1978, Usinor's financial situation had become so critical that the government of France intervened with the Rescue Plan described above, under which most of Usinor's debt was converted into PACS. In light of Usinor's inability by 1978 to raise funds without the French government's heavy involvement in the company, and the continuing deterioration of the company's financial position (as indicated by certain financial ratios such as the current ratio, the debt/equity ratio, the finance charges to sales ratio, and the operating loss to sales ratio), we consider Usinor to have been uncreditworthy since 1978.

c. *Dilling.* There were no allegations, and no evidence, that Dilling is uncreditworthy.

5. *Calculation of Countervailable Benefits.* Preferential loans and loan guarantees, PACS, and equity infusions have been treated in the following five ways:

a. *Preferential Loans and Loan Guarantees Issued Prior to 1978.* The subsidy rate for any loan and loan guarantee from CDC, FDES, Crédit National, bank syndicates in which Crédit National participated, the ECSC, and the EIB that was made prior to 1978 for which principal was still outstanding in 1981, and which was made at a rate below the commercial benchmark for a comparable loan in the year of issue, is calculated according to the general methodology for loans and loan grarantees outlined in Appendix 2. For France, we used the monthly financial statistics published by the Organization for Economic Cooperation and Development (OECD) to determine the commercial benchmark. For the discount rate, we used the annual statistics published by the OECD. Using the method outlined in Appendix 2, we computed the following subsidies:

Manufacturer/producer/exporter	Ad valorem rate (percent)
Dilling:	
Hot-Rolled Carbon Steel Sheet and Strip	0.021
Cold-Rolled Carbon Steel Sheet and Strip	0.028
Sacilor:	
Carbon Steel Structural Shapes	0.000
Hot-Rolled Carbon Steel Sheet and Strip	0.036
Cold-Rolled Carbon Steel Sheet and Strip	0.018
Usinor:	
Carbon Steel Structural Shapes	0.161
Hot-Rolled Carbon Steel Sheet and Strip	0.170
Cold-Rolled Carbon Steel Sheet and Strip	0.161

b. *Preferential Loans and Loan Guarantees Issued Since 1978.* Because we consider Sacilor and Usinor to have been uncreditworthy since 1978, loans and loan guarantees issued since then by CDC, FDES, Crédit National, bank syndicates in which Crédit National participated, the ECSC, and the EIB, with principal still outstanding during 1981, are treated as loans to companies considered to be uncreditworthy. Using the equity methodology for loans to uncreditworthy companies (see Appendix 2), we compared the national average rate of return on equity in France with Sacilor's and Usinor's 1981 rates of return on equity. To prevent countervailing a higher amount than if the loan had been an outright grant to the company, we compared the 1981 benefit of these loans under the equity methodology used for loans to uncreditworthy companies, with the result under the grant methodology described in Appendix 2.

Since we do not consider Dilling to be uncreditworthy, for loans and loan guarantees given since 1978 with principal still outstanding during 1981, we treated the portion of each loan attributable to Dilling according to the preferential loan methodology described in Appendix 2.

We calculated the following subsidies:

Manufacturer/producer/exporter	Ad valorem rate (percent)
Dilling:	
Hot-Rolled Carbon Steel Sheet and Strip	0.385
Cold-Rolled Carbon Steel Sheet and Strip	0.042
Sacilor:	
Carbon Steel Structural Shapes	1.791
Hot-Rolled Carbon Steel Sheet and Strip	4.578
Cold-Rolled Carbon Steel Sheet and Strip	2.678
Usinor:	
Carbon Steel Structural Shapes	1.551
Hot-Rolled Carbon Steel Sheet and Strip	2.529
Cold-Rolled Carbon Steel Sheet and Strip	1.551

c. *Loans and Loan Guarantees Converted into PACS.* The benefits of Sacilor's and Usinor's PACS were calculated using the equity methodology for loans to uncreditworthy companies as described in part 5(b) above and as outlined in Appendix 2. In calculating the benefit of loans that were converted into PACS, we did not include those PACS that were subsequently cancelled in exchange for stock. These are discussed in section 5(e) below.

For Dilling, which we determined not to be uncreditworthy, we treated that portion of each PACS attributable to Dilling according to the preferential loan methodology described in Appendix 2.

We calculated the following subsidy rates:

Manufacturer/producer/exporter	*Ad valorem rate*
Dilling:	
Hot-Rolled Carbon Steel Sheet and Strip	3.600%
Cold-Rolled Carbon Steel Sheet and Strip	3.600%
Sacilor:	
Carbon Steel Structural Shapes	6.450%
Hot-Rolled Carbon Steel Sheet and Strip	10.816%
Cold-Rolled Carbon Steel Sheet and Strip	10.816%
Usinor:	
Carbon Steel Structural Shapes	4.041%
Hot-Rolled Carbon Steel Sheet and Strip	9.732%
Cold-Rolled Carbon Steel Sheet and Strip	4.041%

d. *Loss Coverage.* Since the cash infusions in exchange for stock and the interest refunds are not tied to capital assets nor explicitly earmarked, we consider these funds are available to cover cash-based losses.

We assume that when a company running large cash-based losses receives funds, these funds will be used to meet immediate obligations such as wages, materials, and interest expenses, which are items normally expensed in one year. Based on the above, we are expensing the funds in the year in which they were received to cover the losses of the previous year.

We calculated the annual cash losses as explained in Appendix 2, and compared the funds received to the previous year's losses. In making this comparison, we considered interest refunds before the cash infusions in exchange for equity.

With the exception of 1981, for those years in which the amounts received exceeded losses, we treated the excess as follows:

- In the case of interest refunds, we treated the excess as a grant and allocated it over 15 years, the average useful life of capital assets in steel mills;
- In the case of cash infusions made in 1979 in exchange for stock, since the providers of the infusions received stock in exchange for cash, we calculated average stock prices for the two-week period preceding the infusions. We then compared the market value of the new stock issued with the actual value to the company of the equity infusion. As the actual value was greater than the market value, we treated the difference as a grant and allocated it over 15 years, the average useful life of capital assets in steel mills (see grants section in Appendix 2).

For 1981, the period for which we are measuring subsidization, we treated the entire amount as a grant for loss coverage, and expensed it in the year received. Because Dilling incurred no losses, Dilling's share of the interest refunds was treated as an untied grant and allocated over 15 years, the average useful life of capital assets in steel mills, according to the methodology outlined in Appendix 2.

We calculated the 1981 countervailable benefits, and allocated them over the total value of each company's sales:

Manufacturer/producer/exporter	Ad valorem rate (percent)
Dilling:	
Hot-Rolled Carbon Steel Sheet and Strip	0.025
Cold-Rolled Carbon Steel Sheet and Strip	0.025
Sacilor:	
Carbon Steel Structural Shapes	0.183
Hot-Rolled Carbon Steel Sheet and Strip	0.183
Cold-Rolled Carbon Steel Sheet and Strip	0.183
Usinor:	
Carbon Steel Structural Shapes	0.370
Hot-Rolled Carbon Steel Sheet and Strip	0.370
Cold-Rolled Carbon Steel Sheet and Strip	0.370

e. *Cancellation of Debt.* In 1978, as part of the government-directed Rescue Plan, Marine-Wendel and DNEL cancelled part of Sacilor's and Usinor's debt. Since they did not receive anything in exchange for this cancellation, we treated the amount cancelled as a grant, and allocated it over 15 years, the average useful life of capital assets in steel mills (see grants section in Appendix 2).

At the end of 1981, the government of France cancelled PACS owed to it by Sacilor and Usinor in exchange for additional shares in these companies. At that time, the government's share of ownership in each company reached approximately 90 percent. Since both Sacilor's and Usinor's stock was traded on the Paris Bourse at the time the French government announced its intention to cancel its PACS for equity (see equity section in Appendix 2), we calculated average stock prices for the period immediately preceding the government's action. We then compared the average stock price with the actual value to the company of the government's equity infusion. As the actual value was greater than the market value, we treated the difference as a grant and allocated it over 15 years, the average useful life of capital assets in steel mills (see grants section in Appendix 2). We then applied the 1981 net benefit over the value of all sales, and computed the following subsidies:

Manufacturer/producer/exporter	Ad valorem rate (percent)
Sacilor:	
Carbon Steel Structural Shapes	4.845
Hot-Rolled Carbon Steel Sheet and Strip	4.845
Cold-Rolled Carbon Steel Sheet and Strip	4.845
Usinor:	
Carbon Steel Structural Shapes	4.543
Hot-Rolled Carbon Steel Sheet and Strip	4.543
Cold-Rolled Carbon Steel Sheet and Strip	4.543

B. *Certain Labor-Related Aid*

1. *Early Retirement and Layoff Benefits*

French corporations have certain statutory and contractual obligations to pay severance to their employees in case of interruption or cessation of employment. There are several French government early retirement plans designed to compensate for the effects of mass layoffs. The plan designed to cover all industries is the Fonds National de l'Emploi (FNE). Because of the significant problems faced by the steel industry with respect to restructuring, two early retirement and layoff agreements were negotiated between certain steel companies and the labor unions.

These are the Convention de Protection Sociale of June 1977 (CPS), which applies to engineers and executives of the steel industry, and the Convention Générale de Protection Sociale of July 1979 (CGPS), which applies to all other steel industry workers.

Under these special steel agreements, workers laid off between the ages of 55 and 60 must retire. This is the "anticipated cessation of activity" plan which is financed in the same manner as the FNE; that is, government, employer, and employee contributions to the unemployment fund and government contributions financed by company payments.

Workers between the ages of 50 and 55 who are laid off fall under the "dispensation of activity" plan. Under this plan, the workers are still under contract to the company but their salaries are paid by the government. While the companies are under no contractual or statutory obligation to pay wages to laid-off workers, they do have contractual and statutory obligations to pay severance to laid-off workers. Since the workers who are laid off at age 50 continue to receive wages, the companies' requirement to pay severance is deferred until the worker reaches age 55. The benefit to the steel companies is the difference between the liability accrued in each year for severance pay and the actual expense incurred in each year for severance pay.

We consider this benefit to be a grant to the steel companies. Because the benefit is less than one percent of the total value of 1981 steel production, and is tied to an item normally expensed in one year, we allocated the 1981 benefit over the total value of each company's 1981 steel sales, and calculated the following subsidy rates:

Manufacturer/producer/exporter	Ad valorem rate (percent)
Dilling:	
Hot-Rolled Carbon Steel Sheet and Srtip	0.000
Cold-Rolled Carbon Steel Sheet and Strip	0.000
Sacilor:	
Carbon Steel Structural Shapes	0.947
Hot-Rolled Carbon Steel Sheet and Strip	0.947
Cold-Rolled Carbon Steel Sheet and Strip	0.947
Usinor:	
Carbon Steel Structural Shapes	0.593
Hot-Rolled Carbon Steel Sheet and Strip	0.593
Cold-Rolled Carbon Steel Sheet and Strip	0.593

2. *Relocation and Moving Benefits.* A number of employees have been relocated from Sacilor, Sollac, and Usinor to Solmer's plant at Fos-sur-Mer near Marseille. The workers' relocation and moving expenses were initially financed by advances from Sacilor, Sollac, and Usinor to Solmer. The workers were reimbursed with ECSC funds channeled through the Fonds National de l'Emploi (FNE), which were forwarded to Solmer by the workers. Solmer in turn repaid Sacilor, Sollac, and Usinor.

Since we requested and were not furnished any evidence concerning the exact amounts or the type of assistance received, we are using, as best information available, the information provided in the response that this was a special ECSC loan for employee relocation. As explained in Appendix 3, the ECSC borrows funds on world capital markets. These funds are relent at the same interest rate plus a one percent fee to cover administrative expenses. Since this ECSC loan was not financed from producer-generated funds (see Appendix 3), and was provided for the relocation of workers within the steel industry, we consider it to be a government payment of a company's costs, and thus countervailable.

Because the loan was awarded in 1980, a year in which we concluded Sacilor and Usinor were uncreditworthy, we treated the entire amount as a loan to an uncreditworthy company, as described above and in Appendix 2, except that portion attributable to Dilling, which we treated as a preferential loan. We calculated the following subsidy rates:

Manufacturer/producer/exporter	Ad valorem rate (percent)
Dilling:	
Hot-Rolled Carbon Steel Sheet and Strip	0.000
Sacilor:	
Hot-Rolled Carbon Steel Sheet and Strip	0.004
Usinor:	
Hot-Rolled Carbon Steel Sheet and Strip	0.002

C. *Assistance for Plant Operating Expenses.* Under the restructuring plan, three of Usinor's plants were scheduled to be shut down. In 1980 and 1981, the French government made payments to Usinor in order to postpone the closings. The government payments reimbursed Usinor for certain of the expenses incurred as a result of the government's postponing the closings. Two of the plants have since been completely closed and the third shut down its steel melting operations.

The monies received constitute a countervailable grant to Usinor because the plants continued to produce steel. Because the payments from the government reimbursed operating expenses, we are allocating the benefits to the year in which the payments were received, as explained in Appendix 2. According to this method, we calculated the following subsidy rates:

Manufacturer/Producer/Exporter	Ad valorem rate (percent)
Usinor:	
All Products	0.034

D. *Research and Development (R&D).* Research and development for the

French steel industry is conducted by the Institut de Recherches de la Sidérurgie Francaise (IRSID). IRSID was established by the French steel companies, which underwrite the major portion of IRSID's budget. However, according to IRSID's 1980 annual report, the French government contributed at least three percent of IRSID's yearly budget, and the ECSC ten percent.

At verification, we were not allowed to meet with IRSID officials and were not provide with a 1981 annual report or any IRSID official documents. We were told, however, that the results of IRSID research were not released to the public. Because this research is industry-specific, and the results are not made publicly available, we consider that portion of IRSID's budget funded by the government of France to be countervailable. However, we find that R&D funding provided to IRSID by the ECSC is not countervailable, as the results of the research are made publicly available by the ECSC. To calculate the 1981 countervailable benefit, we are using IRSID's 1980 annual report as the best information available. The French government's share of IRSID's budget is 3 percent. We applied this amount to the total value of 1980 French steel sales, since the benefits of the research were available to all steel companies that are members of IRSID. We calculated an estimated net subsidy for all products and all companies of 0.007 percent *ad valorem*.

II. Programs Determined Not To Confer Subsidies

We have determined that subsidies are not being provided under the following programs to manufacturers, producers, or exporters in France of carbon steel structural shapes, hot-rolled carbon steel sheet and strip, and cold-rolled carbon steel and strip.

A. *Export Credit Insurance.* The Compagnie Francaise d'Assurance pour le Commerce Extérieur (COFACE) is a government corportation that provides export insurance to cover commercial, political, exchange rate fluctuation and inflation risks. For our preliminary determinations, we reviewed COFAC's 1980 annual report (the most recent report available) and found that, while the company showed an overall profit, its insurance activities operated at a deficit. Revenues from financial and real estate investments allowed COFACE to offset the operating deficit on insurance. Our preliminary review of the annual reports for 1976–1980 revealed a pattern of yearly operating deficits on insurance activities that were offset by revenues from investments. However, we reviewed the 1981 data and verified that only the political risk program suffered losses, not the commercial risk program. The political risk program is not used for exports to the United States by the companies under investigation. We also verified that premiums for COFACE's commercial risk insurance program exceeded losses incurred by that program. Consequently, we have determined that COFACE export insurance does not confer a subsidy with respect to exports to the United States.

B. *Vocational Training Assistance.* We verified that the only vocational training assistance programs utilized by the respondents during 1981 were provided through the European Social Fund (ESF), the Fonds National de l'Emploi (FNE), and the Association de Formation de l'Est (AFOREST), a regional training organization operating under the auspices of the regional Chamber of Commerce and financed by dues from members.

In our preliminary determinations, we assumed that these programs were aimed at retraining steelworkers for jobs within the steel industry. However, we verified that Vocational training programs are aimed at retraining a majority of workers for jobs outside the steel industry. For those workers subsequently reemployed in the steel industry, we found that they were reemployed in jobs not related to steel production. Therefore, we have determined that these programs do not confer subsidies under the countervailing duty law.

C. *ECSC Worker Housing Loans.* For the reasons described in Appendix 3, we are reversing our preliminary determinations that these loans confer a subsidy on steel companies whose workers receive them, and determine instead that they do not.

D. *Research and Development Assistance.* Three government organizations provided a small amount of R&D funding to French steel companies included in these investigations:

Agence Nationale de Valorisation de la Recherche (ANVAR): a public corporation which is designed to support innovation and enhance resarch;

Direction Générale de la Recherch Scientifique et Technique (DGRST): a subdivision of the Ministry of Research and Technology; and

Agence de l'Informatique (ADI): a public corporation which promotes the use of computer technology.

We verified that R&D funding was not awarded on a regional or industry-specific basis, and research results were made publicly available. Therefore, we have determined that the amounts received through these programs did not confer subsidies within the meaning of the Act.

E. *Energy Assistance.* The French steel companies involved in these investigations received a few small grants from the Agence pour les Economies d'Energie (AEE). The AEE is a government agency, created in 1974, that provides grants to foster energy efficiency. Grants received from the agency may have to be repaid if target efficiency levels are not met. Early in 1982, the AEE was merged with several other agencies to form the Agence Française pour la Maîtrise de l'Energie (AFME). We verified that these grants were not provided on an regional or industry-specific basis. Therefore, we have determined that the amounts received from AEE by the steel companies included in these investigations do not confer subsidies.

F. *Regional Anti-Pollution Agencies.* Created by Law No. 64–1245 of 1964, these regional agencies known generically as "Agences Financières de Bassin" provide incentives for the installation of anti-pollution devices. We believe that these programs are generally available, and do not benefit a specific group of industries. The agencies' operations are funded by dues from industrial users. In return, they award bonuses and loans to combat pollution.

Since the dues paid to these agencies by the steel companies involved in these investigations exceeded the amounts that they received, we find that the funds received do not confer subsidies.

G. *Assistance to Improve Working Conditions.* One of the steel companies involved in these investigations indicated that it had received a small grant from the Agence Nationale pour l'Amélioration des Conditions de Travail (ANACT). ANACT is a public corporation, established in 1973, to promote better working conditions. As ANACT funds are not granted on a regional or industry-specific basis, we find that the amounts provided do not confer subsidies.

H. *Assistance to Iron Ore Suppliers.* We verified that the only benefit provided to the iron ore industry in France was the assumption by the French government of part of the employers' share of pensions due to miners under a special pension plan for all employees of extractive industries. Because these pensions are not specific to one industry, we find that no subsidy was conferred.

I. *Assistance to Coal Suppliers.* In our preliminary determinations, we found

that subsidies to French coal producers did not bestow a countervailable benefit upon the production, manufacture or exportation of French steel.

Between the preliminary determinations and these final determinations, we analyzed and verified aspects of the French coal subsidy program as it applies to steel. Based upon the verified information in the records of these investigations, we find that this program does not confer a countervailable benefit on French steel producers for the following reasons.

Benefits bestowed upon the manufacturer of an input do not flow down to the purchaser of that input if the sale is transacted at arm's length. In an arm's length transaction, the seller generally attempts to maximize its total revenue by charging as high a price and selling as large a volume as the market will bear.

These principles apply to French coal sales as follows. We find that the price charged for French coal does not undercut the market price. Absent special circumstances warranting a contrary conclusion, the French steel producers apparently do not benefit from French coal subsidies as long as the price for French coal does not undercut the market price.

Further consideration is warranted, however, for one special circumstance. The government of France directly or indirectly owns all French coal producers and partially owns major French steel companies. The issue arises whether transactions between them are conducted on an arm's length basis. We do not believe that government ownership *per se* confers a subsidy, or that common government ownership of separate companies necessarily precludes arm's length transactions between them. To determine whether coal sales between government-owned coal and steel producers appear to have been consummated on arm's length terms, we considered whether the government-owned coal producers sold to the government-owned steel producer at the prevailing market price. We found that French coal producers did charge the prevailing market prices. On this basis, we conclude that coal subsidies were not conferred on steel producers as a result of government ownership.

Based upon the above considerations, we determine that French coal subsidies do not confer upon French steel producers a subsidy within the meaning of the Act.

Regarding the allegation that the French steel industry indirectly benefits from German government assistance provided to the coal industry in the Federal Republic of Germany, we do not consider such assistance to confer a countervailable benefit on the French steel industry for the reasons outlined in Appendix 2.

The ECSC provides various production and marketing grants to ECSC coal and coke producers. However, we do not consider this assistance to confer a countervailable benefit on the French steel industry for the reasons described in Appendix 3.

J. *Tax Exemptions and Assistance for Land Purchases.* Petitioners alleged that Solmer purchased the land for its Fos plant at reduced prices, and received exemptions from value-added taxes on the purchase of the land and equipment. The Fos industrial complex was developed by the Port Autonome de Marseille (Marseille Port Authority), and is part of "Europort South."

Besides Solmer, a number of other companies are located at Fos. We found no evidence that Solmer's purchase of land at Fos was not at a commerical price. Solmer paid several times more for the land than its acquisition cost, and paid for the entire cost of a dock used by Solmer and other companies.

With regard to tax exemptions, we found no evidence that Solmer benefited from any value-added tax advantages on the purchase of land and equipment that were not available to all manufacturers constructing new plants.

K. *Funding for Infrastructure.* Petitioners alleged that the French government provided funding for infrastructure such as road, port, rail and communication facilities, at Usinor's Dunkirk plant and Solmer's Fos plant.

Regarding the Dunkirk facilities, we verified that Usinor paid the French government for constructing and improving the infrastructure. Other companies besides Usinor use the facilities. Since we have no evidence that these facilities benefit Usinor exclusively or even predominantly, we determined that no subsidies were conferred.

Solmer is only one of a number of companies located at Fos, all of which share port, road, rail and communication facilities. Since we have no evidence that these facilities benefit the Solmer plant exclusively or even predominantly, we determine that no subsidies were conferred.

II. Programs Determined Not To Be Used

We have determined that the following programs which were listed in the notice of "Initiation of Countervailing Duty Investigations" are not used by the manufacturers, producers, or exporters in France of carbon steel structural shapes, hot-rolled carbon steel sheet and strip, and cold-rolled carbon steel sheet and strip.

A. *Regional Development Incentives.* The government of France provides a series of tax and non-tax regional incentives to French and foreign businesses to establish new, or to expand existing, businesses in certain French regions.

The Délégation à l'Aménagement du Territoire et à l'Action Régionale (DATAR) coordinates the programs of various government agencies and ministries. For incentive purposes, France is divided into four zones. Each zone, or part of a zone, is eligible for different types or levels of assistance. The assistance includes development grants, non-industrial grants, research and development grants, decentralization indemnities, and job training subsidies.

We have no evidence that DATAR provided any benefits to the steel companies involved in these investigations.

B. *Special Fund for Industrial Adaptation.* Petitioners alleged that French steel companies received grants and preferential loans through the Fonds Spécial d'Adaptation Industrielle (FSAI). FSAI was established in 1978 to promote job creation and industrial diversification in the steel, textile, shipbuilding and coal regions of France. We have no evidence that the steel companies included in these investigations received benefits from FSAI.

C. *Export Financing.* In France, exports may be financed or guaranteed through the Commission Interministérielle des Garanties et du Crédit au Commerce Extérieur and the Banque Française du Commerce Extérieur (BFCE). We have no evidence that the steel companies involved in these investigations availed themselves of any of these programs.

D. *European Regional Development Funds (ERDF).* This program is described in Appendix 3. We found no evidence that any company under investigation received ERDF funds.

IV. Petitioners' Comments

Comment 1

Counsel for Bethlehem and Armco contends that Solmer purchased land at Fos at a preferential price.

DOC Position

We verified through the Marseille Port Authority that Solmer's purchase of land at Fos was not on terms more

preferential than those afforded to other purchasers.

Comment 2

Counsel for Bethlehem and Armco argues that infrastructure provided at Usinor's Dunkirk plant should be countervailable even though the company reimbursed the government for this assistance. Counsel argues that we should determine whether the company reimbursed the government for the full amount of the funds expended. Further, counsel contends that even if the company did reimburse the full amount, we should take into account the time value of money with respect to the extended repayment terms given to Usinor.

DOC Position

We verified that the government billed Usinor for the construction of the facilities and that Usinor paid these amounts in full. We have no reason to believe that the amount paid was insufficient, nor that the payment terms were unusually long.

Comment 3

Counsel for Bethlehem and Armco argues that a more thorough investigation should be done with respect to Marine-Wendel's forgiveness of debt to Sacilor.

DOC Position

During verification, we requested additional information concerning Marine-Wendel's actions in relation to the debt owed to it by Sacilor. We also reviewed Marine-Wendel's participation in the Rescue Plan. Our determination in regard to Marine-Wendel's actions is included in the "Preferential Financing" section of this notice.

Comment 4

Counsel for Bethlehem and Armco argues that assistance from anti-pollution agencies is countervailable since it is not available to all industries but just to those that pollute. Counsel also contends that the dues and fines imposed by the agencies cannot be used to offset the grants provided by the agencies.

DOC Position

We do not consider loans for pollution control to confer susidies, because such loans constitute general assistance to any company with a pollution problem. Although not all companies would necessarily be eligible at any one time, loans for pollution control are not selective in the same manner as regional or industry-specific programs, because there is no predetermination of eligible areas or industries and no part of the country, and no industry, is excluded from eligibility in principle.

We verified that the levies paid by the steel companies to these anti-pollutions agencies exceeded the amounts they received from the agencies.

Comment 5

Counsel for petitioner argues that all domestic subsidies in a country should be countervailed, even if they are available to all industries.

DOC Position

See Appendix 4.

Comment 6

Counsel for petitioners argue that the Department allowed an offset or did not give full weight to the term subsidy as defined in the Act when it did not countervail ECSC assistance programs to the extent that funds for these programs were derived from the ECSC budget.

DOC Position

See Appendix 3.

Comment 7

Counsel for petitioners argue that the Department has improperly applied offsets to preferential loan benefits by subtracting principal and interest paid in 1981 and by use of the grant cap.

DOC Position

See Appendix 2.

Comment 8

Counsel for petitioners argue that the Department should have considered purchases of German-subsidized coal by unrelated European steel producers to be countervailable because the intent of these subsidies is to stabilize coal supplies to the ECSC's steel industry, insure against the risk of adverse price developments on the world market, and without this subsidized coal the ECSC steel companies would have had to pay higher world market prices.

DOC Position

See Appendix 2.

Comment 9

Counsel for petitioners argue that aid programs funded by the ECSC constitute subsidies to ECSC steel producers, even though they pay levies into the ECSC budget, because the ECSC has borrowed massively to supplement the levies.

DOC Position

See Appendix 3.

Comment 10

Counsel for petitioner argues that the time period to use to determine if critical circumstances exist is the time period before the countervailing duty petitions are filed.

DOC Position

See Appendix 4.

Comment 11

Counsel for petitioner argues that in reviewing the critical circumstances assertion the Department should have considered the cumulative effects of the imported merchandise during the period prior to the filing of the petitions.

DOC Position

See Appendix 4.

Comment 12

Counsel argue that, in our preliminary determinations, we used incorrect benchmarks.

DOC Position

See Appendix 2.

Comment 13

Counsel for petitioners argue that ECSC subsidies to coal benefit French steel companies and are therefore countervailable.

DOC Position

See Appendix 3.

Comment 14

Counsel argue that, in the absence of subsidies, the steel companies included in these investigations would not have been able to obtain supplier credits. Therefore, supplier credits confer countervailable benefits.

DOC Position

See Appendix 2.

Comment 15

Counsel argues that French government subsidization of coal producers confers subsidies on French steel producers. Counsel further argues that, by purchasing domestic coal rather than imported coal, the Sacilor and Sollac group receives advantages such as savings in carrying charges of inventories, terms of payment, and exchange rate risks.

DOC Position

For the reasons indicated above in the "Assistance to Coal Suppliers" section, we have determined that subsidies conferred by the French government on coal producers do not pass through to steel producers. Further, we believe that

the "advantages" cited by counsel are merely factors which any purchaser takes into consideration in deciding from which supplier to buy. Such business practices do not confer subsidies.

V. Respondents' Comments

Comment 1

Counsel contend that Crédit National is not a government credit institution, but a private bank subject to normal commercial practices, and that CN loans and loan guarantees are not industry-specific.

DOC Position

We agree, as indicated in the section on preferential financing above, that there is some evidence to suggest that Crédit National loans are available to all industries. However, the government of France would not provide us with the criteria on which the loans were based. We were not allowed to meet with Crédit National officials or to view sample Crédit National loan applications. Therefore, we were not satisfied that CN loans were not industry-specific, and that they were not subsidies.

With regard to Crédit National's legal status, France's foremost authority in administrative law, Professor André de Laubadère, states in the "Traité Elémentaire de Droit Administratif" (Librairie Générale de Droit et de Jurisprudence, Paris, 1966, vol. 3):

(pp. 439–440)

"Un troisième groupe d'organismes est constitué par les *Instituts spécialisés* que l'on dénomme fréquemment 'auxiliaires' ou encore 'alliés' * * * du Trésor et dont l'intervention est née du fait qu'elle prote sur des secteurs dont la rentabilité n'est pas suffisante pour attirer les crédits bancaires. Mais ces instituts sont eux-mêmes très divers: (* * *)

"D'autres sont des *sociétés de droit privé*, mais dotées d'un statut particulier qui les soumet à un contrôle étroit de l'Etat et qui conduit à les appeler généralement *organismes para- ou semi-publics* (Crédit National, etc.)."

(pp. 448–449)

"A côté des établissements publics (* * *), on rencontre des institutions financières spécialisées qui jouent un rôle analogue et qui, quoique privées, occupent encore une place dans les institutions de l'Etatbanquier parce qu'elles servent également d'intermédiaires ou relais pour le Trésor; elles reçoivent du reste, en raison de ce rôle, des dotations de l'Etat et comportent, de sa part, des contrôles très particuliers qui les font qualifier d'organismes 'para-publics' ou 'semi-pubics'.

"Ce sont notamment le *Crédit National* (* * *).

"Le cas du *Crédit National* est particulièrement intéressant car il * * * illustre la montée du rôle bancaire de l'Etat.

"(* * *) le Crédit National est devenu un instrument de financement de l'industrie par des prêts à long et moyen terme mais il est, à cet égard, un moyen de réaliser une politique de prêts des pouvoirs publics, un relais de l'Etat.

"Il en résulte un caractère complexe de cette institution aussi bien en ce qui concerne sa structure que son rôle:

"En ce quie concerne sa *structure*, le Crédit National est une société anonyme de droit privé dont le capital a été souscrit par les principaux établissements de crédit et par les plus importantes entreprises industrielles françaises. Mais l'Etat posséde des prérogatives exorbitantes sur son organisation et son fonctionnement: le président du conseil d'administration et les deux directeurs sont nommés par décret; deux des censeurs, chargés des fonctions de surveillance, sont nommés par le ministre des Finances et sont, en fait, le directeur du Trésor et les directeur de la Caisse des Dépôts.

"Quant à son *rôle*, le Crédit National, s'il est une banque, est une banque chargée d'une mission d'intérêt général. Ce trait est accentué par l'importance actuelle du rôle du Crédit National comme distributeur de fonds du F.D.E.S. et comme auxiliaire de l'éxécution du Plan. Sans doute, certains prêts sont consentis par le Crédit National sur sa seule décision, lorsqu'ils proviennent de fonds propres; mais d'autres prêts sont consentis soit après avis spontanément demandé au Commissariat du Plan, soit sur décision préalable du Conseil de direction du F.D.E.S.; ces derniers sont ceux qui sont effectués à l'aide des fonds du F.D.E.S. transitant par le Crédit National; ils constituent la partie la plus importante des opérations de celui-ci."

(Translation)

(pp. 439–440)

"A third group of organizations comprises the *Specialized Institutions*, which are frequently labeled as 'auxiliaries' or 'allies' * * * of the Treasury, and whose intervention was brought about by the fact that it bears on areas the profitability of which is inadequate to attract bank loans. These institutions, however, are themselves very diverse in nature: (* * *)

"Others are *private corporations* under a special legal status that submits them to tight state control and causes them to be generally referred to as *para- or semi-public organizations* (Crédit National, etc.)."

(pp. 448–449)

"In addition to public entities (* * *), one also encounters specialized financial institutions which play a similar part and which, although they are private, also fit within the framework of the Banker-State because they also serve as intermediaries or relays for the Treasury; besides, they receive, because of this role, funds from the State which entail very particular controls by the State, which causes them to be called 'para-public' or 'semi-public' organizations.

"Among these are Crédit National (* * *).

"The case of Crédit National is particularly interesting as it * * * illustrates the ever-growing role of the State as a banker.

"(* * *) Crédit National has become a financing instrument for industry through medium- and long-term loans, but it is, in this regard, a means for the implementation of the government's lending policy, a relay of the State.

"As a consequence, this institution presents complex characteristics as regards its structure as well as its role:

"With respect to its *structure*, Crédit National is a private corporation whose capital stock was subscribed by the principal credit institutions and the largest French industrial corporations. The State, however, possesses exorbitant rights of oversight with regard to its organization and activities: its president and both executive directors are appointed by government decree; two of its four censors, which supervise the organization's activities, are appointed by the Minister of Finance and are actually the Director of the Treasury and the Director of the Caisse des Dépôts (et Consignations).

"With respect to its *role*, Crédit National * * * is a bank entrusted with a mission of general interest. This is emphasized by Crédit National's role as a conduit for F.D.E.S. funds and as an auxiliary to the implementation of the (Five-Year) Plan. It is true that certain loans are granted by Crédit National on its own, when they are backed by Crédit National's own funds; other loans, however, are granted either after seeking the National Planning Board's opinion, either by a prior decision of the F.D.E.S. executive board; the latter loans are those made with F.D.E.S. money transiting through Crédit National; they constitute the larger part of its operations."

These excerpts demonstrate that although Crédit National is legally a private corporation, it was created by a special law, the majority of its stockholders are state-owned banks and financial institutions, and the government of France exercises tight control over Crédit National's operations. Further, Crédit National does not make loans under purely commercial considerations and acts as an agent of the government of France.

Comment 2

Counsel argue that FDES loans are not made on a regional basis, and therefore are not countervailable.

DOC Position

As indicated above in the section on preferential financing, there is some evidence to suggest that FDES loans are available to all regions. However, FDES is a government fund administered by the French Treasury. The government of France would not provide us the criteria on which the loans were based. Therefore, we were not satisfied that FDES loans were not regional and that they did not confer subsidies.

Comment 3

Counsel for Usinor contends that CN and FDES loans issured prior to 1976 are not countervailable, since they are included in the purchase price Usinor paid for Cockerill's plant at Rehon.

DOC Position

Usinor, in acquiring the assets of the Rehon plant, thereby acquired the benefit of the preferential rates on loans to Cockerill.

Comment 4

Counsel for Sacilor argues that the Rescue Plan was not instituted by the government of France, but rather was the product of negotiations between Sacilor and its creditors, and that because the Rescue Plan was consistent with rational commercial policies, there were no countervailable benefits from either the PACS or other elements of the Plan.

Counsel contend that the creditors acted reasonably, based on their conclusion that Sacilor and Usinor would return to profitability as a result of the Rescue Plan.

Counsel for Sacilor further contends that "Sacilor's borrowing capacity, and hence its creditworthiness, was restored" as a result of the Rescue Plan.

Counsel for Usinor contends that the fact Usinor showed a profit for the first half of 1980 demonstrates the accuracy of the assumptions underlying the Rescue Plan.

DOC Position

We concur that the negotiations that led to the Rescue Plan included Sacilor's creditors. However, this point is immaterial since the result of the negotiations was substantial government intervention in the steel companies' financing, which was the intent of the creditors. Further, normal commercial considerations do not usually involve government intervention to the extent of the Rescue Plan.

With respect to the second argument, the creditors' forecast of return to profitability hinged on the guarantees given by the government of France that the steel companies would be relieved of the responsibility of servicing their debt. Those circumstances are not consistent with commercial considerations.

With regard to the Rescue Plan, we are not in a position to determine its success or failure; however, we do note that Sacilor continued to sustain persistent, heavy losses in succeeding years when loans were made, up to the present time.

With respect to the fourth argument, the fact that Usinor sustained a profit in the first half of 1980 is indisputable; it is no less certain, however, that Usinor incurred a net loss for 1980 as a whole, which is the legal fiscal year, and that Usinor incurred an even greater loss in 1981. Assuming that this argument is made to demonstrate that the Rescue Plan was based on commercial considerations, it is our position, as discussed in Comment 5, that increasing government intervention indicates that the actions taken under the Rescue Plan were not on terms consistent with commercial considerations.

Comment 5

Counsel contend that the steel companies involved in these investigations are creditworthy because they received loans from both nationalized and private banks through 1980.

Counsel for Usinor also contends that the fact that GIS bonds were sold in public markets from 1976 to 1980 is conclusive evidence that the public perception at that time was that Usinor was creditworthy.

Counsel for Usinor contends that actions taken by lenders cannot be viewed as non-commercial, since they faced only two options, foreclosure or revitalization.

Counsel for Sacilor argues that the Department should not have used hindsight in deciding whether the lenders acted in accordance with commercial considerations.

DOC Position

In our preliminary determinations, we found Sacilor and Usinor to have been uncreditworthy since the end of 1975. Upon further examination of the relevant data, we determined that, although Sacilor and Usinor had deterioratting fanancial situations through 1977, they were still in a position to obtain credit from private lenders on terms consistent with commercial considerations without government involvement.

In a supplemental submission to its response, Usinor included an evaluation of its financial situation. This evaluation paraphrases a speech by the President of Usinor stating that "* * * indeed, the financial results which were already qualified as disastrous at the end of fiscal 1975 further seriously deteriorated during the second half of 1977, thus cornering Usinor in a dramatic situation."

Even though the companies received loans from private banks after 1978, most of these loans were given with express government guarantees, and thus are not evidence of the ability of the firms to raise funds on their own, and several were made at the express request of the government to the banks.

Beginning with the 1978 Rescue Plan, there has been an obvious pattern of French government direction of funds into the steel industry. We judge that the funds poured into these companies have been the result of French government targeting, and that, absent that targeting, the companies could not have obtained the funds on an arm's-length, commercial basis, in view of the heavy persisting losses and the unfavorable financial ratios. Consequently, we determine that Sacilor and Usinor remained uncreditworthy from 1978 into the period for which subsidies are being measured.

Under the 1978 Rescue Plan, GIS bonds were converted into PACS and to protect the private bondholders, debt service was assumed by CAPA and GECS with government guarantee.

With regard to respondents' third argument, we determine that even though there were only two options open to the lenders, the fact that the government of France had to intervene massively in the reorganization of Sacilor and Usinor indicates that private investors were unlikely to invest additional funds in these companies without government intervention.

With regard to the hindsight argument, we reiterate that our assessment of the creditworthiness of the companies for any given year is based on *at that time*, and not hindsight (see Appendix 2).

Comment 6

Counsel argue that, when PACS are properly viewed as equity, the debt/equity ratio decreases to an acceptable level, and that PACS are at least as valuable to the creditors as the loans that they replaced.

DOC Position

We consider the PACS to be debt, because they are actually called loans ("*Prêts* à Caractéristiques Spéciales"), bear interest, albeit at a very special rate, and must be repaid when the recipients return to profitability. Accordingly, they should not be included in the equity side of the debt/equity ratio. As discussed earlier, we calculated the benefit of PACS using the equity methodology for loans to uncreditworthy companies outlined in Appendix 2.

Comment 7

Counsel for Usinor argues that it is a valid commercial consideration to invest further in a company where there is a realistic expectation of ultimate

profitability, when the alternative is foreclosure, and the loss of funds already invested.

DOC Position

We do not disagree that further investment in a company may be based on valid commercial considerations when the alternative is loss of investment. However, in this case, it is our judgment that the government's intervention was not on terms consistent with commercial considerations, as demonstrated by a 0.1 percent interest on loans, suspension of principal repayments, forgiveness of debt, and assumption of payments due to bondholders. Further, we consider that other creditors would not have participated absent the government-directed Rescue Plan.

Comment 8

Counsel for Usinor contends that interest refunds do not constitute a subsidy, because these refunds did not involve the French government, but were part of the financial restructuring plan agreed to by the banks.

Counsel further contends that if interest refunds are determined to be a subsidy, they should be allocated solely to the year of receipt.

DOC Position

We find interest refunds to be a subsidy, because the Rescue Plan was directed by the government of France. We consider them as untied grants available to cover losses, and treated them as described in the section on loss coverage.

Comment 9

Counsel objects to the valuation of Usinor at its stock market price, and argues that estimated future earnings and company prospects must be considered.

DOC Position

The Department has not changed its methodology in this respect since its preliminary determinations in these investigations. While we recognize that the French stock market may involve a relatively low volume of shares, we believe the law shows a strong preference for the use of market standards where available. In this case there is insufficient evidence to rebut the presumptive correctness of the market's valuation of the stock.

Comment 10

Counsel for the respondents argue that premiums paid over market value of stock are common in takeovers where the objective is to gain control over the company. Counsel for Sacilor also asserts that the French securities market is notoriously inefficient because it is a thin market, and cities four examples of premiums for stock in companies with losses.

DOC Position

We agree that in a commercial takeover by private investors, premiums may be paid over the stock market price. However, in this instance we are not dealing with a commercial undertaking, but rather with a French government nationalization of the steel companies, which were not in a financial condition where a "control premium" would be expected in a commercial context (see Appendix 2).

As described in Comment 9, we used Sacilor's and Usinor's stock market prices as best information available to make a fair valuation of the companies' shares, for the reasons described above and in Appendix 2.

Comment 11

Counsel for Usinor argues that conversion of PACS to common stock took place on December 21, 1981, yet the equity subsidy is allocated over the entire year, resulting in an allegedly exaggerated subsidy.

DOC Position

We compute benefits received by a firm during a period of time (in this case, the 181 calendar year), and apply them to the total value of sales for the same period. We do not make adjustments for the fact that a particular benefit was received earlier or later in the year for which we are measuring subsidization. Throughout these steel determinations, we have not tied any subsidy to any time period shorter than a year.

Any other approach would not only be unnecessary as a matter of law, it would be administratively impossible, given the information and time available.

Comment 12

Counsel for Sacilor contends that Sollac and Solmer are independent corporations. Therefore, none of Sacilor's subsidies should be attributed to Sollac and Solmer, and none of Sollac's and Solmer's subsidies should be passed on to their shareholders.

DOC Position

We find that neither Sollac nor Solmer are independent corporations for the following reasons:

- They cannot sell their products on the open market, but only to their respective shareholders;
- They operate without either profit or loss, as they must sell their products at cost to their shareholders, in proportion to their respective holdings.

Our treatment of these companies is fully explained in the "Analysis of Programs" section of this notice.

Comment 13

Counsel contends that neither Sollac nor Solmer are uncreditworthy.

DOC Position

As we find that Sollac and Solmer are not independent companies, the issue of their creditworthiness need not be addressed.

Comment 14

Counsel for Usinor contends that COFACE's commercial risk and political risk insurance programs should be considered separately, as the former operates at a profit and the latter at a loss. Usinor's exports to the United States are insured under the commercial risk program exclusively.

DOC Position

We agree with counsel's argument, and have taken it into account in section II–A of this notice.

Comment 15

Counsel for Usinor contends that the government did not relieve the company of any responsibilities under French labor laws. Counsel for Sacilor argues that French labor assistance programs are not subsidies, because they are not regional or industry-specific.

Counsel argues that, as Sacilor's obligation is contractual rather than statutory, there can be no subsidy. He also contends that Sacilor's contractual agreement was to serve as a conduit for government largesse.

DOC Position

We determine that the steel companies do have contractual and statutory obligations to pay severance to laid-off workers.

Counsel's contention that these programs are not regional or industry-specific is inaccurate, as we found that there were specific social welfare protection agreements relating to the steel industry.

We agree with counsel for Sacilor that the companies have contractual obligations to their workers. We find these contractual obligations to be legally binding under law.

We agree that the companies serve as conduits for the distribution of certain funds, and we are not countervailing against them in this respect.

Comment 16

Counsel for Usinor alleges that money received from the French government to postpone three plant closings is not countervailable.

DOC Position

Money received from the French government enabled Usinor to continue to produce steel, and therefore confers a countervailable benefit.

Comment 17

Counsel stated that Usinor has not received a subsidy as a result of its involvement in IRSID. Usinor is a dues-paying member of IRSID. Only 3 percent of IRSID's budget is provided by the government of France. The only benefit that Usinor has received from IRSID is the right to receive the results of the research performed by the organization. No specific research was done for Usinor.

DOC Position

Although IRSID research may not have been carried out specifically for Usinor, Usinor does derive a countervailable benefit from the results of this research, as described in section I–D of this notice.

Comment 18

Counsel for Sacilor alleges that while the total amount of subsidies to Solmer was included in the subsidy base for Sacilor in the preliminary determinations, only approximately half of the value of Solmer's production was included in the total value of Sacilor's production.

DOC Position

We agree with counsel, and are now allocating Solmer's production to Dilling, Sacilor, and Usinor, in proportion to their direct or indirect holdings in Solmer.

Comment 19

Counsel for Sacilor alleges that the interest rates chosen as benchmarks for our preliminary determinations often exceeded the official rates. Counsel argues that rates in excess of those published by the OECD are arbitrary.

DOC Position

We are using the rates published by the OECD in these final determinations.

Comment 20

Counsel for Sacilor contends that the *ad valorem* allocation of the subsidy is incorrect. Counsel for Sacilor states that the Department "allocated all subsidies received by Sacilor solely to the sales of the rather restricted set of products at issue in this determination." Counsel contends that we should either trace the use of funds from each subsidy to a particular product, or allocate the subsidies over all Sacilor's income, not merely the value of products challenged in this proceeding.

DOC Position

In our preliminary determinations, we did not allocate benefits to the products under investigations, but to the total value of steel production. For our final determinations, we are allocating the benfits as described in the "Analysis of Programs" section of this notice, except for the benefits from loss coverage and equity infusions, which we are allocating over the value of all sales of each company.

Comment 21

Counsel for Sacilor asserts that our preliminary determinations treat funds received by Sacilor from FNE and AFOREST as subsidies. Counsel states that the funds received from FNE for relocation and moving expenses and retraining of workers did not benefit in any manner Sacilor. Sacilor was at no time under any legal or contractual obligation to retrain these employees.

DOC Position

We agree that the retraining of workers did not provide any benefits to Sacilor, for the reasons stated in section II–B of this notice. However, for the reasons stated in section I–B–2 of this notice, we find that relocation assistance provided a countervailable benefit.

Comment 22

Counsel for Usinor and Sacilor assert that the allegedly new methodology used in the preliminary determinations should be rejected for failure to follow proper administrative procedures.

DOC Position

See Appendix 4.

Comment 23

Counsel for respondents argue that the methodology used in the preliminary determinations to calculate the benefits of loans and equity infusions is incorrect.

DOC Position

Neither counsel for petitioners nor counsel for respondents provided convincing reasons for adopting their suggestions. For further information, see Appendix 2.

Comment 24

Counsel argue that the grants methodology which involves the imputation of a future value designed to reflect the time value of money is a violation of the prohibitions in Article IV, ¶ 3 of the GATT; Article IV, ¶ 2 of the Subsidies Code; and Section 701(a) and Section 703(d)(2) of the Act, against imposing countervailing duties in excess of subsidies.

DOC Position

See Appendix 4.

Comment 25

Counsel argue that no standards have been articulated for determining creditworthiness.

DOC Position

See Appendix 2.

Comment 26

Counsel contends that, because the Rescue Plan is akin to a Chapter XI reorganization proceeding under U.S. bankruptcy law, it is not countervailable.

DOC Position

See Appendix 4.

Comment 27

Counsel for Sacilor argues that the assumption of financing costs is not countervailable. Relying on the illustrative list of domestic subsidies contained in section 771(5)(B) of the Act, he argues that only the assumption of operational costs is countervailable. In addition, he argues that because the accounting definition of "operating costs" does not include interest-related revenues and expenses, we should not countervail the provision by the government of funds which relieve a business of its interest obligations.

DOC Position

We disagree. Any preferential absorption by a government of a cost of doing business—be it wages, materials, taxes on income, or interest expenses—can give rise to a subsidy, as recognized in subsection 771(5)(B)(iv) of the Act. We find that a subsidy to relieve debt expenses is an assumption of a cost of manufacture, production, or distribution within the meaning of subsection 771(5)(B)(iv), and is therefore countervailable. Although subsection 771(5)(B)(iii) of the Act lists as an example of a subsidy "funds * * * to cover operating losses," this illustrative example does not permit us to ignore the language of subsection 771(5)(B)(iv).

Negative Determination of Critical Circumstances

Bethlehem Steel Corporation and the Five alleged that imports of carbon steel structural shapes, hot-rolled carbon steel sheet and strip, and cold-rolled carbon steel sheet and strip under investigation present "critical circumstances." Under §§ 355.29 and 355.33(b) of the Department's regulations, critical circumstances exist when the alleged subsidies include an export subsidy inconsistent with the Agreement, and there have been massive imports of the class or kind of merchandise which is the subject of the investigation over a relatively short period.

We have not found any export subsidy in these investigations. Therefore, critical circumstances do not exist in the investigations for carbon steel structural shapes, hot-rolled carbon steel sheet and strip, and cold-rolled carbon steel sheet and strip from France.

Verification

In accordance with section 776(a) of the Act, we verified the data used in making our final determinations. During this verification, we followed normal procedures, including inspection of documents, discussions with government officials and on-site inspection of manufacturers' operations and records.

Administrative Procedures

The Department has afforded interested parties an opportunity to present oral views in accordance with its regulations (19 CFR 355.35). A public hearing was held on July 12, 1982. In accordance with the Department's regulations (19 CFR 355.34(a)), written views have been received and considered.

Suspension of Liquidation

The suspension of liquidation ordered in our preliminary affirmative countervailing duty determinations shall remain in effect until further notice. The estimated net subsidy for each firm and for each product is as follows:

Manufacturer/producer/exporter	Ad valorem rate (percent)
Dilling:	
Hot-Rolled Carbon Steel Sheet and Strip	4.038
Cold-Rolled Carbon Steel Sheet and Strip	3.702
Sacilor:	
Carbon Steel Structural Shapes	14.223
Hot-Rolled Carbon Steel Sheet and Strip	21.416
Cold-Rolled Carbon Steel Sheet and Strip	19.494
Usinor:	
Carbon Steel Structural Shapes	11.300
Hot-Rolled Carbon Steel Sheet and Strip	17.960
Cold-Rolled Carbon Steel Sheet and Strip	11.300
All Other Manufacturers/Producers/Exporters:	
Carbon Steel Structural Shapes	14.223
Hot-Rolled Carbon Steel Sheet and Strip	21.416
Cold-Rolled Carbon Steel Sheet and Strip	19.494

We are directing the United States Customs Service to require a cash deposit or bond in the amount indicated above for each entry of the subject merchandise entered on or after September 7, 1982. Where the manufacturer is not the exporter, and the manufacturer is known, the rate for that manufacturer shall be used in determining the amount of cash deposit or bond. If the manufacturer is unknown, the rate for all other manufacturers/producers/exporters shall be used. Where a company specifically listed above has not exported a particular product under investigation during the period for which we are measuring subsidization, the amount of cash deposit or bond for these products shall be based on the highest rate for products that were exported by that company.

ITC Notification

In accordance with section 705(d) of the Act, we will notify the ITC of our determinations. In addition, we are making available to the ITC all non-privileged and non-confidential information relating to these investigations. We will allow the ITC access to all privileged and confidential information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order without the written consent of the Deputy Assistant Secretary for Import Administration. The ITC will determine within 45 days of the publication of this notice whether these imports are materially injuring, or threatening to materially injure, a U.S. industry. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated and all securities posted or cash deposited as a result of the suspension of liquidation will be refunded or cancelled. If, however, the ITC determines that such injury does exist, within 7 days of notification by the ITC of that determination, we will issue a countervailing duty order, directing Customs officers to assess countervailing duty on certain steel products from France entered, or withdrawn from warehouse, for consumption after the suspension of liquidation, equal to the net subsidy determined or estimated to exist as a result of the annual review process prescribed by section 751 of the Act. The provision of section 707(a) of the Act will apply to the first directive for assessment.

This notice is published pursuant to section 705(d) of the Act and § 355.33 of the Department of Commerce Regulations (19 CFR 355.33).

Dated: August 24, 1982.

Gary N. Horlick,

Acting Assistant Secretary for Trade Administration.

[FR Doc. 82-23875 Filed 8-21-82; 8:45 am]

BILLING CODE 3510-25-M

Final Affirmative Countervailing Duty Determinations; Certain Steel Products From the Federal Republic of Germany

AGENCY: International Trade Administration, Commerce.

ACTION: Final affirmative countervailing duty determinations.

SUMMARY: We have determined that certain benefits which constitute subsidies within the meaning of the countervailing duty law are being provided to manufacturers, producers, or exporters in the Federal Republic of Germany (FRG) of certain steel products, as described in the "Scope of Investigations" section of this notice. The estimated net subsidy for each firm and for each product is indicated under the "Suspension of Liquidation" section of this notice. The estimated net subsidy on the steel products under investigation produced by each of 7 companies is *de minimis*. However we have not excluded the products of one of these companies from these determinations for reasons stated in the "Suspension of Liquidation" section of this notice. With respect to the products of the other 6 companies, the suspension of liquidation ordered in our preliminary affirmative countervailing duty determinations shall be terminated. All estimated countervailing duties shall be refunded and all appropriate bonds shall be released with respect to imports of the products under investigation from the 7 companies for which we have determined *de minimis* estimated net subsidies. The U.S. International Trade Commission (ITC) will determine within 45 days of the publication of this notice whether these imports are materially injuring, or threatening to materially injure, a U.S. industry.

EFFECTIVE DATE: September 7, 1982.

FOR FURTHER INFORMATION CONTACT: Mary S. Clapp, Office of Investigations, Import Administration, International Trade Administration, U.S. Department

of Commerce, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230, telephone: (202) 377-2438.

SUPPLEMENTARY INFORMATION:

Final Determinations

Based upon our investigations, we have determined that certain benefits which constitute subsidies within the meaning of section 701 of the Tariff Act of 1930, as amended (the Act), are being provided to manufacturers, producers, or exporters in the FRG of certain steel products, as described in the "Scope of Investigations" section of this notice. The following programs are found to provide benefits which constitute subsidies:

- Investment Premium Act—Articles 1, 2, and 3.
- Joint Scheme: Improvement of Regional Economic Structure (partially countervailable).
- Capital infusion—Peine-Salzgitter.
- European Coal and Steel Community (ECSC) loan guarantees.
- ECSC loans.
- ECSC loan guarantees.
- ECSC interest rebates.
- Labor assistance from ECSC rehabilitation aids.
- ECSC research and development (capital equipment).
- European Investment Bank (EIB) loans.
- Special case—Rochling.
- Special case—Dillinger.

We have determined the estimated net subsidy to be the amount indicated for each firm and for each product in the "Suspension of Liquidation" section of this notice. The estimated net subsidy for each firm and for each product is indicated under the "Suspension of Liquidation" section of this notice. The estimated net subsidy on the steel products under investigation produced by each of 7 companies is *de minimis*. However we have not excluded the products of one of these companies from these determinations for reasons stated in the "Suspension of Liquidation" section of this notice. With respect to the products of the other 6 companies, the suspension of liquidation ordered in our preliminary affirmative countervailing duty determinations shall be terminated. All estimated countervailing duties shall be refunded and all appropriate bonds shall be released with respect to imports of the products under investigation from the 7 companies for which we have determined *de minimis* estimated net subsidies.

Case History

On January 11, 1982, we received petitions from United States Steel Corporation; counsel for Bethlehem Steel Corporation; and counsel for Republic Steel Corporation, Inland Steel Company, Jones & Laughlin Steel, Inc., National Steel Corporation, and Cyclops Corporation (the Five), filed on behalf of the U.S. industry producing carbon steel structural shapes, hot-rolled carbon steel plate, hot-rolled carbon steel sheet and strip, and cold-rolled carbon steel sheet and strip. The petitions alleged that certain benefits which constitute subsidies within the meaning of section 701 of the Act are being provided, directly or indirectly, to the manufacturers, producers, or exporters in the FRG of the steel products listed above. Counsel for Bethlehem Steel Corporation and counsel for the Five alleged that "critical circumstances" exist, as defined in section 703(e) of the Act. We found the petitions to contain sufficient grounds upon which to initiate countervailing duty investigations, and on February 1, 1982, we initiated countervailing duty investigations (47 FR 5741).

Since the FRG is a "country under the Agreement" within the meaning of section 701(b) of the Act, injury determinations are required for these investigations. Therefore, we notified the ITC of our initiations. On February 26, 1982, the ITC preliminarily determined that there is a reasonable indication that these imports are materially injuring, or threatening to materially injure, a U.S. industry.

We presented questionnaires concerning the allegations to the Delegation of the Commission of the European Communities and to the government of the FRG in Washington, D.C. On April 30, 1982 we received the responses to the questionnaires. Supplemental responses were received on May 17, 1982. On June 10, 1982, we issued our preliminary determinations in these investigations (47 FR 26321).

We stated in our preliminary determinations that the government of the FRG was providing benefits which constitute subsidies to its manufacturers, producers, or exporters of certain steel products. The programs preliminarily determined to bestow subsidies were:

- FRG government investment grants (referred to in this notice as Investment Premium Act).
- State government grants.
- FRG/state investment grants (referred to in this notice as Joint Scheme: Improvement of Regional Economic Structure.
- Research and development grants.
- Regional labor program
- ECSC loans, including housing loans.
- ECSC loan guarantees.
- Capital infusions by the FRG.
- Special case—Rochling.

This determination was amended on July 30, 1982, pursuant to an order of the Court of International Trade, to include the estimated net subsidy provided under the coking coal production assistance program (47 FR 33728).

Scope of the Investigations

The products covered by these investigations are:

- Carbon steel structural shapes.
- Hot-rolled carbon steel plate.
- Hot-rolled carbon steel sheet and strip.
- Cold-rolled carbon steel sheet and strip.

The products are fully described in Appendix 1 which appears with the notice of "Final Affirmative Countervailing Duty Determinations: Certain Steel Products from Belgium," in this issue of the **Federal Register**. The product definition of hot-rolled carbon steel sheet and strip has been amended since the initiation of these investigations (47 FR 5739-49).

AG der Dillinger Huttenwerke (Dillinger), Thyssen AG (Thyssen), Stahlwerke Peine-Salzgitter AG (P & S), Klockner-Werke AG (Klockner), Stahlwerke Rochling-Burbach GmbH (Rochling), Hoesch Werke AG (Hoesch), Krupp Stahl AG (Krupp), and Otto Wolff AG (Otto Wolff) are the only known producers and exporters in the FRG of the subject products which were exported to the United States. The period for which we are measuring subsidization is the calendar year 1981, except for Thyssen, Klockner, and P & S, for which we are using their fiscal year, October 1, 1980 to September 30, 1981.

Analysis of Programs

In their responses, the government of the FRG and the Delegation of the Commission of the European Communities provided data for the applicable periods. Additionally, we received information from the following firms, which produced and exported the following products under investigation, which were exported to the United States:

Firms and Carbon Steel Products

Dillinger—Hot-rolled carbon steel plate
Thyssen—Carbon steel structural shapes, hot-rolled carbon steel plate, hot-rolled carbon steel sheet and strip, and cold-rolled carbon steel sheet and strip
P & S—Carbon steel structural shapes, hot-rolled carbon steel plate, hot-rolled carbon steel sheet and strip,

and cold-rolled carbon steel sheet and strip

Klockner—Carbon steel structural shapes, hot-rolled carbon steel plate, hot-rolled carbon steel sheet and strip, and cold-rolled carbon steel sheet and strip

Hoesch—Carbon steel structural shapes, hot-rolled carbon steel plate, hot-rolled carbon steel sheet and strip, and cold-rolled carbon steel sheet and strip

Krupp—Carbon steel structural shapes, hot-rolled carbon steel plate, hot-rolled carbon steel sheet and strip, and cold-rolled carbon steel sheet and strip

Otto Wolff—Cold-rolled carbon steel sheet and strip

Rochling did not submit a response but is known to be a producer and exporter of the carbon steel structural shapes under investigation, which were exported to the United States. Therefore, for Rochling we are applying a rate which is based, in part, on the highest rate calculated for individual programs. Our calculations for Rochling are discussed in the "Programs Determined to Confer Subsidies" section of this notice.

Throughout this notice, general principles and conclusions of law applied by the Department of Commerce to the facts of the current investigations concerning certain steel products are described in detail in Appendices 2–4, which appear with the notice of "Final Affirmative Countervailing Duty Determinations: Certain Steel Products from Belgium," in this issue of the **Federal Register.** Based upon our analysis of the petitions, responses to our questionnaires, our verification, and oral and written comments by interested parties, we have determined the following.

I. Programs Determined To Confer Subsidies

We have determined subsidies are provided under the following programs to manufacturers, producers, or exporters in the FRG of carbon steel structural shapes, hot-rolled carbon steel plate, hot-rolled carbon steel sheet and strip, and cold-rolled carbon steel sheet and strip:

A. *Federal Programs.* 1. Investment Premium Act, Articles 1, 2, and 3. Domestic investors building new, or expanding existing, operations in certain regions of the FRG receive cash reimbursements from the FRG tax authority based on a percentage of capital investment costs. These reimbursements are available to industries situated in the "zonal border areas" adjacent to the German Democratic Republic, as well as other areas which are economically depressed. Under the Investment Premium Act investors have a legal claim to reimbursements once the eligibility requirements are satisfied. In principle, all industries meeting the requirements receive the reimbursements and no industrial sector in the regions covered by the Investment Premium Act benefits more than any other. However, because articles 1, 2, and 3 of the Investment Premium Act limit assistance to regions with depressed economic structures, there is a regional preference and, therefore, the reimbursements are countervailable.

Subsidy amounts were determined by using the grants methodology described in Appendix 2. The discount rates used in the calculations were based on the annual average FRG government bond yields reported by the Organization for Economic Cooperation and Development (OECD). The subsidies were then allocated over the value of total steel sales of the companies in 1981 to determine the *ad valorem* subsidy for 1981.

Companies Receiving Benefits:

P & S. Under Articles 1, 2, and 3 of the Investment Premium Act, we calculated an *ad valorem* subsidy rate of 0.182 percent to P & S.

Dillinger. Under Articles 1, 2, and 3 of the Investment Premium Act, we calculated an *ad valorem* subsidy rate of 0.0001 percent to Dillinger.

2. Joint Scheme: Improvement of Regional Economic Structure. This Joint Scheme combines equal portions of federal and state funds that are provided by the budgets of those two levels of government. The funds are used to reimburse companies for capital investment costs up to certain ceilings, usually between 10 and 25 percent of investment costs. In the preliminary determinations we referred to this program as the "Improvement of Regional Trade."

State governments administer the program and make the decisions on whether to grant an investor assistance under the Joint Scheme. Investors have no legal claim on the funds and once the annual budgetary allocation is exhausted, no further applications are considered. Of the funds disbursed, no sector of industry within a state receives any preference.

We verified that the state government of North Rhine Westphalia (NRW) allocated the Joint Scheme funds in that state without sectoral preference. However, the federal portion is allocated by the Bundestag according to a discretionary apportionment formula which assigns to each region a percentage of the total funds available.

Federal funds are disbursed on a state-by-state basis and then they are matched by state budgetary allocations. Since the federal funds are allocated using a specific and unequal regional apportionment formula, we find that the federal portion of the Joint Scheme operates on a regionally preferential basis and, therefore, constitutes a subsidy within the meaning of the Act.

We treated the loan and grants that the government of the FRG provided to Krupp, under the Joint Scheme program, according to the appropriate methodologies described in Appendix 2, we compared the interest rate on the loan with the German corporate bond yield as reported by the OECD, which we used as our benchmark. This rate was the best available in the absence of any published, long-term rates for commercial loans. For the grant we used as the discount rates the German government bond yields as reported by the OECD and estimated the average life of capital assets for the steel industry to be 15 years. The resulting amounts were allocated across the value of total steel sales for the company.

Companies Receiving Benefits:

Krupp. Under this program we calculated *ad valorem* subsidy rates of 0.001 percent for the loan and of 0.004 for the grants to Krupp.

3. Capital Infusion—Peine-Salzgitter. According to sections 291–307 of the German Stock Corporation Law, profit transfer agreements may be entered into whereby a subsidiary company transfers both its profits and losses to its parent. Salzgitter AG (SAG), a government-owned holding company, has established transfer agreements with many of its subsidiaries, including P & S. This account, comprised of accumulated profits and capital infusions, is used to cover the consolidated losses of SAG, including the losses transferred to SAG from its subsidiaries which participate in the profit transfer agreement. We do not consider a transfer agreement with a government controlled company a subsidy *per se.* In this case, however, when losses are transferred, they are covered by a free reserve account at SAG which received capital infusions from the FRG. Therefore, to the extent the government subsidizes SAG, we believe this arrangement establishes a mechanism for passing subsidies through SAG to P & S.

The actual replacement of losses occurs in the year after the loss is incurred and the amount of loss coverage actually given never exceeds the amount of the previous year's losses.

Thus we consider this arrangement between SAG and P & S as a means for covering losses on a continuing basis. The fact that the transfers of losses are charged agains the free reserve in a subsequent year is merely an administrative convenience.

In 1981, P & S incurred losses, which were not transferred to SAG until May of 1982. Furthermore, P & S incurred no losses in 1980 which would have been transferrable to SAG in 1981. Since P & S had no occasion to draw on the free reserve in 1981, it received no countervailable benefit through SAG in that year. However, it may reasonably be assumed that P & S is continuing to receive benefits under its arrangement with SAG. Any countervailable benefits flowing to the company which occur outside the period for which we are measuring subsidization would be included in an annual review following the issuance of countervailing duty orders in these investigations.

B. *ECSC Programs.* 1. *Loans from the ECSC.* For the reasons described in Appendix 3, we determine that ECSC loans from borrowings by the ECSC on world capital markets confer subsidies to the extent that they are made at preferential rates. To calculate the subsidy we used the loan methodology described in Appendix 2. The benchmark used is the corporate bond yield reported by the OECD based on the currency in which the loan was denominated. The rate was the best available in the absence of any published, long-term rates for commercial loans. In the particular case where a company was able to obtain a comparable loan from a commercial lender, we compared EECSC loans with the commercial loans to determine any interest rate benefit. We allocated the subsidies over the value of each company's total steel sales.

Companies Receiving Benefits:

P & S. Under this program we calculated an *ad valorem* subsidy rate of 0.053 percent to P & S.

Otto Wolff. Under this program we calculated an *ad valorem* subsidy rate of 0.015 percent to Otto Wolff.

Thyssen. Under this program we calculated an *ad valorem* subsidy rate of 0.029 percent to Thyssen.

Krupp. Under this program we calculated an *ad valorem* subsidy rate of 0.047 percent to Krupp.

Dillinger. Under this program we calculated an *ad valorem* subsidy rate of 0.055 percent to Dillinger.

Hoesch. Under this program we calculated an *ad valorem* subsidy rate of 0.025 percent to Hoesch.

Klockner. Under this program we calculated an *ad valorem* subsidy rate of 0.032 percent to Klockner.

2. *ECSC loan guarantees.* For reasons described in Appendix 3 we determined that ECSC loan guarantees confer subsidies to the extent that they enable a company to receive preferential rates. We determined that the interest rate given to P & S under its loan guarantee was not preferential and yielded no benefit. No other company in the FRG received benefits under this program.

3. *Labor Assistance from the ECSC Rehabilitation Aids.* As described in Appendix 3, grants from the ECSC under this program are used to assist the resettlement and retraining of steel workers within and outside the steel industry as well as to provide some unemployment and early retirement aids. For the reasons described in Appendix 3, we have determined that these grants confer countervailable benefits to the products under investigation where they relieve respondents of expenses they would ordinarily incur in the normal course of business. We are countervailing 20.05 percent of the total grants bestowed in 1981 because 20.05 percent of the ECSC budget for 1981 was financed by government contributions.

We allocated the subsidy for each company across the value of that company's total steel sales. Because we considered that the grant was used for an item which is relatively small and is normally expensed in the year received, we allocated the entire amount to the year of receipt (as described in Appendices 2 and 3).

Companies Receiving Benefits:

Hoesch. Under this program we calculated an *ad valorem* subsidy rate of 0.014 percent to Hoesch.

Thyssen. Under this program we calculated an *ad valorem* subsidy rate of 0.000002 percent to Thyssen.

4. *Interest Rate Rebates.* The ECSC provides interest rate rebates on all or part of loans it makes to companies. The rebate, in the form of a reduced rate, is granted on the condition that some of the new jobs created will be reserved primarily for workers made redundant in ECSC industries.

For the reasons described in Appendix 3, we consider 20.05 percent of the interest rebates received in 1981, on loans which benefited steel production, to be countervailable. To arrive at our *ad valorem* rates we allocated the countervailable amount over the total value of sales of steel products by each steel company for 1981. As indicated in Appendix 2, we treated the subsidy as an expense item, and allocated it exclusively to the year of receipt of the benefit.

Companies Receiving Benefits:

Thyssen. Under this program we calculated an *ad valorem* subsidy rate to Thyssen of 0.006 percent.

Dillinger. Under this program we calculated an *ad valorem* subsidy rate to Dillinger of 0.007 percent.

D. *European Investment Bank (EIB).* The EIB is described in Appendix 3. In the FRG we learned that one company, Dillinger, had received an EIB loan. Article 130 of the Treaty of Rome states that the EIB grants loans and furnishes guarantees first and foremost for projects promoting development of areas confronted with economic difficulties. Because of this regional preference we have determined that preferential loans provided by the EIB confer countervailable subsidies within the meaning of the Act.

Only one company in the FRG, Dillinger, received EIB loans but since the interest rate was not preferential we have determined that it received no countervailable benefit.

E. *ECSC Research and Development (Capital Equipment).* The purchase of capital equipment by a steel company with funds from ECSC R & D grants is partially countervailable as explained in Appendix 3. Two companies in the FRG purchased capital equipment with ECSC R & D grants, Dillinger and P & S.

Companies Receiving Benefits:

Dillinger. Under this program we calculated an *ad valorem* subsidy rate of 0.088 percent to Dillinger.

P & S. Under this program we calculated an *ad valorem* subsidy rate of 0.001 percent to P & S.

F. *Special Case—Rochling.* Rochling did not respond to our questionnaire. Therefore, we have determined that all the above programs, from which the petitioners alleged that Rochling benefited, are subsidies for Rochling. Subsidies were calculated on the basis of the best information available. In calculating these subsidies we used the highest rate calculated for each program which was used by other companies under these investigations.

These programs and *ad valorem* subsidy rates for Rochling are:

Program	Ad valorem subsidy rate (percent)
Investment Premium Act—articles 1, 2, and 3	0.182
Joint Scheme: Improvement of Regional Economic Structure	0.004
ECSC Loans	0.055
Labor Assistance from the ECSC	0.014

Where we found that the purpose of a program was expressly to assist Rochling, we calculated subsidies on the basis of publicly available company data.

The FRG program specific to Rochling provided loans that were conditionally repayable, depending on future profits. Because profits were unlikely, we regarded the benefits as grants and calculated subsidies using the grant methodology in Appendix 2. We allocated the calculated benefit over 15 years, the average life of capital assets in the steel industry.

We allocated the resulting subsidies across the total value of Rochling's steel sales. The benchmark used in the calculations is based on the FRG government bond yield as reported by the OECD. We determined an *ad valorem* subsidy of 0.876 percent on these conditionally repayable loans.

The total *ad valorem* subsidy rate calculated for Rochling is 1.131 percent.

G. *Special Case—Dillinger.* Counsel for Dillinger requested that we consider production for the account of Dillinger by Solmer and Sollac, French "cost-companies," as products of Dillinger. Solmer and Sollac produced hot-rolled carbon steel sheet and strip and cold-rolled carbon steel sheet and strip for Dillinger's account. Counsel for Dillinger stated that Solmer and Sollac are really acting as integral extensions of Dillinger's production operations. We have determined that the Solmer and Sollac production for Dillinger is carbon steel sheet and strip of French origin.

For a more detailed explanation of this situation, refer to the notice of "Final Affirmative Countervailing Duty Determinations: Certain Steel Products from France" in this issue of the **Federal Register.** Products sold by Dillinger but produced in France are not included in this suspension of liquidation.

II. Programs Determined Not To Confer Subsidies

We have determined subsidies are not being provided under the following programs to manufacturers, producers, or exporters in the FRG of carbon steel structural shapes, hot-rolled carbon steel plate, hot-rolled carbon steel sheet and strip, and cold-rolled carbon steel sheet and strip:

A. *Federal Programs.* 1. *Investment Premium Act—articles 4, 4a, and 4b.* The Investment Premium Act was described in part in the "Programs Determined to Confer Subsidies" section of this notice. Benefits under articles 4, 4a, and 4b of the Investment Premium Act are generally available to all industries in the FRG without regard to sector or location. We reviewed the eligibility requirements as stated in FRG administrative regulations.

Our analysis of the payments under articles 4, 4a, and 4b revealed that reimbursements granted under these sections were to domestic producers throughout the FRG for research and development projects, for investments in energy production and distribution, and for the general promotion of capital investments. There is no regulatory or administrative directive or guideline which indicates that any specific industry or group of industries or a particular geographical region is preferred. Some steel companies in these investigations have received reimbursements.

Based on these facts and the reasons in Appendix 4, we have determined that benefits provided to the steel companies under articles 4, 4a and 4b of the Investment Premium Act are not preferential and, therefore, do not constitute subsidies within the meaning of the Act.

2. *Federal Ministry of Research and Technology (BMFT).* The BMFT provides grants for research and development projects that conform to the policies and objectives of the FRG, including expanding scientific knowledge and the competitive position of the FRG economy, improvement of living and working conditions, and the conservation and preservation of natural resources. Organized into Directorates General, the BMFT funds projects in three basic areas of research: 1) energy and environmental protection, 2) information and production technologies, and 3) aerospace technology, transportation, medicine and biology. Any FRG industry interested in conducting research under one of these Directorates General may apply there for funding and project approval. Under the "General Program on Raw Materials Research" (a subgroup of the Directorate General for energy and environment), the iron and steel industry has participated in a number of R & D projects funded by the BMFT.

BMFT guidelines stipulate that the results of funded R & D projects must be made publicly available. This is done through the publication of articles in scientific journals and BMFT research reports.

In our preliminary determinations, we found the BMFT R & D grants to be countervailable. At that time, it was our understanding that funds were set aside specifically for use by the iron and steel industry, and that research results were available only to firms in the FRG. Information obtained during the course of these investigations now indicates that funds are not allocated by industrial sector, but by area of general research applicability. Additionally, research results are available to any interested party, not only in the FRG, but worldwide. Inasmuch as the BMFT funds are not allocated by specific industrial sector, and the results of research projects are generally available, we now find that these R & D grants do not constitute subsidies within the meaning of the Act.

3. *Federal Environment Agency, Umweltbundesamt (UBA).* The UBA manages federal government funds which can be provided as reimbursement for up to 50 percent of a company's investment in air pollution equipment. The investment must be for a demonstration project and the technology must be transferable to comparable existing facilities.

We have determined that UBA pollution control funds do not confer countervailable benefits because we have verified that they are allocated across a broad spectrum of industries ranging from chemicals to food and beverages. Further, all industries receive similar reimbursements for similar portions of pollution control projects funded by the UBA.

4. *Labor Assistance.* The Labor Promotion Act of 1969 provides FRG steel companies with labor assistance pursuant to articles 54, 49, 41, 47, 91 and 97 which is part of a national manpower policy.

a. *Article 54.* This article provides employers with loans relating to costs incurred for training hard-to-place employees.

b. *Article 49.* This program provides funds for costs incurred in training workers in need of training to update outmoded skills.

c. *Articles 41 and 47.* We verified that these articles provide for training assistance, in the form of direct payments to employees, which will enable workers to change jobs through the improvement of skills.

d. *Article 91.* Funding provided by this article goes to an employing company to reimburse its expenses for training unemployed workers sent to it for that purpose by public employment offices.

e. *Article 97.* This program provides employers with funds to hire more than the required number of older people, thus reducing the level of unemployment among the elderly.

Conclusions

Benefits under these programs are available to all industries or employees in all industries in the FRG, regardless of location or sector. Therefore, we have

determined that these benefits do not constitute subsidies within the meaning of the Act.

In the preliminary determinations we treated Article 91 as conferring subsidies (under the heading "Regional Labor Program") because we believed the reason for providing funds was to assist particular geographical regions. In our verification we learned that the qualifications for assistance was an unemployment level (6 percent or above), and that the regional designation was in administrative convenience. Because assistance under this article is part of a national policy to relieve unemployment and is not targeted to specific regions or industries as such, we do not now consider it is conferring a subsidy within the meaning of the Act.

B. *Federal Loan Guarantees.* The FRG guarantees loans made by commerical lenders to industrial firms under this program: "Domestic Guarantees of the Federal Government to Promote Trade and Industry." They are provided according to budgetary legislation and are meant to serve broad national social and economic objectives not realizable without such financial guarantees. Such guarantees enable companies to borrow at rates lower than they would otherwise pay. Since the loan guarantees are available on equal terms to all industrial borrowers in the FRG, and since our investigation indicates that no specific industry, group of industries, or industries in particular regions are the main beneficiaries of these guarantees, we have determined that these loan guarantees are not countervailable.

C. *State Programs.* 1. *North Rhine-Westphalia—Research and Development.* The NRW government has an "Action Program for the Ruhr District" which is an overall program of assistance, to industries, funded entirely by the NRW government. Steel companies under investigation have participated in a sub-program of the Action Program entitled "Technology Program Steel," which focuses on R & D.

The main objective of the sub-program is to provide R & D funds to projects with innovative features. There are no specific eligibility criteria or application forms. The state allocates the funds based on the merits of the proposals.

During verification, we learned that once fund allocations are approved by the state, the projects and the funding levels are publicly announced. Any reports generated by the project and any patents that result from technological innovations must also be publicly announced and made publicly available.

We have determined that R & D funds provided for projects under the "Technology Program Steel" are not subsidies because the results must be made publicly available. Therefore, they convey no specific benefit to the recipients of the funds.

In the preliminary determinations we found this part of the Action Program to provide countervailable benefits because we believed the research results were available only to FRG companies. Our verification established the results were also publicly available. Therefore, these funds are not countervailable under the Act.

2. *North Rhine-Westphalia—Labor Programs.* a. *Unemployed Young People.* Training facilities situated in the state of NRW are eligible for assistance. Emphasis is placed on increasing the number of young people trained in existing training facilities.

b. *Trade Apprenticeships for Young People.* Under this program, training facilities in the state of NRW receive assistance only if they provide additional places for young females in technical trade positions.

c. *Places for Young People Without Appreciceships.* This program provides assistance to training facilities in the state of NRW which create training positions for youths.

d. *Jobs for Disabled Persons.* Investment grants are given by the state government through the Landschaftsverbank Westfalen-Lippe and Landschaftsverbank Rheinland as an incentive to firms which voluntarily create more jobs for the disabled.

Conclusions

Steel companies under investigation received funds under these programs. These state labor assistance programs are available on equal terms to all industries in the relevant political subdivision and are not specific to an industry or a group of industries. For this reason, we have determined that benefits under these programs do not constitute subsidies within the meaning of the Act.

3. *North Rhine-Westphalia—Worker Housing Program.* Under the state's program for the "Promotion of Building of Houses" of December 23, 1977, housing construction loans are made available at concessionary interest rates. Steel companies use this source of funds for construction of residential housing for their employees. The program specifies the type and capacity of the units to be built and the qualifications of the occupants. To further assist the occupants, the same program provides grant funds to the builders of homes in compensation for reducing their rental charges. The program is open to all applicants regardless of type of firm or industry or location within the state. Therefore, we have determined that the funds received under this program are not subsidies within the meaning of the Act.

4. *North Rhine-Westphalia—Pollution Control Grants.* The state of NRW provides partial funding for installing pollution control equipment through direct grants to firms whose plants need to meet new environmental standards. Steel companies under investigation received funds under this program. While the program is open to firms in any industry with pollution problems, applicants must demonstrate the financial ability to undertake these projects. We have determined that this program does not confer benefits which constitute subsidies on the products under investigation because the allocation of state funds for the program is for all industries located in the state of NRW, and is not to specific industries or to companies in particular regions within the state.

5. *Neidersachsen—Investment Grants.* The state of Niedersachsen provides assistance through investment premium grants under a rationalization program to improve the state's basic economic structure. Grants may be made of up to 7.5 percent of the qualified amount of a project or to a maximum of DM 15 million. the program is open to all commercial and industrial enterprises within Neidersachsen, but applicants have no legal right to the funds. Steel companies under these investigations received funds under this program. Since we verified that the grants are not allocated to specific industries or regions, we find the program not to confer benefits which constitute subsidies on the products under investigation within the meaning of the Act.

We preliminarily determined that this program and the preceding NRW program were countervailable because we believed then that they were targeted at specific industries. Our verification revealed that this is not the case, and that the funds are allocated across a number of different industries.

D. *Other FRG Programs.* 1. *European Recovery Program (ERP).* This program began with the Marshall Plan for the postwar rehabilitation of Western Europe. ERP funds are reserved exclusively for industrial rehabilitation and promotion. The source of funds for this program is a system of principal and interest repayments from Marshall Plan loans. A committee, which includes members of the government, directs the

allocation of ERP funds according to the guidelines of the ERP Special Fund. These guidelines, adopted annually, state eligibility criteria, application procedures and use of ERP funds. The terms and conditions of ERP loans are published in the Federal Journal. Steel companies in these investigations received funds under this program.

We verified that ERP funds are disbursed to all branches of industry and that no specific industry, group of industries or industries in particular regions is the main beneficiary of these funds. Therefore, we have determined that this program does not confer benefits which constitute subsidies within the meaning of the Act.

2. *Loans From Credit Institutions Controlled by the FRG.* The Kreditanstalt fur Weideraufbau was established as part of the national recovery program after World War II. This credit institution is approximately 80 percent owned by the FRG and 20 percent owned by the state. The bank offers long-term commercial development loans to industries at interest rates lower than those available from comparable commercial loans. In the preliminary determinations, we stated that this program was not used. During the verification we learned Hoesch received loans from this source.

Information developed during the verification indicates that this institution makes loans available without regard to specific industries or regions. Therefore, we do not find benefits it may confer to be subsidies on the products under investigation within the meaning of the Act.

D. *German Coal Subsidies—Final Negative Determinations.* In the preliminary determinations, we found that production assistance paid to FRG producers of coking coal did not bestow a countervailable benefit upon the production, manufacture or exportation of FRG steel. The sole ground cited for that determination was that FRG coking coal is not used solely by the FRG steel industry, but instead is used in significant amounts by many FRG industries (*e.g.*, by the chemical and nonferrous metal industries and for home heating). Therefore, we concluded that subsidization of FRG coking coal could not be considered subsidization of a specific enterprise or industry (other than the coal industry) within the meaning of section 771(5)(B) of the Act (47 FR 26325).

Subsequently, Republic Steel Corporation sought judicial review of this finding under section 516A(a)(1)(B) of the Act. The government conceded for the purposes of the litigation that the rationale stated in the preliminary determinations for the conclusion that the program was not countervailable was not supported by the administrative record as of the date of the preliminary determinations, June 10, 1982. On July 29, 1982, at the government's request, the court remanded the case to the Department and instructed it to calculate the amount of the countervailable benefit preliminarily attributable to the FRG coking coal price support program for each manufacturer/producer/exporter, and to add it to the amount of the countervailable subsidies previously determined. On July 30, 1982, the Department issued amended preliminary determinations, effective June 17, 1982, which found preliminarily that the FRG coking coal price support subsidy was 1.76 percent *ad valorem* (47 FR 33728, August 4, 1982).

Between the preliminary determinations and these final determinations, we have analyzed and verified the FRG coal subsidy program as it applies to steel. Based upon the verified information in the records of these investigations, we find that production assistance paid to producers of coking coal used by the iron and steel industry does not confer a countervailable benefit on either non-FRG or FRG steel producers.

As we stated in Appendix B to "Preliminary Affirmative Countervailing Duty Determinations, Certain Steel Products from Belgium" reached on June 10 (47 FR 26309), benefits bestowed upon the manufacturer of an input do not flow down to the purchaser of that input if the sale is transacted at arm's length. In an arm's length transaction, the seller generally attempts to maximize its total revenue by charging as high a price and selling as large a volume as the market will bear.

These principles apply to FRG coal sales as follows. With respect to sales of FRG coal outside the FRG, the price charged for subsidized FRG coal certainly does not undercut the freely available market price. We note that the FRG Government is required by the Treaty of Paris of 1951 to obtain the approval of the EC for any FRG production assistance to its coal industry. Commission Decision (73/287/ECSC) of July 25, 1973 states that the EC cannot and does not sanction production assistance to coal mining by member states if it reduces the price below the world market price. Therefore, non-FRG purchasers of subsidized FRG coal do not benefit from FRG coal subsidies.

In support of this conclusion, we note that if non-FRG steel producers did benefit from FRG coal subsidies, they would attempt to purchase FRG coal rather than unsubsidized coal from other sources, including the United States, since there is no restriction on their ability to do so. The fact that they purchase significant amounts of unsubsidized United States coal indicates that the subsidies on FRG coal do not flow to non-FRG coal consumers.

Moreover, it is extremely unlikely that the FRG Government would significantly subsidize non-FRG coal consumers unless compelled to do so by obligations with respect to the European Communities. Since there is no evidence of such obligation, we have concluded that the FRG Government is not in fact subsidizing non-FRG coal consumers.

With respect to sales of FRG coal within the FRG, on the other hand, the issue is more complicated for two reasons: (1) the FRG government restricts the importation of coal into the FRG; and (2) some FRG steel producers are related to Ruhrkohle, the major subsidized coal producer. With respect to the coal import restrictions, the issue is whether the comparison of prices for FRG coal with prices for non-FRG coal remains valid if FRG manufacturers cannot ordinarily buy non-FRG coal. But for the import restrictions, FRG purchasers of subsidized FRG coal would not be considered subsidized themselves unless the price of FRG coal undercuts the market price of coal.

We have been advised formally by the government of the FRG that the restrictions on the importation of coal into the FRG are inseparably linked with the benefits paid to the FRG coal industry; and that the present restrictions on importation of coal would not exist in the absence of such benefits to the coal industry so long as the cost of producing coal in the FRG remains significantly above world market price levels. As the FRG government has clearly stated, "It is not possible to discontinue the payment of assistance (to the coal industry) and maintain the ban on imports at the same time." To do so "would burden the FRG steel industry with the competitive disadvantages raised by difficult conditions in FRG coal deposits as well as with the costs for FRG coal."

The coal subsidies and coal-import restrictions are thus part and parcel of a comprehensive program designed to assist the FRG coal industry, from which FRG steel producers receive no benefits. In fact, the FRG steel producers are thereby prevented from buying coal at world prices, and required to pay a slight premium. Production assistance to the FRG coal industry benefits that industry alone and does not operate to benefit the manufacture or production of

steel. Therefore, under any reasonably foreseeable conditions, restrictions on the purchase of coal by FRG steel producers cannot properly be viewed as an offset impermissibly used in calculating net subsidies to FRG steel producers. The offset issue simply does not arise since, on the basis of verified information currently available to us, there is no "gross subsidy" (from which an "offset" would occur) to the FRG steel producers resulting from FRG subsidization of coal. As previously noted, the other complication of the issue of sales of FRG coal within the FRG is the fact that some FRG steel producers are related to Ruhrkohle, the subsidized FRG coal producer. In view of this relationship, further consideration is required to determine whether FRG coal subsidies flow to related FRG coal consumers, even where we believe they do not flow to unrelated coal consumers, both FRG and non-FRG. Based on the verified facts of these investigations, we have concluded that even FRG coal consumers related to Ruhrkohle do not benefit from FRG subsidization of coal. In the first place, there appears to be no price discrimination within the FRG between sales to purchasers related to Ruhrkohle and sales to unrelated purchasers. Therefore, the fact of relationship does not detract from the arm's length nature of the transfer price.

Moreover, we have determined that any benefits to FRG steel producers by dint of their partial ownership of Ruhrkohle occurred approximately fifteen years ago, and were dissipated prior to the period for which we are measuring subsidies. By the 1960's the operation of FRG coal mines had become uneconomic, and their owners—including steel producers—tried to close them down in 1967–69. In accord with its energy policy, however, the FRG government compelled mine owners to continue operating the mines. Ruhrkohle was formed. The coal mine owners were relieved of the cost of shutting down the mines, and certain liabilities of the coal companies were assumed by the government. Insofar as a steel producer partially owns Ruhrkohle, it shared these benefits. However, both of these benefits were dissipated prior to the period for which we are measuring subsidies. Therefore, we conclude that even steel producers related to Ruhrkohle are not subsidized as a result of FRG subsidization of Ruhrkohle.

In support of this conclusion, we note that the FRG steel producers have consistently opposed the requirement to continue to operate the FRG coal mines and to buy FRG coal. We conclude that if the related FRG steel producers were benefiting from the FRG government's comprehensive plan to subsidize coal and restrict imports, they would not be so opposed.

Clearly then, the structure of the German coal subsidy system is such as to restrict any benefits to the coal industry itself and provide no advantages to purchasers of German coal, wherever located. If any broader benefits flow from the subsidies in German coal, such benefits apply equally to all consumers in the world, including the U.S. steel industry. Such subsidies may operate to increase worldwide supply relative to worldwide demand and thereby lower the world market price of coal on a uniform basis for all coal purchasers. This universal benefit cannot be viewed as a subsidy to one coal purchaser vis-a-vis another such purchaser.

For the above reasons, we have determined that non-FRG steel producers and FRG steel producers unrelated to Ruhrkohle do not benefit from production assistance paid to producers of coking coal used by the iron and steel industry. Although it is a more difficult judgment, we also have determined, based upon the verified facts of these investigations, that FRG steel producers related to Ruhrkohle do not benefit from coking coal production assistance.

In addition to the above described FRG coking coal production assistance, some FRG steel producers receive rebates of a portion of the cost of transporting coal to their facilities. We have determined that these rebates are funded by contributions of the FRG steel companies, and therefore do not confer countervailable benefits.

E. *ECSC Programs.*

1. *ECSC Research and Development.* For the reasons described in Appendix 3, we have determined that, ECSC R & D funds do not confer any benefits which are subsidies within the meaning of the law.

2. *ECSC Housing Loans.* For the reasons described in Appendix 3, we have determined that ECSC housing loans do not confer any subsidies on the respondent steel companies.

III. Programs Determined Not To Be Used

We have determined that the following programs which were listed in the notice of "Preliminary Affirmative Countervailing Determinations, Certain Steel Products from the Federal Republic of Germany" are not used by the manufacturers, producers, or exporters of the products subject to these investigations:

A. *ECSC Industrial Reconversion Loans.* The program is described in Appendix 3.

B. *The European Regional Development Fund (ERDF).* The ERDF is described in Appendix 3. Based upon our investigations, we have determined that no company under investigation received ERDF funds.

C. *State Government Loan Guarantees.* State governments provide guarantees to commercial lenders on loans to industry. Our verification indicated that no steel firm under investigation carried on its books in 1981 any loans guaranteed by state governments. Therefore, we have determined that this program has not been used in the period for which we are measuring subsidization.

IV. Petitioners' Comments

Comment 1

Bethlehem claims that FRG steel companies with an interest in Ruhrkohle benefit from government coal subsidies, and those coal subsidies effectively reduce the price of coking coal below world market price.

DOC's Position

The Department's position on this issue is described in the "Programs Determined Not to Confer Subsidies" section of this notice.

Comment 2

Petitioners argue that the Department should have considered FRG coal subsidies to subsidize all steel companies purchasing that coal, both FRG and non-FRG, because the intent of the coal subsidies is to stabilize coal supplies to the ECSC steel industry and to insure that industry against the risk of adverse price developments on the world market. Petitioners claim that without this subsidized coal, the ECSC steel companies would have had to pay higher world market prices.

DOC's Position

For the reasons indicated *supra,* we believe the possible effects on world coking coal prices of the hypothetical absence of FRG subsidization of its coal industry are too speculative. However, were coal prices to rise, we believe that they would rise throughout the world. There is no reason to believe that prices would rise more for European purchasers of coal than for non-European purchasers.

As also indicated in detail *supra,* we believe that the real economic effect of FRG subsidies is to penalize, not to assist, the FRG steel companies. The FRG coal policy forces the FRG steel

companies to pay a slight premium for their coal purchases above the world market price. Non-FRG purchasers of subsidized FRG coal are not similarly penalized, but certainly they receive no demonstrable price advantage. These issues are discussed in Appendix 2.

Comment 3

Petitioners reject the Department's view that a party receiving a benefit on the production of its merchandise is not assumed to share that benefit with an unrelated purchaser. They maintain that a party may market its products at a lower price than it would be able to charge absent the subsidy in order to secure or hold on to a larger share of the market, and thus to increase its profitability by realizing lower unit costs and increased unit sales.

DOC's Position

We agree that there is more than one way to seek to achieve maximum profitability. In these investigations, in fact, assistance to coal has been provided to enable some coal companies to sell below their cost of production. However, the FRG coal companies do not sell below the prices of coal in Europe and elsewhere. In fact, the FRG steel producers are required to pay a slight but significant premium for FRG coal. Under these circumstances, we disagree with petitioners' argument that the FRG steel companies are indirectly subsidized through FRG coal subsidies.

Comment 4

Petitioners argue that the ECSC and the FRG government, through an "intense program of coordinated subsidy financing," have assisted the FRG coal and steel industries in order to sustain production at cost efficient levels, in significant part by producing for export.

DOC's Position

Although the arguments seem ambiguous, we believe that petitioners mean to imply that the FRG and ECSC coal assistance programs constitute an export subsidy for steel. If so then we disagree, since in both cases coal assistance is provided without the establishment of any condition concerning the exportation of steel produced using that coal.

Comment 5

Petitioners maintain that since Ruhrkohle is owned by the major FRG steel companies, it has a "focused purpose in passing on the benefit of the coal subsidies to the steel producers."

DOC's Position

To the contrary, our verified information indicates that the FRG steel companies opposed the formation of Ruhrkohle and sought instead to discontinue operation of their uneconomic coal mines. The FRG government effectively mandated the establishment of Ruhrkohle, *not* to benefit the steel companies (which were opposed to its formation), but instead to facilitate national energy policies and to maintain employment for coal miners.

Comment 6

Petitioners object to the Department's alleged requirement that a subsidy be demonstrated to confer an unfair competitive advantage. Petitioners imply that in so doing, the Department is usurping the jurisdiction of the ITC which is authorized to determine injury.

DOC's Position

Under the Act, the Department is required to determine whether respondents have received subsidies within the meaning of the Act. To do so, the Department seeks to determine whether or not respondents have received directly or indirectly an economic benefit. Whereas this is relatively easy in the case of the direct bestowal of a grant, it is quite difficult with regard to indirect subsidies allegedly conferred through the subsidization of inputs used in a final product. In this more complex area, we believe the Department must consider whether there is an economic benefit to manufacturers of the final product from subsidies bestowed on manufacturers of an individual input. This is quite distinct from the ITC's determination whether imports of the final product into the United States injure a United States industry. The Department therefore disagrees with petitioners on this issue.

Comment 7

Petitioners argue that the Department has effectively considered the FRG coal import restrictions as an offset to FRG subsidies to coking coal passed on to the FRG steel industry in the form of lower prices for FRG coking coal. They argue that the FRG import restrictions, a government imposed disadvantage to the FRG steel producers, are like the disadvantage imposed by government regulations mandating strict environmental control standards.

DOC's Position

We would agree that where a government imposes generally applicable regulations and then preferentially exempts some but not all industries from those regulations, a potentially countervailable benefit is bestowed upon the industries so exempted. The FRG coal situation is quite different. The FRG restrictions on the importation of coking coal impose disadvantages only on consumers of coking coal; it is this very same group which is effectively relieved of that disadvantage through the FRG government assistance to its coking coal industry. The preferential element involved in petitioners' environmental regulations example is entirely missing from the FRG coal situation.

Petitioners' environmental regulations example does make a valuable point. If a government were to impose strict, generally available regulations and then universally to exempt anyone from them, the economic effect of the government activity would be completely neutral. One action simply renders the other null and void. This is what we believe is happening with respect to the FRG steel industry. The FRG government assists its coking coal industry, and assures it continued maintenance through restrictions on the importation of coking coal into the FRG. Simultaneously and inseparably it ensures that the FRG steel producers will not bear much of the cost of subsidies to FRG coal by allowing them to purchase FRG coking coal at prices nearly down to world market levels. The effect of assistance to the FRG coal producers and restrictions on the importation of coal into the FRG are largely neutral to the FRG steel makers. The effect on them is that they are required to pay a slight but significant premium for the price of coal used in their steel making operations.

Comment 8

Petitioners argue that the FRG effectively assumes the costs of an input of steel production.

DOC's Position

So long as the price of FRG coking coal exceed the market price in Europe and elsewhere, we do not believe that the record indicates any assumption by the FRG government of the cost of coking coal for the FRG steel producers. Absent the FRG government's system of support for th FRG coal industry, the FRG steel industry could aquire foreign coal at world market prices.

Comment 9

Petitioners suggest that FRG import restrictions would remain in place should the FRG government discontinue assistance to its coal producers.

DOC's Position

We note that the FRG government itself has indicated that "it is not possible to discontinue the payment of assistance (to the coal industry) and maintain the ban on imports at the same time."

Comment 10

Petitioners claim that the proper way to value the commercial benefit to the recipient of grants and loans is to examine each individual company's cost of capital, i.e., the average cost of equity and debt when computing the cost of grants and the average cost of debt capital when computing the cost for loans.

DOC's Position

We based our discount rate on annual government bond yields, for the reasons described in Appendix 2.

Comment 11

Petitioners claim that DOC should have found certain ECSC programs to constitute subsidies even if they were financed through levy funding. The ECSC borrows to finance its programs and there is not differentiation between those programs funded by levy and those funded by debt. The DOC should not have disaggregated the ECSC levies in determining the subsidies conferred under each program. Petitioners state that the ECSC is a quasi-governmental organization, created to aid the economic development of the steel and coal industries, rather than a commercial entity as the respondents claim.

DOC's Position

The treatment of levy funded programs of the ECSC is discussed in Appendix 3.

Comment 12

Petitioners claim that an immediate return on an investment is not necessary. However, when the FRG government injected funds into SAG, it should have been under terms that were consistent with commercial practice. In fact, the FRG received no additional return on its investment in SAG.

DOC's Position

We do not consider the government ownership of a company, as such, to be a subsidy. However, we did consider the capital infusion into SAG to constitute a grant for purposes of loss coverage and, therefore, a subsidy as discussed in the "Programs Determined to Confer Subsidies" section of this notice.

Comment 13

Petitioners stated that our preliminary calculations regarding preferential loans should have taken suppliers' credit into account. They also believed we used the wrong benchmarks.

DOC's Position

These issues are discussed in Appendix 2.

IV. Respondents' Comments

Comment 1

Respondents argue that FRG coking coal production assistance is not a subsidy because if offers no unfair competitive advanatge; the FRG users of coking coal pay more than the equivalent world market price for coking coal.

DOC's Position

As indicated in detail *supra*, we agree.

Comment 2

Respondents argue that FRG coking coal assistance is not conferred upon a specific group of industries, since only 63 percent of coking coal produced in the FRG is used in German steel blast furnaces. (The remaining 37 percent is sold to non-German steel producers in the EC.)

DOC's Position

We disagree. The vast majority of FRG coking coal is used by the steel industry in the FRG or other countries, and most of it used within the FRG.

Comment 3

Respondents argue that if there were no subsidization of the FRG coal industry, neither would there be a ban on imports of coal into the FRG.

DOC's Position

As indicated in detail *supra*, we agree.

Comment 4

Respondents argue that the FRG government coal programs are part of its overall energy policy and programs.

DOC's Position

We have noted and considered the FRG government's submission on this issue. The fact that these programs are part of the FRG government's energy program would not *per se* preclude them from being considered subsidies.

Comment 5

Respondents argue that they pay more for their coal than would otherwise be the case if the FRG coal assistance program and import restrictions were not in effect.

DOC's Position

As indicated in detail *supra*, we agree. Largely on this basis we have determined that FRG assistance to its coal producers does not indirectly subsidize either FRG steel producers or non-FRG steel producers.

Comment 6

Respondents argue that even if the FRG entered the world market for coal and world coal prices were driven up, they would be the same to all purchasers.

DOC's Position

We have no firm basis upon which to predict possible effects on world coal prices caused by cessation of FRG subsidization of its coal industry.

Comment 7

Counsel for P & S claims that it has not received any subsidies resulting from government capital infusions into the free reserve account of SAG. The assumption of P & S's losses by SAG is part of a profit transfer agreement commonly found in the German corporate structure.

DOC's Position

When government funds are infused during a year in which there is a loss transfer, we view it as a pass-through from the government to the subsidiary and therefore a subsidy as discussed in the "Programs Determined to Be Subsidies" section of this notice.

Comment 8

Respondents claim that federal and state environmental grants should not be considered countervailable subsidies because they are not directly related to the production, manufacture, or exportation of the products under investigation and are not industry specific.

DOC's Position

The federal and state environmental grants are generally available to industry throughout the FRG and the individual states of the FRG respectively. Therefore, we determine that they do not confer a benefit which constitutes a subsidy within the meaning of the Act.

Comment 9

Respondents claim that articles 4, 4a and 4b of the Investment Premium Act are not regionally preferential and that articles 1, 2 and 3 show no regional preference because the areas of eligibility are determined by economic conditions which change periodically.

Therefore, the Investment Premium Act does not constitute a subsidy under the Act.

DOC's Position

Articles 4, 4a and 4b provide benefits which are generally available to all industry and therefore, do not constitute subsidies.

Benefits provided under articles 1, 2, and 3 are given on a regional basis and therefore confer countervailable benefits.

Comment 10

Respondents claim that the BMFT does not fund research on an industry sectoral basis. Its relationship with the steel industry is such that it pays firms to perform the research. Those firms provide the research results to the BMFT, and the BMFT publishes reports which are made publicly available.

DOC's Position

For the reasons stated in the "Programs Determination Not to Confer Subsidies" section of this notice, we find the funds provided by the BMFT for R & D projects not to confer benefits which constitute subsidies within the meaning of the Act.

Comment 11

Krupp claims that the R & D grants to it for technology development were part of the state of North-Rhine Westphalia research program which is not industry specific and, therefore, are not subsidies.

DOC's Position

As discussed in the "Programs Determined Not To Confer Subsidies" section of this notice, we found that the results of the R & D are publicly available and, therefore, we determine that the program does not confer benefits.

Comment 12

Respondents claim that the federal and state labor program funds are generally available, and therefore, benefits conferred under these programs do not constitute subsidies.

DOC's Position

DOC concurs with respondents and finds that these programs do not confer benefits which constitute subsidies within the meaning of the Act.

Comment 13

Respondents claim that the ECSC housing loans benefit the workers, not the companies and, therefore, they do not constitute a subsidy.

DOC's Position

A full discussion of this issue is contained in Appendix 3.

Comment 14

Respondents stated that our preliminary calculations regarding preferential loans utilized benchmarks that were inapplicable because they were for short-term commercial loans of relatively small amounts.

DOC's Position

These issues are discussed in Appendix 2.

Negative Determination of Critical Circumstances

Bethlehem Steel Corporation and the Five alleged that imports of carbon steel structural shapes, hot-rolled carbon steel plate and hot-rolled carbon steel sheet and strip, and cold-rolled carbon steel sheet and strip present "critical circumstances." Under section 355.29 and 355.33(b) of the Department's Regulations, critical circumstances exist when the alleged subsidies include an export subsidy inconsistent with the Agreement and there have been massive imports of the class or kind of merchandise which is the subject of the investigation over a relatively short period.

We have not found any export subsidy in these investigations. Therefore, "critical circumstances" do not exist in the investigations for carbon steel structural shapes, hot-rolled carbon steel plate and hot-rolled carbon steel sheet and strip, and cold-rolled carbon steel sheet and strip.

Verification

In accordance with section 776(a) of the Act, we verified the data used in making our final determinations. During the verification, we followed normal procedures, including inspection of documents, discussions with government officials and on-site inspection of manufacturers' operations and records.

Administrative Procedures

The Department has afforded interested parties an opportunity to present oral views in accordance with its regulations (19 CFR 355.35). A Public hearing was held on July 8, 1982. In accordance with the Department's regulations (19 CFR 355.34(a)), written views have been received and considered.

Suspension of Liquidation

The suspension of liquidation ordered in our preliminary affirmative countervailing duty determinations shall remain in effect with regard to P & S and Rochling until further notice. The estimated net subsidy for P & S, Rochling, and manufacturers/producers/exporters who are not named in this notice has been amended, since our preliminary determinations. The estimated net subsidy for each firm and for each product under investigation is as follows:

Manufacturer/producer/exporter	Ad valorem rate (percent)
Stahlwerke Peine-Salzgitter AG:	
Carbon steel structural shapes	0.000
Hot-rolled carbon steel plate	0.000
Hot-rolled carbon steel sheet and strip	0.000
Cold-rolled carbon steel sheet and strip	0.000

As explained above, we have determined that a subsidy is being provided to P & S. The amount of the estimated net subsidy during the period for which we are measuring subsidization is 0.235 percent which is *de minimis*. However, because it is likely that P & S will continue to receive benefits under its arrangement with SAG as described in the "Programs Determined to Confer Subsidies" section of this notice, the products subject to this investigation produced by P & S are not being excluded from these final affirmative countervailing duty determinations. All estimated countervailing duties deposited subsequent to the preliminary determinations on entries of merchandise manufactured by P & S shall be refunded, and the appropriate bonds shall be released.

Stahlwerke Rochling-Burbach Gmbh:	*Percent*
Carbon steel structural shapes	1.131

The estimated net subsidy for Dillinger is 0.150 percent, for Klockner is 0.032 percent, for Krupp is 0.051 percent, for Otto Wolff is 0.015 percent, for Hoesch is 0.039 percent, and for Thyssen is 0.035 percent. These are *de minimis*. Accordingly, the products subject to these investigations produced by these 6 companies are being excluded from these determinations.

The suspension of liquidation ordered in our preliminary affirmative countervailing duty determinations shall be terminated with respect to these firms. All estimated countervailing duties shall be refunded and all appropriate bonds shall be released for entries of the products under investigation manufactured by these firms.

All other manufacturers/producers/exporters	Ad valorem rate (percent)
Carbon steel structural shapes	1.131
Hot-rolled carbon steel plate	0.000
Hot-rolled carbon steel sheet and strip	0.000
Cold-rolled carbon steel sheet and strip	0.000

Where the manufacturer is not the exporter, and the manufacturer is known, the rate for that manufacturer shall be used in determing the cash deposit or bond amount. If the manufacturer is unknown, the rate for all other manufacturers/producers/exporters shall be used.

Where a company specifically listed above has not exported a particular product during the period for which we are measuring subsidization, the cash deposit or bond amount shall be based on the highest rate for products that were exported by that company. We are directing the U.S. Customs Service to require a cash deposit or bond in the amount indicated above for each entry of the subject merchandise entered on or after the date of publication in **Federal Register.**

ITC Notifications

In accordance with section 705(d) of the Act, we will notify the ITC of our determinations. In addition, we are making available to the ITC all non-privileged and non-confidential information relating to these investigations. We will allow the ITC access to all privileged and confidential information in our files, provided the ITC confirms that it will not diclose such information, either publicly or under an administrative protective order, without the written consent of the Deputy Assistant Secretary for Import Administration. The ITC will determine within 45 days of the publication of this notice whether these imports are materially injuring, or threatening to materially injure, a U.S. industry. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated and all cash deposits or securities posted as a result of the suspension of liquidation will be refunded or cancelled. If, however, the ITC determines that such injury does exist, within 7 days of notification by the ITC of that determination, we will issue a countervailing duty order, directing Customs officers to assess a countervailing duty on certain steel products from the FRG entered or withdrawn from warehouse, for consumption after the suspension of liquidation, equal to the estimated net subsidy determined to exist as a result of the annual review process prescribed by section 751 of the Act. The provisions of section 707(a) of the Act will apply to the first directive for assessment.

This notice is published pursuant to section 705(d) of the Act and § 355.33 of the Department of Commerce Regulations (19 CFR 355.33).

Dated: August 24, 1982.

Gary N. Horlick,

Acting Assistant Secretary for Trade Administration.

[FR Doc. 82-23879 Filed 8-31-82: 8:45 am]

BILLING CODE 3510-25-M

Final Affirmative Countervailing Duty Determinations: Certain Steel Products From Italy

AGENCY: International Trade Administration Commerce.

ACTION: Final Affirmative Countervailing Duty Determinations.

SUMMARY: We have determined that certain benefits which constitute subsidies within the meaning of the countervailing duty law are being provided to manufacturers, producers, or exporters in Italy of certain steel products, as described in the "Scope of the Investigations" section of this notice. The estimated net subsidy for each firm and for each product is indicated under the "Suspension of Liquidation" section of this notice. The U.S. International Trade Commission (ITC) will determine within 45 days of the publication of this notice whether these imports are materially injuring, or threatening to materially injure, a U.S. industry.

EFFECTIVE DATE: September 7, 1982.

FOR FURTHER INFORMATION CONTACT: Charles E. Wilson, Office of Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230, telephone: (202) 377-5288.

SUPPLEMENTARY INFORMATION:

Final Determinations

Based upon our investigations, we have determined that certain benefits which constitute subsidies within the meaning of section 701 of the Tariff Act of 1930, as amended (the Act), are being provided to manufacturers, producers, or exporters in Italy of certain steel products, as described in the "Scope of the Investigations" section of this notice. The following programs are found to confer subsidies:

- Recapitalizations and a conversion of debt to equity.
- Preferential loans.
- Capital grants.
- Social security payment exemption.
- Preferential transportation rates.
- European Communities (EC) labor assistance.
- European Coal and Steel Community (ECSC) interest rebates.

We determine the estimated net subsidy to be the amount indicated for each firm and for each product in the "Suspension of Liquidation" section of this notice.

Case History

On January 11, 1982, we received petitions from United States Steel Corporation; counsel for Bethlehem Steel Corporation; and counsel for Republic Steel Corporation, Inland Steel Company, Jones & Laughlin Steel, Inc., National Steel Corporation, and Cyclops Corporation (the Five), filed on behalf of the U.S. industry producing cold-rolled carbon steel sheet and strip and hot-rolled carbon steel sheet and strip. The petitions alleged that certain benefits which constitute subsidies within the meaning of section 701 of the Act are being provided, directly or indirectly, to the manufacturers, producers, or exporters in Italy of the steel products listed above. Counsel for Bethlehem Steel Corporation and counsel for the Five alleged that "critical circumstances" exist, as defined in section 703(e) of the Act. We found the petitions to contain sufficient grounds upon which to initiate countervailing duty investigations and, on February 1, 1982, we initiated countervailing duty investigations (47 FR 5746).

Since Italy is a "country under the Agreement" within the meaning of section 701(b) of the Act, injury determinations are required for these investigations. Therefore, we notified the ITC of our initiations. On February 26, 1982, the ITC determined that there is a reasonable indication that these imports are materially injuring, or threatening to materially injure, a U.S. industry (47 FR 9087).

We presented questionnaires concerning the allegations to the Delegation of the Commission of the European Communities and to the government of Italy in Washington, D.C. On April 30, 1982, we received the responses to the questionnaires. On June 10, 1982, we issued our preliminary determinations in these investigations (47 FR 26327). We stated in our preliminary determinations that the government of Italy was providing its manufacturers, producers, or exporters of certain steel products with benefits which constitute subsidies. The programs preliminarily determined to bestow subsidies were:

- Recapitalizations and a conversion of debt to equity.
- Preferential loans.
- Capital grants.
- Social security payment exemption.

Scope of the Investigations

The products covered by these investigations are:

- Cold-rolled carbon steel sheet and strip.
- Hot-rolled carbon steel sheet and strip.

The products are fully described in Appendix 1 which appears with the notice of "Final Affirmative Countervailing Duty Determinations: Certain Steel Products from Belgium", in this isue of the **Federal Register.** The product definition of hot-rolled carbon steel sheet and strip has been amended since the initiation of these investigations (47 FR 5739).

Italsider S.p.A., now reorganized in part as Nuova Italsider S.p.A., Teksid S.p.A., and A.F.L. Falck S.p.A. are the only known producers and exporters in Italy of the subject products which were exported to the United States. The period for which we are measuring subsidization is the calendar year 1981. Italsider and Nuova Italsider's fiscal years coincide with the calendar year.

Analysis of Programs

In their responses, the government of Italy and the Delegation of the Commission of the European Communities provided data for the applicable periods. Additionally, we received information from Nuova Italsider S.p.A. This company produced and exported cold-rolled sheet and strip and hot-rolled carbon steel sheet and strip which were exported to the United States during 1981. We received no response from Teksid S.p.A. Therefore, we are applying to it and any other manufacturer, producer, or exporter the highest subsidy rate found in Italy for each product under these investigations. We received a response from A.F.L. Falck, S.p.A. too late to perform a verification and proper analysis. Therefore, we are applying to it the subsidy rates for other manufacturers, producers, or exporters, except that, because no allegation was made and we have no information of government equity participation in this company, we will not include in the subsidy rate for Falck benefits arising from government equity participation.

Throughout this notice, general principles and conclusions of law applied by the Department of Commerce to the facts of the current investigations concerning certain steel products are described in detail in Appendices 2 through 4, which appear with the notice of "Final Affirmative Countervailing Duty Determinations: Certain Steel Products from Belgium", in this issue of the **Federal Register.** Unless otherwise noted, one subsidy rate is calculated for each company for all products under investigation produced by that company.

Where benefits were provided to specific products, they were allocated over the value of sales of only those products in calculating the subsidy rate. Where subsidies were provided to specific factories producing the products under investigation, we allocated the subsidies by multiplying them by the percentage that these products represented of the factory's total value of sales in order to determine the value of the subsidy for the products under investigation. We then divided this amount by Italsider's total value of sales of cold- and hot-rolled carbon steel sheet and strip. Based upon our analysis of the petitions, responses to our questionnaires, our verification, and oral and written comments by interested parties, we determine the following.

I. Programs Determined To Confer Subsidies

We have determined that subsidies are being provided under the programs listed below to manufacturers, producers, or exporters in Italy of cold-rolled carbon steel sheet and strip and hot-rolled carbon steel sheet and strip.

A. *Recapitalizations and a Conversion of Debt to Equity.* As we noted in our preliminary determinations in these investigations, Italsider, an indirectly government-owned steel producer, received five equity infusions (including a conversion of debt to equity in 1977) from 1977 through 1981. Italsider is approximately 98 percent owned by its parent, Finsider. Finsider, in turn, is owned by a public agency of the Italian government, the Istituto per la Ricostruzione Italiana (IRI). Because of government ownership of Finsider, we consider money from Finsider to Italsider to represent a pass through of money from the Italian government and not simply money passing between a parent company and its subsidiary.

For each of these years 1977 through 1981 in which Italsider received equity infusions, we examined standard financial ratios for Italsider, as well as the pattern of its losses, and found that this company exhibited unhealthy financial behavior. We have concluded that these infusions were made on terms inconsistent with commercial considerations at the time and that, therefore, a subsidy potentially exists (see Appendix 2).

We have further determined that these equity infusions in 1978 through 1981 were available to cover losses in those years and thus we expensed, in the year it was received, the amount of the subsidy which arises from this infusion that was used to cover losses of the previous year (see Appendix 2). This subsidy is expensed and is equal to the difference between the market price and the government's purchase price for the equity used to cover losses. The equity infusions in 1978, 1980 and 1981 were less than the losses and were entirely expensed in the year received. For 1979, we treated the residual recapitalization, i.e., the amount of the infusion after subtracting losses, according to the equity methodology outlined in Appendix 2.

We measured the potential subsidy for this residual recapitalization by comparing the price the Italian government paid per share when it bought Italsider's stock through Finsider with the average price of Italsider's stock the month before the equity infusion was announced. We used the market price for Italsider's stock as our comparison because the stock was traded on the Italian stock market and because we believe our countervailing duty law indicates a strong presumption for using market-based methods of value.

Since equity infusions give the purchaser ownership rights to the entire company, we allocated the subsidy amount (the entire 1981 equity infusion plus the 1981 subsidy amounts from the 1977 debt to equity conversion and the remainder of the 1979 infusion) over Italsider's total value of sales. This resulted in an *ad valorem* subsidy of 8.24 percent for each of the two products under investigation.

B. *Preferential Loans.* Italsider has received benefits from several types of preferential loans, both in years when we consider it creditworthy and years when we consider it uncreditworthy for purposes of these investigations. Three of these we have determined not to be countervailable: loans for disaster relief, a loan given from the United States Export-Import Bank, and ECSC housing loans (see also Appendix 3). These three loans are discussed below in the section entitled "Programs Determined Not to Confer Subsidies."

At the verification we learned that Italsider did not pay the entire amount of principal and interest due in 1981 for every long- and medium-term loan outstanding. Since the firm could not tell us, loan by loan, which loan payments had been made and which had not, we were forced to use the best information

available. Therefore, for each loan, we subtracted from the original amount due to be repaid in 1981 the average percentage that, in fact, had not been repaid.

The Department also discovered at the verification that a number of loans were tied to more than one facility. Where we verified that a loan was used both for a facility producing the products under investigation and other facilities not producing the products under investigation, we considered only the portion of the loan which benefitted the products under investigation to be countervailable. The respondent provided information for all loans made through 1981 with outstanding principal in 1981. Since loans made in 1981 would not usually have any payments due in 1981, no benefits, and therefore no subsidy, flow from 1981 loans until 1982.

1. Loans granted in years in which Italsider was creditworthy.

We have determined that Italsider was creditworthy for the years through 1975 for reasons described below. For loans made in those years with principal outstanding in 1981, we compared a repayment schedule of the loan with a repayment schedule of a comparable commercial loan made at a commercial interest rate. Where we found preferential loans, we used the general loan methodology in Appendix 2 to calculate the subsidy.

According to our methodology, we would prefer to compare Italsider's loans from special credit institutions to comparable loans from private lenders. However, almost all long- and medium-term lending in Italy is done by these special credit institutions which are non-private lenders in which the Italian government is involved. These institutions provide loans to all sectors of the Italian economy, at both subsidized and non-subsidized rates. The iron and steel sector receives a substantial portion of the subsidized loans.

Since these special credit institutions represent such a large part of the country's debt rate, they may reasonably be expected to influence that debt rate significantly. Therefore, we assume that a loan to Italsider from a special credit institution provides a countervailable benefit if Italsider's interest rate is preferential compared to the average long-term interest rate in Italy at the time the loan was made. For our final determinations, we relied on average industry debt rates from the special credit institutions, by quarter, for the benchmark rates.

When comparing the interest rate Italsider paid for a loan to the benchmark rate, we added to Italsider's interest rate an amount which Italsider paid to its parent, Finsider, as a guarantee fee for all loans which Finsider guaranteed. In creditworthy years we consider this guarantee fee, which we verified as a normal commercial fee, to be part of Italsider's cost of debt.

We have evidence that a grace period is a normal commercial term in Italy for a long-term captial expansion loan and that the length of the deferral depends upon when the loan project becomes productive. Italsider's loans have been for large capital expansion projects and, according to our information, it takes at least two years for major improvements in a steel mill to become productive. Because we have no evidence to sustain a finding that a longer grace period is normal in Italy for similar projects for major capital investments, we have determined that deferral of payments on such loans for a period in excess of two years constitutes a countervailable element of preferentiality.

Some loans to Italsider from the Cassa per il Mezzogiorno (Casmez), a regional development program for southern Italy, contained an interest rebate provision, as well as having an interest rate potentially below the benchmark interest rate. After the preliminary determinations, we learned that, instead of receiving an interest rebate, Italsider pays a reduced interest rate. The government pays the difference between that rate and the commercial interest rate directly to the creditor. Therefore, we are treating these loans using the methodology for low-interest rate loans and comparing the reduced interest rate actually paid by Italsider with the benchmark interest rate. The difference is treated according to the loan methodology in Appendix 2.

2. Loans in years in which Italsider is considered uncreditworthy for purposes of these investigations.

As stated in the preliminary determinations, petitioners alleged that Italsider has been uncreditworthy. Italsider has lost money consistently in recent years, losing 72 billion lire in 1975, 130 billion lire in 1976, 395 billion lire in 1977, 349 billion lire in 1978, 258 billion lire in 1979, 747 billion lire in 1980, and 1,688 billion lire in 1981. Having examined several standard financial ratios, as well as the pattern of Italsider's losses, we concur with the petitioners with respect to the period from 1976 through 1981. Key ratios in which Italsider exhibited unhealthy financial behavior in the years 1974 through 1981 are: times interest earned (operating income divided by interest charges); the current ratio (current assets compared to current liabilities); equity as a percentage of debt; net income as a percent of sales; and cash flow. Our preliminary determinations stated that Italsider was uncreditworthy in 1975, because of large losses incurred that year. While losses occurred in 1975, we cannot say that Italsider was uncreditworthy in that year because commercial lenders during 1975, not having the year-end figures for this year, might have made loans to Italsider. We do not consider Italsider creditworthy in 1976 for purposes of these investigations because, despite a positive operating income of 224 billion lire in that year, the other financial indicators we examined showed Italsider to be increasingly unhealthy. For 1977 through 1981, our preliminary determinations in this respect did not change because of continued unhealthy financial ratios, increasing losses, almost annual government infusions of capital, and a lengthening picture of preceding unhealthy years.

Having decided to consider Italsider uncreditworthy for years 1976 through 1981, we treated loans during these years with principal outstanding in 1981 as similar to equity investments. We compared Italsider's rate of return in 1981 with the average rate of return for equity in Italy (see Appendix 2 for further details).

Italsider received one loan given under Article 54 of the ECSC which included an interest rebate for environmental purposes. Following the methodology in Appendix 3, we determine that the rebate is given through ECSC budget, 20.05 percent of which is countervailable, and we have expensed the 1981 rebate in 1981. Since Article 54 loans are funded through ECSC borrowings, the loan itself is also countervailable. We verified that 81.6% of the loan was tied and went to a factory which produces the products under investigation (the remainder was tied to a factory not producing the products under investigation). Therefore, we consider that percentage of the loan principal as an infusion of equity.

Italsider received a preferential loan for R&D from a special credit institution which we consider countervailable. In the preliminary determinations we allocated this loan over all of Finsider's value of production because our information indicated that the results of the research were shared by the entire Finsider group companies. We verified that, while the R&D results were theoretically available to all Finsider group companies, only one of Italsider's factories producing the products under investigation could actually benefit from this R&D. Therefore, we consider this

loan to confer a subsidy and for the final determinations we have calculated the loan subsidy using the uncreditworthy company loan methodology and allocated the subsidy as described above in the "Analysis of Programs" section.

The ECSC granted an industrial reconversion loan to Italsider under Article 56. At the verification, Italsider did not satisfy us that this loan was not used to benefit a factory which produces the products under investigation. Therefore, we consider this loan to be countervailable (see also Appendix 3). Italsider also received an interest rebate as part of this loan. See section G. below for our analysis of this rebate. We used the uncreditworthy loan methodology to calculate the subsidy amount of the loan itself and allocated the subsidy as described above in the "Analysis of Programs" section.

Using the methodology described in the "Analysis of Programs" section above, we have determined that the net subsidy arising from preferential loans for each of the two product under investigation is 15.37 percent *ad valorem*.

C. *Capital Grants.* Firms locating in the Mezzogiorno (southern Italy) are eligible for special incentives. As we stated in the preliminary determinations and later verified, Italsider received grants from the Cassa per il Mezzogiorno as well as loans. These grants were awarded from 1967 through 1981 for the construction and expansion of its facilities in southern Italy. We find these grants to be countervailable because they are available only to plants located in this region.

To determine the amount of the subsidy, we used the grant methodology in Appendix 2 and allocated the grants over 15 years. To determine the *ad valorem* benefit from this program, we allocated the subsidy as described above in the "Analysis of Programs" section. Based on our calculations, we have determined the subsidy on cold- and hot-rolled sheet and strip to be 0.70 percent *ad valorem*.

D. *Social Security Payments Exemption.* Under the Cassa per il Mezzogiorno regional development program, the government of Italy allows exemptions from social security payments in 1981 for companies with plants in the south of Italy. We have determined these exemptions to be countervailable because they are available only to plants located in this region. Upon verification, we learned that the actual benefit to Italsider's Taranto facility (Italsider's only factory located in the Mezzogiorno which produces the products under investigation) was different than that reported in Italsider's response. We used the verified figure for the final determinations and expensed this amount in the year received. We allocated this amount as described above in the "Analysis of Programs" section. This resulted in a subsidy of 1.65 percent *ad valorem* for the products under investigation.

E. *Preferential Transportation Rates.* Petitioners alleged that Italian steel companies receive preferential transportation rates. We were told at the verification that the state-owned Italian railroad gives volume rebates to many firms in Italy which ship a certain amount of freight over a certain time period. Italsider received such rebates. However, we do not know whether the volume rebate to Italsider received in 1981 is more favorable than that to other companies. We asked both the company and the government for further information; this information, however, was not provided and we have no evidence demonstrating that the rebates are not preferential. Based upon the best information available, we conclude that the volume rebate is preferential to Italsider. We therefore consider the rebate received by Italsider to be a subsidy. We have allocated the subsidy amount actually received in 1981 over total Italsider sales because we have no knowledge that it was specifically tied to a product or factory under investigation. We found the *ad valorem* subsidy to be 0.02 percent for each of the products under investigation.

F. *EC Labor Assistance.* Italsider received labor aid in the form of training grants from the EC's European Social Fund (ESF) to factories producing the products under investigation. The ESF funds come from the EC budget and are financed by the EC's "own resources". Our analysis of the "own resources" section of the EC budget (98% of the entire EC budget in 1981) is that 87% is derived directly from Member States (through customs duties and the value added tax) and that 13%, agricultural and sugar levies, is generated from the agricultural sector, primarily under the Common Agricultural Policy. As indicated in Appendix 3, we do not consider levies paid by steel producers and funds generated from those levies, when simply paid back to the steel producers, to confer subsidies. In this case, however, levies are paid into the EC by the agricultural sector, and customs duties are paid by importers, while the funds are paid out of the budget to steel producers, *inter alia*. Consequently, ESF grants to steel producers from the EC's "own resources" are not self-financing by the steel producers, and are countervailable in the appropriate circumstances.

Over half of the total budget of the ESF is used for deprived regions for each Member State, including Italy. We have no information indicating that these training grants are not used for workers engaged in steel production. Therefore, we find this benefit to be a subsidy. We have expensed these grants in the year received and have allocated the subsidy as described in the section entitled "Analysis of Programs" above. This resulted in a subsidy amount of 0.07 percent *ad valorem* for each of the two products under investigation.

G. *ECSC Interest Rebate.* As part of an ECSC industrial reconversion loan under Article 56, Italsider received an interest rebate of three percent for five years, 1976 through 1980. The funds for these rebates come from the ECSC budget, a portion of which we consider countervailable (see Appendix 3). We consider the countervailable rebates to be untied grants to Italsider; therefore, we first looked to see if Italsider used these rebates to cover losses in these years (see Appendix 2). We determined that Italsider used the entire countervailable interest rebate received in each year to cover losses and we have expensed the rebates in the year they were received. Since the rebates ended in 1980, there is no subsidy because of the interest rebates in 1981.

II. Programs Determined Not To Confer Subsidies

We have determined that subsidies are not being provided under the following programs to manufacturers, producers, or exporters in Italy of cold-rolled carbon steel sheet and strip and hot-rolled carbon steel sheet and strip.

A. *Italian Government Labor Assistance.* Petitioners alleged that the Italian steel industry benefits from labor assistance programs under which the government of Italy assumes such costs as redundancy payments, housing allowances, and special assistance to support employment. Italsider has received such assistance from the ordinary and the extraordinary Fund for Wages Integration (CIG); however, we have determined that these programs are not countervailable because Italian laws indicate that these programs are generally available on equal terms to all firms in Italy.

B. *Assistance to Coal Suppliers.* Petitioners alleged that Italsider received a subsidy through its purchases of subsidized coking coal from the Federal Republic of Germany (FRG). Italsider claims that it buys all its coal at world prices from various suppliers,

including companies in the United States. A review of Italsider's invoices of purchases of coal and commercial statistics kept by them, showing different prices from each supplier, indicated no preferential treatment to Italsider by any vendor, including those in the FRG. For the reasons described in Appendix 2, we have determined that Italsider does not receive a countervailable benefit from its purchases of German coking coal.

C. *ECSC Housing Loans.* Italsider received housing loans for workers at its Taranto facility. For the reasons described in Appendix 3, we have determined that ECSC housing loans are not subsidies to Italian steel producers.

D. *ECSC R&D Grant.* One of the petitioners alleged that Italsider received subsidies through ECSC funding of R&D projects directed by the Centro Sperimentale Metallurgico, an Italian research organization. Italsider reported receiving one grant from the ECSC under Article 55 for R&D applicable to one of the products under investigation. As Appendix 3 states, because the results of ECSC R&D grants are publicly available, we have determined that this program does not confer countervailable benefits. We have no allegations or evidence of Italian government funding for R&D grants.

E. *Disaster Relief Loan.* We do not consider loans made for disaster relief to confer countervailable subsidies since this was general assistance available to anyone in affected areas. Although not all areas would be eligible at any one time, disaster relief is not selective in the same manner as other regional programs since there is no predetermination of eligible areas and no part of the country, and no industry, is excluded from eligibility in principle.

F. *United States Export-Import Bank Loan.* Under the Act, loans granted by the U.S. Export-Import Bank do not provide countervailable benefits.

III. Programs Determined Not To Be Used

We have determined that the following programs are not used by the manufacturers, producers, or exporters in Italy of cold-rolled carbon steel sheet and strip and hot-rolled carbon steel sheet and strip.

A. *Preferential Bond Issuances.* Petitioners alleged that Italsider has received benefits from bond issuances containing preferential provisions. Italsider had no outstanding bonds and our verification of Italsider's financial records did not find that they received indirectly any preferential funding from bonds issued by another entity for the period for which we are measuring subsidization.

B. *Tax Incentives.* Petitioners alleged that under the Cassa per il Mezzogiorno the Italian steel industry receives exemptions from national and local income taxes. To be eligible for any decreased national income taxes under this program a company must be headquartered in the south of Italy. As the preliminary determinations stated, Italsider is headquartered in Genoa which is not in southern Italy and, therefore, receives no exemption from national income taxes. We verified through both Italsider and government officials that Italsider received no local tax exemption during the period for which we are measuring subsidization.

C. *Forgiveness of Utility Payments.* One of the petitioners alleged that the Italian government excused Italsider from paying several of its utility bills for the first half of 1981 but supplied no other information on the matter. Italsider indicated that the exemption only applied to electric furnace operations. Since there are no such furnaces at Taranto or Oscar Sinigaglia, the two plants producing the products under investigation, these products did not receive any subsidy under this program. Our verification of Italsider's records found no evidence of exemptions from utility payments for these plants.

D. *Preferential Export Financing.* Petitioners alleged that the Italian steel industry benefits from preferential export financing. Verification of Italsider's financial records yielded no indicatioin of any preferential export financing.

E. *Wage Payment Subsidy.* One petitioner asserted that the Italian government paid Italsider's monthly payroll costs for part of 1981 but gave no further information on the matter. At the verification we found no evidence of such government intervention. Italsider stated that it had borrowed short-term funds from Finsider in order to pay its wages. We therefore examined short-term lending rates between Finsider and Italsider to see if they were preferential compared to the short-term interest rate commercial lenders were charging Italsider. We found that Finsider charged Italsider the same interest rates as three commercial banks charged Italsider. Therefore, we have determined that there is no countervailable benefit resulting from these short-term loans from Finsider.

Petitioners' comments

COMMENT 1

Petitioners argued that Italian corporate bond rates were not the appropriate measure of the cost of capital for an uncreditworthy company such as Italsider. One petitioner stated that an uncreditworthy company could at most secure short-term debt; therefore, the correct cost of debt capital rate should be the highest short-term interest rate charged by a lending institution plus a risk premium. This petitioner also stated that the venture capital market or the cost of debt should be the proxy for the cost of equity in the weighted cost of capital.

DOC Position

For the methodology used in these final determinations concerning the appropriate discount rate for present value calculations, see Appendix 2.

Comment 2

One of the petitioners stated that the respondent steel companies clearly could not borrow at average or national rates absent government backing and that, therefore, a creditworthiness proxy should be included in the benchmark interest rate for preferential loans.

DOC Position

For the Department's methodology regarding the appropriate type of benchmark rate to choose for loan comparisons for creditworthy companies, see Appendix 2.

Comment 3

One of the petitioners stated that domestic subsidies that are available to all industries in a country should be countervailed.

DOC Position

The Department's position regarding this issue is found in Appendix 4.

Comment 4

One of the petitioners alleged that the provision of supplier credit to an uncreditworthy company constitutes a countervailable subsidy because, once it is uncreditworthy, suppliers would have required cash payments instead of extending credit, absent government support of the company.

DOC Position

Our response to this allegation is found in Appendix 2.

Comment 5

Petitioners alleged that the Department allowed an offset or did not give full weight to the term subsidy, as

defined in the Act, when it did not countervail ECSC assistance programs to the extent that funds for these programs were derived from the ECSC budget.

DOC Position

Our methodology regarding the ECSC programs and our response to petitioners' allegations are contained in Appendix 3.

Comment 6

Petitioners stated that the Department should have looked at the competitive advantage foreign producers received from assistance given them, not from where the funds for such assistance came. They also claimed that the Department has disregarded its own precedents in Lamb Meat from Australia and New Zealand.

DOC Position

See Appendix 3 for our response to this comment.

Comment 7

Petitioners alleged that the Department has improperly applied offsets to preferential loan benefits by subtracting principal and interest paid in 1981 and by use of the grant cap.

DOC Posistion

The Department's position on preferential loans is found in Appendix 2.

Comment 8

Petitioners alleged that the Department should have considered purchases of German-subsidized coal by unrelated European steel producers to be countervailable because the intent of these subsidies is to stabilize coal supplies to the ECSC's steel industry and to insure against the risk of adverse price developments on the world market, and because without this subsidized coal the ECSC steel companies would have had to pay higher world market prices.

DOC Position

German coal and coking coal issues as they affect non-German steel producers are discussed in Appendix 2. ECSC coal and coking coal issues are discussed in Apendix 3.

Comment 9

Petitioners alleged that aid programs funded by the ESCS constitute subsidies to ECSC steel producers, even though they pay levies into the ECSC budget, because the ECSC has borrowed massively to supplement the levies.

DOC Position

The Department's position on this issue is set forth in Appendix 3.

Comment 10

One of the petitioners alleged that the time period to use to determine if critical circumstances exist is the time period before a countervailing duty petition is filed.

DOC Position

Our position on critical circumstances is contained in Appendix 4.

Comment 11

One of the petitioners alleged that in reviewing the critical circumstances allegation the Department should have considered the cumulative effects of the imported merchandise during the period prior to the filing of the petitions.

DOC Position

Our position on critical circumstances is contained in Appendix 4.

Comment 12

One of the petitioners claimed that Italsider received subsidies through an IRISIDER bond issuance in 1981 which the Department should have countervailed.

DOC Position

Through verification, the Department determined that no money from this bond issuance had been received by Italsider in the calendar year 1981, which is our period for measuring subsidization. If a countervailing duty order is eventually issued, any future benefits from this bond will be examined during annual administrative reviews under section 751 of the Act.

Comment 13

One of the petitioners stated that Italsider did not provide information on all Article 54 loans from the ECSC.

DOC Position

The Department verified all outstanding long- and medium-term loans, including all outstanding loans received under Article 54.

Comment 14

One of the petitioners claimed that Italsider received an exemption from utility payments and failed to respond adequately regarding this program.

DOC Position

Through verification the Department learned that exemptions from utility payments were given under certain conditions which were not present at the factories at which Italsider produced the products under investigation. Petitioners alleged the existence of other general subsidies in this category, but the Department found nothing in Italsider's books to substantiate this allegation.

Comment 15

One of the petitioners stated that the Department failed to recognize the benefit conferred upon the Italian steel companies by the commitment of funds before they were disbursed.

DOC Position

The mere authorization of funds does not ensure their disbursement. Money can be promised but never paid out. Therefore, any determination of the value of a possible future receipt would be mere speculation and unsupportable.

Comment 16

Petitioners alleged that the Italian stock market is not a reliable gauge for setting the true value of Italsider's stock. Therefore, they challenged our calculation of the value of the subsidy to Italsider conferred by the government's purchase of equity. Instead, petitioners claimed that the Department should have treated government equity infusions to Italsider as we treated loans to uncreditworthy companies.

DOC Position

The Department has not changed its methodology in this respect since its preliminary determinations in these investigations. While we recognize that the Italian stock market may involve a relatively low volume of shares, we believe the law shows a strong preference for the use of market standards where available. In this case there is insufficient evidence to rebut the presumptive correctness of the market's valuation of the stock.

Respondents' Comments

Comment 1

Italsider objected to the Department's change in practice in calculating subsidies and to the disregard of the conclusions reached by the Department in prior countervailing duty investigations of the Finsider Group companies.

DOC Position

The Department's position regarding its practice is set forth in Appendix 2. With respect to the prior Department of the Treasury (Treasury) investigations of members of the Finsider group, the Department took these investigations into account in making its determinations in the instant

investigations. However, the Department decided that it should not follow certain of the precedents set by these investigations, because the valuation methodology used here more accurately reflects the facts and economic reality. Moreover, there is no substantial evidence in the record from which the Department could conclude that Italsider and its parent relied to their detriment on these Treasury precedents in conducting their affairs.

Comment 2

Italsider claimed that the Department's analysis is contradictory because the preliminary determinations state that, since Italsider is uncreditworthy, loans would not have been received without government intervention. However, the Department then quantifies the subsidy assuming such intervention does not exist because the loans are characterized as having "great risk, very junior status, and low probability of repayment * * *" (See Appendix B to "Preliminary Affirmative Countervailing Duty Determinations: Certain Steel Products from Belgium," 47 FR 26300, 26307).

DOC Position

The Department considered that national or country-wide market interest rates would not be available to uncreditworthy companies without government intervention. Therefore, we decided that the most accurate treatment of a subsidized loan to an uncreditworthy company would be to treat the loan as if it were a government equity infusion, less principal and interest repaid. New debt obtained only through government intervention holds a position similar to equity regarding its junior rights and claims to the assets of the uncreditworthy firm (see Appendix 2).

Comment 3

Italsider stated that the Department's method of present value analysis has no basis in financial theory or practice and is not in accord with prior practice under the law.

DOC Position

Our methodology regarding present value and our response to this comment are set forth in Appendix 2.

Comment 4

Italsider claimed that the Department erred in preliminarily determining that Italsider was uncreditworthy during the years 1975 through 1981.

DOC Position

The Department, using Italsider's annual reports, calculated a number of standard financial ratios for the years 1974 through 1981, as well as examining Italsider's losses in the last ten years. We took into consideration the fact that Italsider had losses in 1972, made only small profits in 1973 and 1974 (boom years for steel companies everywhere) and, since 1972, paid only one stock dividend (6% in 1974). We viewed these facts as we believe a commercial investor would in each year in question. In 1975, not having available the 1975 end-of-year data, we believe commerical investors could have considered Italsider creditworthy. The result of our analysis is that, for purposes of these investigations, we consider Italsider uncreditworthy from 1976 through 1981.

Comment 5

Italsider stated that the Department overstated the benefit to it of preferential loans, grants and INPS exemptions to specific facilities producing the products under investigation by simply allocating these subsidies over total Italsider cold- and hot-rolled sheet and strip sales.

DOC Position

The Department agrees with the respondent and has recalculated the subsidies resulting from those programs (see "Analysis of Programs" section above).

Comment 6

Italsider alleged that the Department has applied the commercial benchmark interest rate (with which to compare loans in years in which Italsider was found to be creditworthy to determine if a loan is at a preferential rate) in an unreasonable manner. Respondent claimed the Department should bear in mind that the benchmark is only an average, and should not consider loans preferential when the difference in rates is within commercial bounds of acceptability.

DOC Position

We asked respondents for information on comparable commercial loans. The information we received is insufficient to serve as the basis for these determinations. Consequently, we used as our benchmark the average commerical interest rates available in Italy for special credit institutions, pursuant to our authority to estimate the amounts of subsidies under section 706(a)(1) of the Act.

Comment 7

Italsider claimed that the Department erred in its calculation of the subsidy resulting from loans to Italsider from the Casmez since credit institutions, by law, must lend at prevailing market interest rates (the "reference rate"). The Casmez reimburses the lending institution for the differcen between the reference rate and the subsidized rate given to Italsider.

DOC Position

The Department has not received any law or any other document giving details of reference rates which show that these loans were indeed at prevailing market rates. Further, the Department has learned that government agencies and special credit institutions which are controlled, directly or indirectly, by the Italian government can lend money at subsidized rates. We therefore consider that Casmez—a government agency—loans can be subsidized loans. Since the interest differential is paid directly by Casmez to the lending institution and not to Italsider, we have considered these loans to be preferential loans instead of loans with interest rebates. Thus, we valued the benefit of the subsidized loan as the difference between the commercial benchmark rate and the subsidized interest rate for years in which we consider Italsider creditworthy. We value the benefit in a manner similar to equity infusions for years when we consider this firm uncreditworthy (see Appendix 2).

Comment 8

Italsider claimed that the initial deferral of principal payments in its loans was a normal commercial practice and did not constitute a benefit since it still had to repay the entire principal and incurred additional interest expenses on the unpaid balance; thus, this deferral should not be countervailed.

DOC Position

The Department made inquiries to determine if grace periods for long-term capital expansion loans are normal commercial terms in Italy and found that this is a normal condition in such loans. Therefore, for preferential loans in creditworthy years with grace periods, we allowed a deferral of two years (see section above on preferential loans).

Comment 9

Italsider claimed that the Department erred in considering two loans to be countervailable, one from the U.S. Export-Import Bank and one made in

1951 to another company which Italsider later bought.

DOC Position

The Department does not consider loans from the U.S. Export-Import Bank to confer countervailable benefits. As for the 1951 loan, when Italsider bought these other company's assets, it also assumed its debts. To the extent that this former company had preferential loans, Italsider assumed this benefit and we consider the benefit countervailable.

Comment 10

Italsider alleged that the Department erred in determining that Italsider maintained access to lenders solely through government intervention in uncreditworthy years and stated that Italsider received no capital infusions between the mid-1960's and 1978. Therefore, Italsider objected to the Department's treatment of all loans after 1974 as similar to equity infusions.

DOC Position

The Department reconsidered its preliminary determination that Italsider was uncreditworthy from 1975 through 1981. For the reasons stated above, we determine that it is uncreditworthy from 1976 through 1981. While there may have been no equity infusions in the 1960's, government lending institutions and the Cassa per il Mezzogiorno gave preferential loans and capital grants in the 1960's and 1970's to Italsider and made large equity infusions beginning in 1978. We have thus calculated all loans in 1976 through 1981 according to the uncreditworthy company methodology, as described in Appendix 2.

Comment 11

Italsider claimed that it received three unguaranteed medium-term loans and an unguaranteed long-term loan in 1981, which prove that it can borrow from private financial markets.

DOC Position

Given the enormous involvement of the Italian government in this firm and its unhealthy financial status in 1981 (e.g., a negative 79 percent net return on equity and other unhealthy financial ratios), the Department does not consider that three medium-term loans in 1981 (which were tied to certain purchases and represented less than 2 percent of Italsider's medium- and long-term loans made in 1981) are sufficient to prove that Italsider is creditworthy in 1981. Further, although we requested data regarding the long-term loan to determine its terms and conditions to see if this affected our view of Italsider's creditworthiness in 1981, we did not receive any additional information. Therefore, for these final determinations, we have continued to consider Italsider uncreditworthy for 1981.

Comment 12

Italsider claimed that it should be considered creditworthy with regard to Casmez loans and that lenders would have lent money without government guarantees because the lenders were preferred creditors and held first mortgages on specific assets in case of default.

DOC Position

The Department believes that the decision regarding creditworthiness reflects the financial state of the company rather than the particular circumstances of any one lender.

Comment 13

Italsider alleged that the Department used incorrect methodology to calculate the benefits of a loan to an uncreditworthy borrower by comparing the average return on equity investments in Italy with the government's equity return in Italsider. It claimed that lenders would focus on the return on total assets, not return on equity and, further, that an investor's rate of return on Italsider equity could not be negative: either they received a dividend or they did not, in which latter case the return is zero, not negative.

DOC Position

The Department believes, as explained above and in Appendix 2, that loans to uncreditworthy companies should be viewed as equity in these firms. Therefore, to determine it this capital infusion is a subsidy, what the government could have recieved as a return on its money had it invested elsewhere must be compared with the government's investment in the steel company. We believe it is most reasonable to look at return on equity, not total assets, since we are viewing the return from the perspective of an equity holder. This return can be positive, negative, or zero since it measures the earnings, of which dividends are a part, as compared to owner's equity. A sharp decline in the company's worth could easily yield a negative return to equity holders.

Negative Determination of Critical Circumstances

Bethlehem Steel Corporation and the Five alleged that imports of cold-rolled carbon steel sheet and strip and hot-rolled carbon steel sheet and strip under investigation present "critical circumstances." Under §§ 355.29 and 355.33(b) of the Department's regulations, critical circumstances exist when the alleged subsidies include an export subsidy inconsistent with the Agreement and "there have been massive imports of the class or kind of merchandise which is the subject of the investigation over a relatively short period."

We have not found any export subsidy in these investigations. Therefore, critical circumstances do not exist in these investigations for cold- and hot-rolled carbon steel sheet and strip.

Verification

In accordance with section 776(a) of the Act, we verified the data used in making our final determinations. During this verification, we followed normal procedures, including inspection of documents, discussions with government officials and on-site inspection of manufacturers' operations and records.

Administrative Procedures

The Department has afforded interested parties an opportunity to present oral views in accordance with its regulations (19 CFR 355.35). A public hearing was held on July 15, 1982. In accordance with the Department's regulations (19 CFR 355.34(a)), written views have been received and considered.

Suspension of Liquidation

The suspension of liquidation ordered in our preliminary affirmative countervailing duty determinations shall remain in effect until further notice. The estimated net subsidy for each product is as follows:

Manufacturer/producer/exporter	Ad valorem rate (percent)
Nuova Italsider, S.p.A.:	
Cold-rolled carbon steel sheet and strip	26.05
Hot-rolled carbon steel sheet and strip	26.05
A.F.L. Falck, S.p.A.:	
Cold-rolled carbon steel sheet and strip	17.81
Hot-rolled carbon steel sheet and strip	17.81
All Other Manufacturers/Producers/Exporters:	
Cold-rolled carbon steel sheet and strip	26.05
Hot-rolled carbon steel sheet and strip	26.05

We are directing the United States Customs Service to require a cash deposit or bond in the amount indicated above for each entry of the subject merchandise entered on or after the date of publication of this notice in the **Federal Register**. Where the manufacturer is not the exporter, and the manufacturer is known, the rate for that manufacturer shall be used in

determining the amount of cash deposit or bond. If the manufacturer is unknown, the rate for all other manufacturers/producers/exporters shall be used.

ITC Notifications

In accordance with section 705(d) of the Act, we will notify the ITC of our determinations. In addition, we are making available to the ITC all non-privileged and non-confidential information relating to these investigations. We will allow the ITC access to all privileged and confidential information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order, without the written consent of the Deputy Assistant Secretary for Import Administration.

The ITC will determine within 45 days of the publication of this notice whether these imports are materially injuring, or threatening to materially injure, a U.S. industry. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated and all securities posted as a result of the suspension of liquidation will be refunded or cancelled. If, however, the ITC determines that such injury does exist, within seven days of notification by the ITC of that determination, we will issue a countervailing duty order, directing Customs officers to assess a countervailing duty on cold-rolled carbon steel sheet and strip and hot-rolled carbon steel sheet and strip from Italy entered, or withdrawn from warehouse, for consumption after the suspension of liquidation, equal to the net subsidy determined or estimated to exist as a result of the annual review process prescribed by section 751 of the Act. The provisions of section 707(a) of the Act will apply to the first directive for assessment.

This notice is published pursuant to section 705(d) of the Act and § 355.33 of the Department of Commerce Regulations (19 CFR 355.33).

Dated: August 24, 1982.

Gary N. Horlick,

Acting Assistant Secretary for Trade Administration.

[FR Doc. 82-23680 Filed 8-21-82; 8:45 am]

BILLING CODE 3510-25-M

Certain Steel Products From Italy: Amendment to Notice of Final Affirmative Countervailing Duty Determinations

AGENCY: International Trade Administration, Commerce.

ACTION: Notice of Amendment to Notice of Final Affirmative Countervailing Duty Determinations.

SUMMARY: On August 24, 1982, the Department of Commerce signed the final affirmative countervailing duty determinations on certain steel products from Italy.

Due to clerical error, that notice incorrectly stated, in the section entitled "Programs determined to Confer Subsidies," that the net subisdy arising from preferential loans for each of the two products under investigation was 15.37 percent *ad valorem*. The correct net subsidy amount is 3.88 percent *ad valorem* for each of the two products under investigation.

Therefore, the estimated net subsidy rate in the "Suspension of Liquidation" section should read as follows:

Manufacturer/producer/exporter	Ad valorem rate (percent)
Nuova Italsider, S.p.A.:	
Cold-rolled carbon steel sheet and strip	14.56
Hot-rolled carbon steel sheet and strip	14.56
A.F.L. Falck, S.p.A.A	
Cold-rolled carbon steel sheet and strip	6.32
Hot-rolled carbon steel sheet and strip	6.32
All Other Manufacturers/Producers/Exporters:	
Cold-rolled carbon steel sheet and strip	14.56
Hot-rolled carbon steel sheet and strip	14.56

This amendment does not imply that the Department will not issue a more general amendment of the estimated countervailing duty rates in this and the other Final Determinations on Certain Steel Products published in this issue of the **Federal Register** after we have reexamined all our calculations for possible clerical errors.

EFFECTIVE DATE: September 7, 1982.

FOR FURTHER INFORMATION CONTACT: Charles E. Wilson, Office of Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230, telephone: (202) 377-5288.

Dated: August 26, 1982.

William T. Archey,

Acting Assistant Secretary for Trade Administration.

[FR Doc. 82-23681 Filed 8-31-82; 8:45 am]

BILLING CODE 3510-25-M

Final Affirmative Countervailing Duty Determination: Carbon Steel Structural Shapes From Luxembourg

AGENCY: International Trade Administration, Commerce.

ACTION: Final Affirmative Countervailing Duty Determination.

SUMMARY: We have determined that certain benefits which constitute subsidies within the meaning of the countervailing duty law are being provided to manufacturers, producers, or exporters in Luxembourg of carbon steel structural shapes, as described in the "Scope of Investigation" section of this notice. The estimated net subsidy for each firm for carbon steel structural shapes is indicated under the "Suspension of Liquidation" section of this notice. The U.S. International Trade Commission (ITC) will determine within 45 days of the publication of this notice whether these imports are materially injuring, or threatening to materially injure, a United States industry.

EFFECTIVE DATE: September 7, 1982.

FOR FURTHER INFORMATION CONTACT: Michael J. Altier, Office of Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230, telephone: (202) 377-1785.

SUPPLEMENTARY INFORMATION:

Final Determination

Based upon our investigation, we have determined that certain benefits which constitute subsidies within the meaning of section 701 of the Tariff Act of 1930, as amended (the Act), are being provided to manufacturers, producers, or exporters in Luxembourg of carbon steel structural shapes, as described in the "Scope of Investigation" section of this notice. The following programs are found to confer subsidies:

- Capital grants
- European Coal and Steel Community (ECSC) interest rebates
- Anti-Crisis Division (ACD)

We determine the estimated net subsidy to be the amount indicated for each firm for carbon steel structural shapes in the "Suspension of Liquidation" section of this notice.

Case History

On January 11, 1982, we received petitions from United States Steel Corporation; counsel for Bethlehem Steel Corporation; and counsel for Republic Steel Corporation, Inland Steel Company, Jones & Laughlin Steel, Inc., National Steel Corporation, and Cyclops Corporation (the Five), filed on behalf of the U.S. industry producing carbon steel structural shapes. The petitioners alleged that certain benefits which constitute subsidies within the meaning of section 701 of the Act are being

provided, directly or indirectly, to the manufacturers, producers, or exporters of this product. Counsel for Bethlehem Steel Corporation and counsel for the Five alleged that "critical circumstances" exist, as defined in section 703(e) of the Act. We found the petitions contained sufficient grounds upon which to initiate a countervailing duty investigation, and on February 1, 1982, we initiated a countervailing duty investigation (47 FR 11738).

Since Luxembourg is a "country under the Agreement" within the meaning of section 701(b) of the Act, an injury determination is required for this investigation. Therefore, we notified the ITC of our initiation. On February 26, 1982 the ITC preliminarily determined that there is a reasonable indication that these imports are materially injuring or threatening to materially injure a U.S. industry.

We presented questionnaires concerning the allegations to the Delegation of the Commission of the European Communities and to the government of Luxembourg in Washington, D.C. On April 30, 1982 we received the responses to the questionnaires. On June 10, 1982 we issued our preliminary determination in this investigation (47 Fed. Reg. 26331–35). It stated in our preliminary determination that the government of Luxembourg was providing its manufacturers, producers, or exporters of carbon steel structural shapes with benefits which constitute subsidies. The programs preliminarily determined to bestow countervailable benefits were:

- Capital grants
- Preferential loans
- Government equity participation

Scope of Investigation

The product covered by this investigation is carbon steel structural shapes. The product is fully described in Appendix 1, which appears with the notice of "Final Affirmative Countervailing Duty Determinations: Certain Steel products from Belgium," in this issue of the **Federal Register.**

Acieries Reunies de Burbach-Eich-Dudelange S.A. (ARBED) and Metallurgique et Miniere de Rodange-Athus S.A. (MMR–A) are the only known producers and exporters in Luxembourg of the subject product which was exported to the United States.

The period for which we are measuring subsidization is the calendar year 1981. ARBED and MMR–A operate on a fiscal year which runs from January 1 to December 31.

Analysis of Programs

In its response, the government of Luxembourg (GOL) and the Delegation of the Commission of the European Communities provided data for the applicable periods. Additionally, we received information from ARBED. ARBED and MMR–A produced and exported carbon steel structural shapes to the United States during 1981.

At the time the countervailing duty questionnaires were sent to the respondent companies, the Department decided to treat certain related companies as defined in the questionnaire instructions. The questionnaire specified that the term "your company" included all companies in which the respondent company held 20 percent or more of the voting interest. We knew at the time that ARBED owned at least 25.09 percent of all MMR–A shares.

The General Instructions of the questionnaire stated that if the related company was the recipient of a separate countervailing duty questionnaire, the parent company was not obligated to answer for its subsidiary. However, if the related company was not a recipient of a separate questionnaire, then the Department's position was clear that the respondent parent company should answer on the behalf of its related subsidiary.

In our preliminary determination we treated ARBED as the sole respondent for Luxembourg in this investigation. Benefits to its subsidiary MMR–A were treated as benefits to ARBED and MMR–A. A common subsidy rate was applied. Based on information received after the preliminary determination, we are now treating ARBED and MMR–R as separate respondents. WE have verified that ARBED owns nearly 40 percent of MMR–A, but the financial structures of ARBED and MMR–A are separate. MMR–A receives benefits directly from the government of Luxembourg, independently of ARBED participation.

In its response ARBED chose not to answer for MMR–A since it considered common treatment of ARBED and MMR–A as not merited in the circumstances. In our preliminary determination, we decided to quantify countervailable benefits to MMR–A as benefits to all ARBED/MMR–A production based on information that MMR–A produced carbon steel structural shapes and that ARBED/MMR–A production figures were combined in the ARBED annual reports. At verification both ARBED and the GOL disputed the Department's treatment of MMR–A as part of ARBED with the following arguments:

- Financial management of ARBED and MMR–A is separate.
- GOL benefits to MMR–A are separate from those bestowed on ARBED and are not allowed to pass through MMR–A to ARBED in any tangible fashion, with the exception of the Anti-Crisis Division benefits.
- ARBED, as part of the steel restructuring program has invested large amounts in MMR–A and provided some loans to that company. ARBED officials argue that ARBED is a financial contributor to MMR–A, which is further proof that no financial benefits have yet accrued to ARBED from MMR–A subsidies.
- MMR–A exports of the product under investigation were considered insignificant by ARBED and GOL officials.

During our verfication in Luxembourg we acquired information which confirmed the first three arguments. Based on this information, the Department has decided that ARBED and MMR–A should be treated as separate respondents. Separate subsidy rates will be calculated for each company based on our determination that countervailable benefits from the GOL and ECSC were bestowed separately on each company and were not transferred from one company to the other once they were received. Separation of the two companies ensures that the Department's assessment of the countervailing duty rates corresponds more precisely to the actual distribution of the countervailable benefits. We received no response from MMR–A and we are basing its subsidy rate on information obtained from the government and ARBED which we consider a related company.

Throughout this notice, general principles applied by the Department of Commerce to the facts of the current investigations concerning certain steel products are described in detail in Appendices 2 through 4, which appear with the notice of "Final Affirmative Countervailing Duty Determinations, Certain Steel Products from Belgium", in this issue of the **Federal Register.** Unless otherwise noted, one subsidy rate is calculated for each company for product under investigation produced by that company. Where benefits were provided to the specific product, they were allocated over the value of sales of only that product in calculating the subsidy rate. Based upon our analysis of the petition, responses to our questionnaires, our verification, and oral and written comments by interested parties, we determine the following.

I. Programs Determined To Confer Subsidies

We have determined subsidies are being provided under the programs listed below to manufacturers, producers, or exporters in Luxembourg of carbon steel structual shapes.

A. Capital Grants. The Steel Industry Three-Party Conference Agreement of March 19, 1979 on the Restructuring of the Luxembourg Steel Industry (the Tripartite Agreement), its Codicil dated January 22, 1981, the Supplement to the Agreement of the Tripartite Conference on the Restructuring of the Luxembourg Steel Industry approved on January 15, 1981, and the Law of July 1, 1981 (the 1981 law) pertaining to the restructuring and modernization of the steel industry set forth programs which have been used to provide specific assistance to the steel industry. The 1979 Tripartite Agreement, as supplemented, and the 1981 law constitute the basis for the plan to restructure and modernize the steel industry in Luxembourg.

The restructuring plan calls for the granting of aid under previous laws, primarily the Law of July 28, 1973 for economic expansion, which the government claims is not limited to a specific enterprise or industry, or group of enterprises or industries. The plan, however, obligated the government to provide benefits to the steel industry. Prior to adoption of the plan, the government had discretion to reject applications for aid from the steel industry. The plan also increased the range and the limits of the benefits directed specifically to the steel industry. Therefore, we have determined that the programs under the plan provide countervailable benefits to the steel industry.

Under the plan, the GOL may grant an amount equivalent to 15 percent of the total approved capital investments made by a steel company between January 1, 1980, and December 31, 1984. The GOL may also grant an additional "extraordinary and temporary aid" equivalent to 10 percent of these investments. This 10 percent is considered reimbursable once the beneficiary earns taxable income, but under conditions to be set by the government at that time. A company becomes eligible for the grant and reimbursible aid once it has made its investment in the particular project or projects. In the event the grant or aid has been awarded in a lump sum for a number of projects, we have been able to determine which portions of the total grant or aid amount are tied to each individual project by taking 15 percent and 10 percent, respectively of the specific investment on each project on the list. In other cases, such as a grant for the blast furnances at Esch-Belval, we determined that the entire amount was tied to a single investment. Since all of these grants, except for the aid for the rolling beam storage area discussed below, were benefits to all steep production rather than to any specific product, we allocated the benefits over total steel sales value for ARBED and over a 15 year period which is our estimate of the average life of capital assets in the steel industry.

Based on the best information available at the time of the preliminary determination, we identified three separate investment grants which were awarded exclusively for buildings and equipment used exclusively for the production of products not under investigation. We have now determined that the amounts involved represent portions of a single grant received by ARBED for a list of projects. We have determined these portions of the grant were awarded expressly for buildings and equipment used exclusively for the production of products not under investigation. Consequently, we are not considering these portions of the grant as countervailable benefits to the production of the product under investigation.

Based on the best information available at the time we preliminarily determined that all of the reimbursable aid given to ARBED in 1981 was awarded exclusively for buildings and equipment for the production of a product not under investigation. We have now determined that only portions of this reimbursable aid were awarded expressly for buildings and equipment used exclusively for the production of products not under investigation. We have not considered those particular portions of the aid as countervailable benefits. We have determined that all but one of the remaining portions of the aid are subsidies to ARBED's steel production in general and thus provide a countervailable benefit to the product under investigation. We allocated the benefit over total ARBED steel sales value in 1981. A small portion of the reimbursable aid awarded in 1981 went to the expansion of the rolling beam storage area at Differdange. As this confers a specific benefit on the production and export of carbon steel structrual shapes we will allocate the benefit of this portion over ARBED sales value for carbon steel structural shapes.

MMR–A also received reimbursable aid in 1981 under the 10 percent program. Since the aid was for general restructuring investments, we will allocate the amount over the total MMR–A sales value for steel.

We have determined that another grant received by ARBED was tied to the construction of blast furnaces at Esch-Belval and was received in 1981. We find this grant to be a subsidy. We allocated the benefit over total ARBED steel sales value since it was for blast furnaces which produce pig iron, an input common to all steel production.

In addition to grants received pursuant to the Tripartite Agreement of 1979 and the supplemental agreements and laws, the GOL response provides information on several small government grants which were awarded on an "ad hoc" basis and provided to ARBED and MMR–A between 1977 and 1979 pursuant to the 1978 Tripartite Agreement for the purposes of employing surplus labor in investment projects within the steel plants. Although the GOL responded that these programs were not preferential to steel, in the 1978 Tripartite Agreement the government agreed to provide these programs to the steel industry. We have determined that these grants provide countervailable benefits. We have allocated the benefit of the grants over total ARBED and MMR–A turnover, respectively.

The GOL response also shows several government grants and reimbursable aid given to MMR–A in 1980 and 1981. These grants were awarded for investments for the general restructuring of MMR–A's steel production capacity. We have determined these grants provide countervailable benefits because they are targeted to the steel industry. We have allocated the benefit over total MMR–A steel sales values.

In the ABRED response the reimbursable aids were defined as loans. For purposes of quantifying the benefit they confer, we have treated reimbursable aids as grants since the exact terms of their repayment are not given and no interest has been to date charged.

In 1981, MMR–A received an interest free loan from the Societe Nationale de Credit et d'Investissement (SNCI) to cover debt contracted on a specific capital project. The SNCI is a state controlled financial institution which is authorized under the Law of August 21, 1977 to provide long-term investment loans at both preferential and commercial rates. The loan in question was awarded under a specific provision in the January 1981 codicil to the 1979 Tripartite Agreement. The provision stated that the terms of repayment of the principal would be set by the GOL five years after receipt of the loan and based

on the government's review of MMR–A's financial condition. Since we do not have the specific repayment terms, and no interest is being charged, we treated this loan as a grant tied to the purchase of capital equipment. The benefits were allocated over the average useful life of 15 years and allocated over MMR–A's total steel sales.

Each of the above grants was less than $50 million and was less than one percent of the gross revenue (turnover) of ARBED and MMR–A, respectively, but they were not for items normally expensed in one year. Most of the the post-1979 grants for ARBED were tied to specific purchases of capital equipment such as the blast furnace. Some of the other grants (the "ad hoc" and some MMR–A grants) are treated as untied, since they were not targeted for a specific investment. In accordance with the methodology of Appendix 2, all of these grants are allocated over a 15-year period, which is our estimate of the average life of capital assets in the steel industry.

The subsidy rate with respect to this program is 0.269 percent *ad valorem* for ARBED and 0.457 percent *ad valorem* for MMR–A.

B. ECSC Interest Rebates. ARBED indicates that it received interest rebates from the ECSC. For reasons described in Appendix 3, we determine that this program funded from the ECSC budget is countervailable only for that portion of the ECSC budget which is financed from Member State contributions. The value of the rebates is expensed in the year received because it is used to fund interest expenses normally expensed in one year, and because the total value of the rebates in any given year are small (i.e., less than one percent of ARBED's sales). Consequently, we are countervailing the subsidized portion of those rebates received by ARBED in 1981.

The subsidy rate for ARBED with respect to this program is 0.0007 percent *ad valorem.*

Because we received no response from MMR–A we assumed the company received interest rebates on its outstanding ECSC loans in 1981. ECSC interest rebates are generally given in the amount of three percent of the interest paid. A benchmark rate for ARBED's ECSC loans received in 1980 was used to estimate the interest rate on the ECSC loans to MMR–A. We have calculated the amount of rebate as the ECSC mandated three percent of the interest paid on the outstanding ECSC debt.

The subsidy rate for MMR–A with respect to this program is 0.004 percent *ad valorem.*

C. Anti-Crisis Division (DAC). The DAC is an organization managed by ARBED which was established to employ redundant steel workers and white collar employees from both ARBED and MMR–A. Under the restructuring plan, the GOL agreed to pay a varying percentage of the DAC wage expense. ARBED conditionally pays the balance of the expense. Under Luxembourg law, neither ARBED nor MMR–A would otherwise be obligated to pay the DAC wage expenses now covered by the GOL.

To the extent the GOL subsidies to DAC are not for workers engaged in steel production and do not cover a cost of production that would otherwise be incurred by ARBED and MMR–A, we have determined that these funds do not confer a countervailable benefit on the production or export of carbon steel structural shapes from Luxembourg. We have found that in some instances DAC employees are used as construction workers in ARBED and MMR–A capital projects and that the wages of the DAC workers involved in the capital projects are partially subsidized by the GOL. We have determined that some of these capital projects contribute to the production or export of the product under investigation. In those cases where the capital project relates to the product under investigation, we determined the GOL subsidy to the DAC workers involved with the project to be a countervailable benefit. We have allocated the benefits over total ARBED and MMR–A sales where the capital projects relate to the companies' steel production in general. When the capital project is specifically intended to benefit carbon steel structural shapes, we have allocated the benefit over the value of the specific product's sales for the company receiving the benefit.

Since the GOL subsidy to the DAC covers a cost normally expensed in the year received, i.e., wages, we treated the DAC subsidy as a grant expensed in the year received. We have determined the subsidy rates for ARBED and MMR–A on the above program are 0.269 percent *ad valorem* and 1.062 percent *ad valorem,* respectively.

II. Programs Determined Not To Confer Subsidies

We have determined subsidies are not being provided under the following programs to manufacturers, producers, or exporters in Luxembourg of carbon steel structural shapes.

A. Infrastructure Aid. The GOL has committed large sums of money for the creation of new industrial zones. The money is spent on installation of roads, water and electricity in selected areas. Dudelange-Betembourg is one such zone. ARBED is planning to occupy approximately 50 percent of this zone with a new cold-rolling mill. The plan has not yet been approved by the Commission of the European Communities.

The mere provision of generally available, generally used public roads, water and electricity is not a subsidy. Further, since ARBED has not yet used the government-funded infrastructure of this zone for production purposes, there can be no countervailable benefits to ARBED at this time.

B. Coal/Coke Assistance for ARBED's Subsidiary Eschweiler Bergwerks-Verein (EBV). Petitioners alleged that ARBED benefited indirectly from German federal and state assistance to EBV, a German coal/coke producer. ARBED indirectly owns 97 percent of EBV through a 100 percent owned ARBED subsidiary, ARBED-Finanz Deutschland GmbH. ARBED (Luxembourg) purchased 100 percent of its coke supply from EBV.

For reasons described in Appendix 2 and in the "Notice of Final Affirmative Countervailing Duty Determinations, Certain Steel Products From the Federal Republic of Germany" in this issue of the **Federal Register,** we determined that coal and coking subsidies are not passed along to coal purchasers when the coal prices established in an arm's-length transaction are at or above market prices. With respect to coal and coke transactions between related companies, one test of whether the price was, in fact, established at arm's-length is whether the coal is sold at the prevailing market rate. In this investigation, we verified that EBV sells coke to ARBED at prevailing market rates. Therefore, we determined that ARBED does not receive countervailable benefits through its purchases of German subsidized coke from its subsidiary EBV.

C. Equity Participation. The GOL, the government of Belgium, ARBED, the labor unions, and various Luxembourg and Belgian financial institutions formulated the MMR–A rescue plan, beginning in 1977, in response to MMR–A's critical financial situation. As part of the rescue plan, the GOL through the Caisse d'Epargne de l'Etat (CEE) and the SNCI purchased a 23.5 percent of a new MMR–A equity issue in 1978. The new equity issue increased MMR–A capital by 400 percent. ARBED purchased 25.09 percent of the same issue. The remainder was purchased by private banks and investment firms in Luxembourg and Belgium. This infusion of new equity was undertaken jointly by

the GOL and the private firms. (The SNCI acquired additional shares in 1981.)

As described in Appendix 2, our treatment of government equity investment in a company hinges initially on whether the government equity participation appears to have been on terms consistent with commercial considerations at the time of the equity infusion.

MMR–A has suffered successive, substantial losses in each of the fiscal years from 1976 through 1981. Under normal business or financial criteria, deep or significant continuing losses by a company raises doubts as to the commercial soundness of further investment in that company. As discussed in section III E. below, the Department has determined that MMR–A should be considered an uncreditworthy company from 1977 through 1978 based on our analysis of its financial statements. Considering the magnitude of the losses and the length of time over which they occurred the Department would, in most cases, regard equity investments by the GOL in MMR–A during the period beginning with fiscal year 1977 through 1978 as inconsistent with commercial considerations and consequently giving rise to a potential countervailable benefit. In the case of the 1978 purchase, however, the participation of private firms prevents the Department from making the determinations that the GOL participation was inconsistent with commercial considerations. The Department found no documentary evidence that the participation of the private firms in this purchase was directed by the GOL. The circumstances of the purchase make it clear that the purchase was a coordinated cooperative effort made under the auspices of the Belgium-Luxembourg agreements for the MMR–A rescue plan. However, we have found no documents that indicate government action or direction of private parties. Further, both the private parties and the government paid the same price for the shares which also indicates the purchase was not made under terms inconsistent with commercial considerations.

The GOL made an additional purchase of MMR–A equity with concurrent private participation at the same share price in 1981. For the same reasons discussed above, the Department is unable to consider this a purchase made under terms inconsistent with commercial considerations.

D. ECSC Coal and Coke Aid and Research and Development Grants. We have determined that these programs do not confer countervailable benefits, as outlined in Appendix 3.

E. Rail Transportation Rates. We determined that steel producers in Luxembourg received reduced rail rates from the state-controlled Chemins de Fer Luxembourgeois (CFL) under a GOL program available to all industries in that country. The reduced rates are supported by GOL funds. The GOL informed us that approximately 90 percent of all commercial shippers in Luxembourg receive reduced rates which are based on specific conventions between the railroad and each company. We determined that the reduced CFL rates are set according to the rates offered by the most competitive waterway carriers, trucking companies and foreign railways available to commercial shippers in Luxembourg. The special rates may vary depending on the availability of the alternative transportation systems, and, in fact, the steel industry uses the alternative forms frequently. We determined that the central objective of the subsidized rate program is to assure that the CFL remains in business.

As the reduced rates are generally available, and are no lower than available rates for alternative transportation systems in Luxembourg, we have determined that the program does not confer a countervailable benefit on the export of carbon steel structural shapes from Luxembourg.

F. Loans for ARBED. GOL-controlled financial institution and the European Coal and Steel Community (ECSC) have provided a number of steel specific investment loans to ARBED. We have revised our preliminary treatment as follows:

The Petitioners alleged that ARBED was uncreditworthy. We preliminarily determined this allegation to be correct based on the best available information. This included ARBED's history of substantial losses in recent years. The Department has now reversed its preliminary determination that ARBED was uncreditworthy. Information verified at the company has shown ARBED's ability to obtain private loans at commercial rates without special government intervention. Prior to verification we lacked sufficient information to establish that these loans were made: (1) at market rates, (2) under arm's-length conditions and (3) independently of government direction. Verification of ARBED's arm's-length private loans was a primary element in the revision of our preliminary determination. We also considered the following:

- We verified that ARBED used the government aid it received for plant expansion and modernization and not for coverage of losses. Government aid represented only a relatively small portion of ARBED's own investment expenditures.
- We verified that, despite net losses in several of its recent fiscal years, ARBED maintained a positive cash flow in 1979 and 1980.

Loans to ARBED were treated similarly to equity infusions in the preliminary determination according to the Department's methodology for loans to uncreditworthy companies as described in Appendix B to that determination. As we have now determined that the company is creditworthy, loans to ARBED may confer a countervailable benefit only to the extent they are preferential. At our verification we established company-specific benchmarks for ARBED's cost of debt after our review of ARBED's private loans. The benchmarks and an analysis of all the relevant terms were used to determine which government loans were preferential.

The subsidy rate for the preferential loans would be calculated using the methodology in Appendix 2. As discussed below, we determined that ARBED received no preferential loans which benefited the production or export of the product under investigation.

1. Loans from GOL and GOL-Controlled Institutions. received three preferential loans in 1980 and 1981 from the SNCI to finance construction of two six-strand continuous casting installations at Esch-Schifflange. We determined that these loans were preferential, because their interest rates were lower than the company-specific benchmarks for private loans and the loans were steel specific. However, we determined the casters do not provide inputs for the production of the carbon steel structural shapes under investigation and we have no information that carbon steel structural shapes benefit from these loans. Consequently, we have not treated these loans as countervailable benefits in our final determination.

ARBED received other long and short-term loans from the Caisse d'Epargne de 1'Etat (CEE), the state-controlled savings bank, for various investments. We determined that these loans were obtained under commercial terms based on the company-specific benchmarks and, thus, we do not consider these to be preferential loans conferring countervailable benefits on the product under investigation.

For reasons discussed above in the section on "Capital Grants," we are treating the reimbursable aid ARBED received directly from the GOL as a grant, although ARBED has classified this aid as a loan.

2. Industrial Investment Loans from the ECSC (Article 54). The ECSC provided ARBED with a series of loans to assist in the financing of six different investments in plant and capital equipment. We verified that the ECSC loans had interest rates equal to or greater than the company-specific commercial benchmarks that we used for ARBED. We further verified that ARBED was obligated by the ECSC to obtain loan guarantees from the GOL because the company was prevented from giving its own guarantee by negative pledge clauses in its private loan agreements. However, we determined that since the GOL-guaranteed loans were obtained at a rate equal or higher to those ARBED was able to obtain from private lenders, the GOL guarantees in themselves did not confer a countervailable benefit. We have determined that the ECSC loans do not confer any countervailable benefit on the product under investigation. For additional information regarding Article 54 loans from the ECSC, see Appendix 3.

3. Loans from Affiliated Companies. In the questionnaire we requested information on all government aid to related companies. Information in the response indicated a large portion of ARBED's loans was obtained through subsidiary companies.

We found that ARBED Finanz and ARBED Finance Luxembourg are holding companies capitalized and owned by ARBED. ARBED made a number of public bond issues and private placements through ARBED Finance and ARBED Finanz Deutschland because there were tax advantages involved in making such issues through a separate corporate entity. ARBED also obtained some foreign currency loans for exchange purposes through Dutch, German, and French subsidiaries. We have determined that none of the credit obtained through the subsidiaries conferred a countervailable benefit on ARBED, because all of it was obtained through free market mechanisms without government intervention.

III. Programs Determined Not To Be Used

We have determined that the following programs which were listed in the notice of "Initiation of Countervailing Duty Investigations" are not used by the manufacturers, producers, or exporters in Luxembourg of carbon steel structural shapes.

A. GOL Interest Rebates. The Law of July 28, 1973 for economic expansion provided that the GOL could disburse funds to reduce the interest rates of a qualified firm's investment borrowings. This interest rebate measure was incorporated into the Tripartite Agreement. However, the GOL has not to date provided any interest rebates to ARBED or MMR–A. A decision was made after the Tripartite Agreement of 1979 to substitute direct investment grants for the planned interest rebates.

B. European Investment Bank (EIB). ARBED stated and we verified that it had no outstanding debt to the EIB. We have no evidence that MMR–A received loans from the EIB. For further details regarding the EIB, see Appendix 3.

C. Convertible Bonds. Petitioners alleged that the GOL agreed to make a purchase of convertible bonds from ARBED. The GOL stated in its response that it had not acquired bonds issued by either ARBED or MMR–A. We confirmed this at verification.

D. Preferential Tax Programs. A special Luxembourg tax provision permits certain firms to carry forward indefinitely losses equal to 50 percent of annual depreciation. This option is available to any company belonging to a sector of the economy determined by the GOL to be undergoing a structural crisis. The steel sector has been undergoing a structural crisis. The steel sector has been specifically designated as one of those sectors qualified to use this tax provision. However, until such time that ARBED or MMR–A earn sufficient income from which the extra loss carried forward could be deducted, no actual benefit can be derived. Consequently, we have determined that no countervailable benefit has yet been provided by this program.

E. Loans for MMR–A. GOL-controlled financial institutions and the ECSC made a number of loans to MMR–A which were outstanding in 1981. The loans from GOL-controlled financial institutions were awarded pursuant to the 1979 Tripartite Agreements and the related law. The petitioners alleged that MMR–A was uncreditworthy during the period these loans were received. We preliminarily determined that MMR–A was uncreditworthy from 1976 through 1981 based on the substantial losses in net income suffered by the firm in that period. Based on the receipt of additional information we have determined that MMR–A should be treated as uncreditworthy only in 1977 and 1978. In those years, MMR–A suffered a large negative cash flow. Various financial ratios also indicated that the company should be considered uncreditworthy in those two years. Starting in 1977, under a rescue plan organized by the GOL, the GOB, ARBED, and several private investment firms, MMR–A divested itself of the antiquated plant at Athus and its primary production facilities at Rodange and began to modernize its rolling mill. Both the GOL and private investors provided new equity. The government also provided grants, interest-free loans, and preferential loans, all of which we are treating as countervailable. Following this restructuring, MMR–A's financial position improved substantially.

From 1979 through 1981 we have determined MMR–A to be creditworthy based on the marked improvement of various financial ratios, increased sales, improved cash flow, and the effects of the radical restructuring program.

The GOL response stated that MMR–A received two loans in 1981 for investments from the SNCI. We have determined these loans are preferential because they were made under specific provisions of the steel restructuring plan at preferential rates. However, since they were awarded in 1981, no benefit is assessed in the period we are measuring subsidization. The benefit of a preferential loan first accrues to the recipient in the year following receipt of the loan.

We found that MMR–A had outstanding debt to the ECSC from 1977 though 1981. MMR–A's outstanding debt to the ECSC did not increase from 1977 to 1978 and from 1978 to 1979. Thus, we determined it received no ECSC loans in the uncreditworthy period. For the creditworthy period, we used the rates ARBED received on its ECSC loans as the best information to construct what MMR–A would receive on its ECSC loans. Since these rates match the Luxembourg benchmark, the ECSC loans do not confer a countervailable benefit in the creditworthy period.

Petitioners' Comments

Comment 1

Counsel for petitioners argues that ARBED should be considered uncreditworthy. They argue that ARBED's losses and the apparent level of aid it is receiving from the GOL under the Tripartite Agreements are clear manifestations of "ARBED's financial incapacity."

DOC Position

In our preliminary determination we found that ARBED was uncreditworthy

on the basis of the best information available at the time. This information included ARBED's history of substantial losses in recent years. Prior to verification we lacked sufficient information to establish that these loans were made: (1) at market rates, (2) under commercial conditions, and (3) independently of government direction. Based on additional information received, the Department has determined that ARBED should not be treated as an uncreditworthy company. Information verified at the company has shown ARBED's ability to obtain private loans at commercial rates without government intervention. The Department also verified that only a portion of the massive government assistance promised in the Tripartite Agreements has actually been received by ARBED to date. ARBED still obtains a major part of its financing from private sources.

Comment 2

Counsel for petitioners argued that common treatment of ARBED and MMR–A is proper. Counsel cited ARBED's roles as an MMR–A shareholder and a participant in the management of MMR–A as sufficient justification for the common treatment of the companies in the quantification of subsidy rates.

DOC Position

As discussed above in the "Analysis of Programs" section, the Department decided that a more precise determination of subsidy rates for aid received would result if the companies were treated separately, given the two companies' separate financial structures.

Comment 3

Counsel for petitioners argued that the GOL purchase of MMR–A stock should be considered a subsidy to both ARBED and MMR–A because ARBED is a major MMR–A shareholder.

DOC Position

For reasons already discussed, the Department has decided to treat MMR–A and ARBED as separate respondents. Therefore, the Department will not consider the GOL's equity infusion into MMR–A as a countervailable benefit to ARBED.

Comment 4

Counsel for petitioners argued that GOL grants and preferential loans awarded expressly for buildings and equipment used exclusively for the production of products not under investigation should also be considered counteravilable benefits for the product under investigation. They further argued that, insofar as the Act specifies that a subsidy may include government aid bestowed indirectly on the production or exportation of a product, it intends that subsides to products not under investigation be considered for the benefit they bestow on the respondent's total production.

DOC Position

This comment is addressed in Appendix 2.

Comment 5

Counsel for petitioners argued that German coking coal subsidies confer a benefit on EC steel production in general, and on ARBED in particular through ARBED's subsidiary coke supplier in the FRG, EBV. They further argue that a special pricing arrangement exists between ARBED and EBV.

DOC Position

The Department verified that ARBED's purchases of coke from EBV were at arm's-length and at prices no lower than the prevailing market price for coke from other sources. Consequently, we determined that ARBED receives no subsidy through coke purchases from EBV. The issue of German coal and coking coal subsidies is discussed in Appendix 2 and in the "Notice of Final Affirmative Countervailing Duty Determinations, Certain Steel Products from the Federal Republic of Germany" in this issue of the **Federal Register.**

Comment 6

Counsel for petitioner argued that risk premiums should be added to the Department's "cost of capital" benchmarks for quantification of ARBED's benefits from GOL subsidies. Petitioner's counsel based the argument for adding risk premiums to the discount rates used in our calculation on a general analysis of ARBED's financial condition which takes into consideration equity expansion, debt financing, and government aid received.

DOC Position

Verification did not corroborate any of the petitioner's allegations on which this argument is based. Our investigation did not reveal that ARBED was dependent on GOL aid to the extent which was alleged by the petitioner. ARBED's ability to obtain long-term loans from private sources at favorable rates under commercial conditions also indicated that the risk premiums proposed by the petitoner would be inappropriate in these circumstances.

Comment 7

Counsel for petitioners argue that GOL grants to the Anti-Crisis Division (DAC) of ARBED and MMR–A should be considered countervailable benefits in their entirety.

DOC Position

As discussed above, the Department has determined that only part of the benefit from these grants are countervailable benefits to the product under investigation. The portion of the grants that go to the support of DAC employees engaged in non-steel-related projects does not confer a benefit on the production of the product under investigation.

Comment 8

Counsel for petitioners argued that ARBED received a countervailable benefit when it carried over part of its loss in 1981 under a provision of the special tax law.

DOC Position

ARBED did not earn sufficient income in 1981 from which the loss carry-over could be deducted. The loss carry-over, consequently, represents a possible future benefit and not a present one.

Comment 9

Counsel for petitioners argues that ARBED may have derived contervailable benefits through the extension of supplier credits.

DOC Position

During verification the Department examined ARBED's accounts payable and found that supplier credits were obtained from private parties without government intervention under terms consistent with commercial considerations. See additional discussion in Appendix 2.

Comment 10

Counsel for petitioners argues that GOL aid for infrastructure costs should be considered a countervailable benefit.

DOC Position

Infrastructure aid was promised to ARBED, but the company has not begun to build its plant at the site where the aid is to be given. Even if the aid had been used, the Department would question counsel's assertion that aid should be countervailed since GOL funding of infrastructure costs has been found to be available to and used by all industries on a non-preferential basis.

Comment 11

Counsel for petitioner disputed the Department's use of a national average cost of debt as the discount rate when calculating the "grant caps" on the quantification of countervailable benefits from equity infusions. Counsel contended that use of an average national rate for a company determined to be uncreditworthy is inappropriate.

DOC Position

As discussed in Appendix 2, the Department has determined that a national risk free rate for long-term debt is the appropriate discount rate for use in the calculations described above.

Comment 12

Counsel for petitioners noted the absence of adequate information on the Anti-Crisis Division, rail transportation rates, preferential tax programs and loans fom affiliated companies and social institutions in the GOL and ARBED responses.

DOC Position

At verification the Department was able to obtain adequate information on the above programs for the final determination.

Comment 13

Counsel for petitioners questioned the Department's determination that the interest rebate program was not used by ARBED and MMR–A. Counsel fr petitioners notes that the program was made specifically available in the Tripartite Agreement of 1979.

DOC Position

The Department verified that the GOL interest rebate program was not used by either company. The GOL decided to substitute direct investment grants in lieu of the rebate program. To the extent that direct investment grants bestowed a benefit on the product under investigation those benefits have been countervailed.

Respondents' Issues

Comment 1

Counsel for respondent asserted that the Department of Commerce erred in lumping ARBED and MMR–A together for the purpose of quantifying countervailable benefits.

DOC Position

As discussed above, the Department accepts the respondent's position

Comment 2

Counsel for respondent asserted that grants given to the steel industry under the Tripartite Agreements should not be considered countervailable since they are made pursuant to the Law of July 28, 1973 for economic expansion. Counsel argued that programs under this law are available to all industries.

DOC Position

The Department found that grants given to the steel industry under the 1973 law were made pursuant to the Tripartite Agreements. Government aid under the Tripartite Agreements was mandated specifically for the steel industry. While the 1973 law was, on its face, generally available, the effect of the Tripartite Agreements was to remove the GOL's discretion to reject the steel industry's applications for aid under the 1973 law and to direct benefits available under the 1973 law to the steel industry in particular. The range of the benefits outlined in the original law was increased as a result of the agreements.

Comment 3

Counsel for respondent argued that DOC erred in its determination that ARBED has been an uncreditworthy company since 1975. Counsel cited ARBED's receipt of commercial loans at market rates through 1981 as proof of its creditworthiness.

DOC Position

The Department has reversed its preliminary determination that ARBED was uncreditworthy. Information verified at the company has shown ARBED's ability to obtain similar long-term private loans at commercial rates without special government intervention. Prior to verification we lacked sufficient informtion to establish that these loans were made: (1) At market rates, (2) under arm's-length conditions, and (3) independently of government direction. We reached our preliminary determination of ARBED's uncreditworthiness based on information available at the time. This included ARBED's history of substantial losses in recent years. Verification of ARBED's arm's-length private loans was a primary element in the revision of our preliminary determination. We also considered the following:

- We verified that ARBED used the government aid it received for plant expansion and modernization and not for coverage of losses. Government aid represented only a relatively small portion of ARBED's own investment expenditures.
- We verified that, despite net losses in several of its recent fiscal years, ARBED maintained a positive cash flow in 1979 and 1980.

Comment 4

Counsel questioned the Department's preliminary determination that equity participation in MMR–A by the GOL constituted a subsidy to MMR–A. Counsel argued that since several private companies joined the government in purchasing new issues of MMR–A equity at similar prices, the GOL's investment cannot be considered inconsistent with commercial considerations.

DOC Position

As discussed above in the section of this notice titled "Equity Participation," the Department would, in most cases, consider a government purchase of new equity from a company in the financial condition of MMR–A as a purchase inconsistent with commercial considerations and consequently a subsidy to the entire company. However, as counsel has noted, private companies participated jointly in the MMR–A equity purchase with no evidence of GOL direction. The GOL and the private firms paid the same price for the MMR–A shares. In view of the private firms' purchase of shares participation, at the same price as that paid by the GOL, the Department is unable to regard the GOL equity purchase as inconsistent with commercial considerations.

Comment 5

Counsel for respondent maintained that GOL assistance to ARBED's Anti-Crisis Division (DAC) is not a subsidy to steel production because DAC workers are barred from steel production and ARBED would not legally be bound to pay DAC expenses borne by the government. Counsel also argued that the program increases costs to ARBED by requiring the company to forego cheaper alternatives such as dismissal with severance pay or reduction of working hours.

DOC Position

Based on information obtained at verification, the Department agrees in part with counsel's arguments. Benefits under this program to workers engaged in non-steel-related projects are not countervailable. However, assistance to workers engaged in steel-related projects does confer countervailable benefits.

For additional discussion of the DAC program, see the section of this notice titled "Anti-Crisis Division" under "Programs Determined To be Subsidies."

Negative Determination of Critical Circumstances

Bethlehem Steel Corporation and the Five alleged that imports of carbon steel structural shapes under investigation present "critical circumstances." Under §§ 355.29 and 355.33(b) of the Department's regulations critical circumstances exist when the alleged subsidies include an export subsidy inconsistent with the Agreement and there have been massive imports of the class or kind of merchandise which is the subject of the investigation over a relatively short period.

We have not found any export subsidy in this investigation. Therefore "critical circumstances" do not exist in this investigation for carbon steel structural shapes.

Verification

In accordance with section 776(a) of the Act, we verified the data used in making our final determination. During this verification, we followed normal procedures, including inspection of documents, discussions with government officials and on-site inspection of manufacturers' operations and records.

Administrative Procedures

The Department has afforded interested parties an opportunity to present oral views in accordance with its regulations (19 CFR 355.35). A public hearing was held on July 13, 1982. In accordance with the Department's regulations (19 CFR 355.34 (a)), written views were considered.

Suspension of Liquidation

The suspension of liquidation ordered in our preliminary affirmative countervailing duty determination shall remain in effect until further notice. The estimated net subsidy for each firm for carbon steel structural shapes is as follows:

Manufacturer/producer/exporter	Ad valorem rate (percent)
Acieries Reunies de Burbach-Eich-Dudelange S.A. (ARBED)	0.539
Metallurgique et Miniere de Rodange-Athus (MMR-A)	1.523
All Other Manufacturers/Producers/Exporters	1.523

Where the manufacturer is not the exporter, and the manufacturer is known, the rate for that manufacturer shall be used in determining the amount of cash deposit or bond. If the manufacturer is unknown, the rate for all other manufacturers/producers/exporters shall be used.

ITC notification

In accordance with section 705(d) of the Act, we will notify the ITC of our determination. In addition, we are making available to the ITC all non-privileged and non-confidential information relating to this investigation. We will allow the ITC access to all privileged and confidential information in our file, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order, without the written consent of the Deputy Assistant Secretary for Import Administration. The ITC will determine within 45 days of the publication of this notice whether these imports are materially injuring, or threatening to materially injure, a U.S. industry. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated and all securities posted as a result of the suspension of liquidation will be refunded or cancelled. If, however, the ITC determines that such injury does exist, within 7 days of notification by the ITC of that determination, we will issue a countervailing duty order, directing Customs officers to assess a countervailing duty on carbon steel structural shapes from Luxembourg entered or withdrawn from warehouse, for consumption after the suspension of liquidation, equal to the net subsidy determined or estimated to exist as a result of the annual review process prescribed by section 751 of the Act. The provisions of section 707(a) of the Act will apply to the first directive for assessment.

This notice is published pursuant to section 705(d) of the Act and § 355.33 of the Department of Commerce Regulations (19 CFR 355.33).

Dated: August 24, 1982.

Gary N. Horlick,

Acting Assistant Secretary for Trade Administration.

[FR Doc. 82-23882 Filed 8-31-82; 8:45 am]

BILLING CODE 3510-25-M

Final Negative Countervailing Duty Determinations; Certain Steel Products From the Netherlands

AGENCY: International Trade Administration, Commerce.

ACTION: Final negative countervailing duty determinations.

SUMMARY: We have determined that certain benefits which constitute subsidies within the meaning of the countervailing duty law are being provided to manufacturers, producers, or exporters in the Netherlands of certain steel products, as described in the "Scope of Investigations" section of this notice. However, the estimated net subsidies are *de minimis*. Therefore, the suspension of liquidation ordered in our preliminary affirmative countervailing duty determinations shall be terminated. All estimated countervailing duties shall be refunded and all appropriate bonds shall be released.

EFFECTIVE DATE: September 7, 1982.

FOR FURTHER INFORMATION CONTACT: Mary S. Clapp, Office of Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230, telephone: (202) 377-2438.

SUPPLEMENTARY INFORMATION:

Final Determinations

Based upon our investigations, we have determined that certain benefits which constitute subsidies within the meaning of section 701 of the Tariff Act of 1930, as amended, (the Act), are being provided to manufacturers, producers, or exporters in the Netherlands of certain steel products, as described in the "Scope of Investigations" section of this notice. The following programs are found to be subsidies:

- Program for Introducing New Technology.
- ECSC loans.

We determine the estimated net subsidy to be 0.183 percent *ad valorem* which is *de minimis*. Therefore the suspension of liquidation ordered in our preliminary affirmative countervailing duty determinations shall be terminated. All estimated countervailing duties shall be refunded and all appropriate bonds shall be released in accordance with section 355.33(g) of the Department of Commerce Regulations (19 CFR 355.33(g)).

Case History

On January 11, 1982, we received petitions from United States Steel Corporation; counsel for Bethlehem Steel Corporation; and counsel for Republic Steel Corporation, Inland Steel Company, Jones & Laughlin Steel, Inc., National Steel Corporation, and Cyclops Corporation (the Five), filed on behalf of the U.S. industry producing hot-rolled carbon steel sheet and strip and cold-rolled carbon steel sheet. The petitioners alleged that certain benefits which constitute subsidies within the meaning of section 701 of the Act are being provided, directly or indirectly, to the manufacturers, producers, or exporters in the Netherlands of the steel products

listed above. Counsel for Bethlehem Steel Corporation and counsel for the Five alleged that "critical circumstances" exist, as defined in section 703(e) of the Act. We found the petitions to contain sufficient grounds upon which to initiate countervailing duty investigations, and on February 1, 1982, we initiated countervailing duty investigations (47 FR 5743).

Since the Netherlands is a "country under the Agreement" within the meaning of section 701(b) of the Act, injury determinations are required for these investigations. Therefore, we notified the ITC of our initiations. On February 26, 1982, the ITC preliminarily determined that there is a reasonable indication that these imports are materially injuring, or are threatening to materially injure, a U.S. industry.

We presented questionnaires concerning the allegations to the Delegation of the Commission of the European Communities and to the government of the Netherlands in Washington, D.C. on April 20, 1982 we received the responses to the questionnaires. Supplemental responses were received on May 19, 1982. On June 10, 1982, we issued our preliminary determinations in these investigations (47 FR 26335).

We preliminarily determine that the government of the Netherlands was providing its manufacturers, producers, or exporters of certain steel products with benefits which constitute subsidies. The programs preliminarily determined to bestow countervailable benefits were:

- Program for Introducing New Technology.
- ECSC Loans.
- ECSC housing loans.

Scope of the Investigations

The products covered by these investigations are:

- Hot-rolled carbon steel sheet and strip.
- Cold-rolled carbon steel sheet.

The products are fully described in Appendix 1 which appears with the notice of "Final Affirmative Countervailing Duty Determinations: Certain Steel Products from Belgium," in this issue of the **Federal Register**. The product definition of hot-rolled carbon steel sheet and strip has been amended since the initiation of these investigations (47 FR 5739–40).

Estel Hoogovens B.V. (Hoogovens) is the only known producer and exporter in the Netherlands of the subject products which were exported to the United States.

The period for which we are measuring subsidization is the calendar year 1981. Hoogovens operates on a fiscal year which runs from January 1 through December 31.

Analysis of Programs

In their responses, the government of the Netherlands and the Delegation of the Commission of the European Communities provided data for the applicable periods. Additionally, we received information from Hoogovens. This company produced hot-rolled carbon steel sheet and strip and cold-rolled carbon steel sheet which were exported to the United States during 1981.

Throughout this notice, general principles and conclusions of law applied by the Department of Commerce to the facts of the current investigations concerning certain steel products are described in detail in Appendices 2–4 which appear with the notice of "Final Affirmative Countervailing Duty Determinations: Certain Steel Products from Belgium," in this issue of the **Federal Register**. Based upon our analysis of the petitions, responses to our questionnaires, our verification, and oral and written comments by interested parties, we determine the following.

I. Programs Determined To Confer Subsidies

We have determined that subsidies are being provided under the programs listed below to manufacturers, producers, or exporters in the Netherlands of hot-rolled carbon steel sheet and strip and cold-rolled carbon steel sheet:

A. Program for Introducing New Technology

The Ministry of Economic Affairs administers a program designed to provide funds to high-technology industries, which are defined as those industries with a high value-added in production. Projects must introduce technology new to the Netherlands.

While the funds for this program are part of the budget legislation in the Netherlands, the program's eligibility criteria are not published by the government. However, general eligibility guidelines are published by a private concern. The guidelines state that funding is available to high-technology enterprises which are defined as those sophisticated in relation to their sectors and which have a high value-added in their production. Further, funded projects must increase the sophistication of the enterprise. The guidelines are general in nature and appear to be a vehicle for informing industry in the Netherlands of the existence of the program, rather than an enunciation of legal eligibility criteria.

We requested information as to the criteria upon which an application is accepted or rejected, but were unable to obtain such information. Instead, we received only a general description of the administrative procedures for handling applications. First, a firm presents a request informally. The Ministry decides whether the chances for formal acceptance of the project are good. If the project is accepted on an informal basis, a formal application is filed and the project is routinely accepted under the program. If the project is informally rejected, a formal application can still be filed.

However, the information presented to us by the government of the Netherlands indicates that the applicant normally decides not to file a formal application on the basis of discussions held during the informal consideration. Therefore, although a formal rejection can be appealed through the administrative courts in the Netherlands, the initial informal screening process signficantly reduces the likelihood of judicial review. In fact, information provided by the government of the Netherlands indicates that the judicial process has never been used to appeal a rejection, nor does it provide an alternate source of information as to the reasons for which applications are accepted or rejected. On the basis of these facts, we do not consider judicial review to provide a safeguard against the type of "targeting" which the countervailing duty law and the Agreement on Subsidies and Countervailing Measures of the General Agreement on Tariffs and Trade seek to negate.

We were unable to obtain information concerning rejections under the program or an indication of the level of funding to individual firms or industrial sectors in the years in which Hoogovens received funds.

The presumption that the program is available to a relatively small group of industries (high-technology industries) created by the description in the published criteria has not been rebutted. In and of itself, this suggests that the program provides countervailable benefits. Moreover, the administration of the program appears to allow almost unfettered discretion in the decision making process through the use of an informal screening process and consequent reduction in the likelihood of judicial review. Finally, we note that in 1977 and 1980, Hoogovens received a commitment for a disproportionately large amount of the total funds committed under the program in those years. For these reasons, the

Department determines that this program conferred on Hoogovens benefits which constitute subsidies within the meaning of the Act.

During 1978–1981, Hoogovens, received assistance of dfl 45–52 million for the installation of a countinuous caster and dfl 45–50 million in 1981 for the rebuilding and renovation of its coking plant through the above program. Subsidy values were determined by using the grant quantification methodology described in Appendix 2 which assumes a 15-year average useful life of capital assets in the steel industry. The Department determined that the annual averages of the latest three long-term issues of central government bonds in the secondary market in the Netherlands (OECD Financial Statistics-Report) were the most appropriate figures to use as discount rates in our present value calculations. The discount rates chosen were based on the years in which Hoogovens received funds under the Program for Introducing New Technology. Since the grant benefit pertains to Hoogovens' general steel production, we divided the value of the subsidy in 1981 by the value of all steel produced by Hoogovens in 1981. Hoogovens received an *ad valorem* benefit of 0.178 percent under this program.

B. ECSE Loans

For the reasons described in Appendix 3, we have determined that ECSC loans to Hoogovens financed by ECSC borrowings on world markets confer countervailable benefits to the extent that a preferential interest rate is passed on to a steel company.

We calculated the subsidy benefit for these loans by comparing the interest payable with a benchmark rate. Monthly rates for private sector bonds in the secondary market (OECD Financial Statistics Report) were used as the benchmark figures, based on the currency in which the funds were given. The DOC determined that the annual averages of the latest three long-term issues of central government bonds in the secondary market in the Netherlands (OECD Financial Statistics Report) were the most appropriate figures to use as discount rates in our present value calculation.

Since the loans were not targeted to any particular steel product, the benefits calculated for 1981 were allocated over all steel produced by Hoogovens in 1981. An *ad valorem* subsidy rate of 0.005 percent was calculated.

II. Programs Determined Not To Confer Subsidies

We have determined that subsidies are not being provided to manufacturers, producers, or exporters in the Netherlands of hot-rolled carbon steel sheet and strip and cold-rolled carbon steel sheet under the programs listed below:

A. Loans and Loan Guarantees

The National Institute Investment Bank (NIB) and Hoogovens entered into a subordinated loan agreement on December 29, 1980, and into a subordinated, guaranteed loan agreement on January 15, 1981. The NIB is owned jointly by the Dutch government and private entities, and specializes in long-term credit instruments for industrial purposes. The NIB can operate in cooperation with the government or as an independent bank.

The loan and loan guarantee by the NIB were used to help finance the rebuilding and modernization of Hoogovens' coke facilities. Both the loan and the loan guarantee were found to be at rates which fully reflected the prevailing commercial market rates in the Netherlands at the time. Additionally, payment of bank and guarantee fees were required, and the schedule for repayment of the principal is consistent with commercial practices in the Netherlands. Further, we have determined that the terms of the loan and loan guarantee are no more beneficial to the recipient than those that would have been available to the recipient absent this government involvement. Thus, there is no benefit which constitutes a subsidy within the meaning of the Act.

B. Deferral of Interest

The management company ESTEL NV (ESTEL) controls the holding company Estel Hoogovens Koninklijke Nederlandsche Hoogovens en Staalfabrieken NV (KNHS). (The organizational structure of the ESTEL steel group has changed since our preliminary determinations. The German producer Estel Hoesch and the Dutch producer Hoogovens have dissolved their union. Although ESTEL remains a separate legal entity, Hoogovens and Hoesch have operated independently since February 1982. This reorganization does not affect our determinations since during the period for which we are measuring subsidization, January–December 1981, Hoogovens and Hoesch were part of the ESTEL group.) Hoogovens and KNHS maintain an intra-company agreement whereby Hoogovens has a line-of-credit with KNHS. The amount to be drawn down is established annually and a commercial rate equal to the Promessediscounto plus one percent is charged for the use of these funds. We found this rate to be comparable to prevailing commercial market rates in the Netherlands. In the event of an unprofitable year, Hoogovens is charged interest on the principal and interst outstanding.

Despite the partial government ownership of KNHS (24.8 percent held by the government of the Netherlands and 8.6 percent by the city of Amsterdam), there is no indication that the intra-company arrangement between KNHS and Hoogovens was directed by the government. Further, the deferral of interest is on terms which are consistent with commercial practices in the Netherlands.

Since there is no government-directed, financial assistance and the interest deferral was consistent with commercial practices, we do not consider the intra-corporate transfer of funds from KNHS to Hoogovens to constitute a subsidy within the meaning of the Act.

C. Research and Development

1. *Slichting Staalcentrum Nederland (SSN).* SSN is a privately supported institution formed through the merger of an organization of steel producers and an organization composed of end-users, fabricators, and construction firms. The organization's objective is to promote the *use* of steel in the Netherlands, and to maintain a network of contacts with steel centers worldwide. A quarterly report is published which contains articles pertinent to the use of steel. The budget of SSN is funded through the sale of these publications and from membership fees. Hoogovens is a paying member.

2. *Centre de Recherches Mettalurgique (CRM).* CRM is a privately funded research organization composed of members from Belgium, Luxembourg and the Netherlands. The members of CRM meet every two years to discuss possible research projects. Members vote to determine which projects will be undertaken.

The research done by CRM is very basic and requires further development before it can be applied to production processes. Hoogovens, as an associated member, has used some of CRM's research services. Research results are published for use by members, and some research information is published in the world press.

3. *Nederlandse Centrale Organisatie voor toegepast natuurwetenschappelijk onderzoek (TNO).* TNO is the Dutch

Organization for Applied Scientific Research and is administered by the Ministry of Education and Science. TNO conducts research for both government and private enterprises. When responding to a request for assistance, TNO outlines the scope of the project and the cost. Entities requesting assistance pay a fee which covers the cost of research performed by TNO. An official contract is signed prior to all work done. TNO has approximately 50 institutes which administer various types of research and development projects. Hoogovens did contract with TNO during 1981.

TNO does receive some government funds. These funds are targeted at special programs of strategic and basic research. Government funds are not used to reduce the cost of research contracted for by private industries.

Conclusions

Two of the institutions described are privately supported and the third charges fees which cover all costs incurred. Hoogovens is a paying member of the first two institutions and has contracted and paid for research conducted by the third. Nothing in these three programs constitutes a subsidy to Hoogovens.

D. Labor

1. *Cooperative Government and Undertaking Program.* This mutual schooling arrangement between the government and industry provides for general vocational training at firms under labor contracts. The training is not required by law and the salary assistance given by the government is based on the number of days needed to train new employees. Payments are made only while training is being conducted and the rate does not vary from firm to firm or industry to industry. Hoogovens did receive funds in 1981 for retraining workers.

2. *Vocational Training for School-leavers.* This labor program is available to all industries and is designed to assist young people in obtaining the necessary training to qualify for available jobs. The target group in 1981 were persons who left school early and sought an apprenticeship after holding other jobs. Hoogovens has received funds from this program during 1981.

3. *Subsidy for Improvement of Labor Circumstances.* This program was designed to improve the quality of existing work places throughout the Netherlands. Participation is on a voluntary basis and assistance is not given for improvements normally undertaken by the company or required by government regulations. Verification demonstrated that this program is available on equal terms to all industries in the Netherlands. No one project may receive more than a fixed percentage of its total cost. There is a ceiling on the amount of funds allocated to any one project. Hoogovens did receive funds from this program in 1981.

4. *Short-Time Workers.* This program is used only when an employer reduces the number of hours worked by an employee and is available on equal terms to all industries in the Netherlands. According to Dutch law, employees working less than their normal work week are considered unemployed and, as such, are entitled to Social Security payments for part of their lost wages. Wage payments made to employees under this program are partially funded through the Unemployment Insurance Act. Small amounts of funds were paid to some of Hoogovens' employees in 1981 under this program.

5. *Salary Assistance.* Employers who, in consultation with Regional Labor Offices, employ previously unemployed workers can receive limited assistance from the Ministry of Social Affairs. Established criteria concerning an employee's age, length of unemployment, number of work hours per week and the creation of new positions must be met by the employer. This program is equally available to all industries in the Netherlands. The level of funding is based on the employee's age and duration of previous unemployment. Hoogovens received funds pursuant to this program in 1981.

6. *Travelling Expense Allowance.* The Ministry of Social Affairs provides an allowance to workers accepting employment at a distance beyond an established standard. Assistance is also given when an employee relocates due to a work-related transfer. These allowances are paid by the Ministry of Social Affairs through the employer to workers entitled to these benefits. Such assistance is available to workers in all industries. Hoogovens received funds in 1981 pursuant to this program.

7. *Social Plan.* The social plan is an early retirement plan, for 1980, supported by payroll taxes on workers and employers (Social Security Fund, Unemployment Fund). Hoogovens makes up the difference between amounts paid by the government and contributions from a joint company-union fund. Hoogovens received funds in 1981 for the cost of the 1980 plan and a previous 1977 plan.

Conclusions

The programs described above are available to all industries in the Netherlands on equal terms. There is no evidence that the steel industry is a targeted beneficiary of these programs. Therefore, we have determined that these labor programs do not bestow benefits which constitute subsidies within the meaning of the Act.

E. Energy Programs

1. *Energy Demonstration Project.* Grants are given by the government of the Netherlands for projects which introduce new energy-saving technology applicable to all industries in the Netherlands. There is a ceiling on the amount of assistance given to any one project. Funds are disbursed in a nondiscretionary manner. A committee of energy experts monitors all projects to ensure compliance with program criteria.

Hoogovens received funds under this program to build and install a computerized control unit which would monitor energy and gas use at the IJmuiden mill. This unit is new to the Netherlands and can also be used by the chemical industry and by other large-scale energy consumers.

Funds disbursed for energy demonstration projects are sufficiently generally available and are not provided only to a specific industry or group of industries. Project results are publicly available. We have, therefore, determined this program does not bestow benefits which constitute subsidies under the Act.

2. *Energy Conservation Program.* This program operated during 1976–1978 and was designed to stimulate energy savings in the use of natural gas for general utilization by all Dutch industries. Government assistance was provided for capital investments for these projects. This program was available equally to all industries in the Netherlands.

The Ministry of Economic Affairs audits the progress of all projects to ensure each project maintains the established relationship between the investment made and energy saving results developed. Further, all research results are published. All industries in the Netherlands could have applied for funds pursuant to this program. Some payments are still being made under this program. Hoogovens received funds in 1981 for projects approved during 1976–1978.

Conclusions

In light of the general availability of these energy programs and the public availability of research results, we have determined that these programs do not

bestow benefits which constitute subsidies within the meaning of the Act.

3. *Preferential Utility Rates.* a. *Gas.* Gasunie NV is the only supplier of natural gas in the Netherlands. The government fo the Netherlands has a 10 percent direct interest in Gasunie and a 40 percent indirect interest through the Dutch state mines. The price of gas for nonresidential users is fixed quarterly by Gasunie and the Ministry of Economic Affairs and is based on the price of heavy fuel in the Netherlands. Residential rates are set by bargaining within the various localities in the Netherlands.

There are five zones (a–e), each with a different rate. The more gas consumed, the lower the rate per unit. All gas users begin in zone "a" and advance to progressive zones throughout the "gas year" as their consumption increases.

In the first quarter of 1981, zone "e" rates were slightly reduced due to the large difference in gas prices in the Netherlands and Germany. This reduction was not preferential to the steel industry nor to any other specific industry. Besides Hoogovens, there were 16 non-steel users in zone "e" at the time of the reduction.

Hoogovens is charged the appropriate zone rate based on its level of consumption. Rates are above Gasunie's costs and are uniform for all users within a zone. Based on this information, we have determined that no countervailable benefits from preferential gas rates are being received by Hoogovens.

b. *Electricity.* The Provincial Electric Company of North Holland (PEN) calculates electricity rates based on a formula of variable and fixed cost components. Rates for *all* companies are based on the same calculation.

Hoogovens purchases electricity from PEN, and PEN purchases blast furnace gas from Hoogovens. However, these two arrangements are separate and distinct. Each company pays an arm's length price for the energy consumed.

Since Hoogovens is charged a rate based on the calculation used to determine rates for all users, we have determined that no countervailable benefit has been received.

F. *Environmental Programs.*

1. *Development of Clean Technology—Demonstration Project.* Government assistance is available to all industries in the Netherlands for projects of general applicability which make use of new technology to reduce or eliminate pollution or to reuse waste water in the production process. Funds are given as grants and are limited to a set percentage of the investment amount. Any income generated from the project must be remitted to the government. Project results are published and a general survey of projects undertaken is published annually.

Aid received by Hoogovens in 1981 for a pilot study of techniques for reducing particulate waste products does not confer countervailable benefits since this program is available to all industries, and all project results are publicly available.

2. *Air and Water Pollution Control.* *The Air Pollution Act of 1972* and the *Suface Water Pollution Act of 1970* provide the framework for governmental regulation of air and water pollution for all industries. These laws establish normal levels for pollutants in air and water. The law also provides government assistance for firms which undertake investments in plant and equipment to comply with environmental standards. Enforcement and administration is delegated to provincial authorities. Funds disbursed pursuant to these acts are financed by levies on all industries in the Netherlands.

Hoogovens received partial compensation in 1980/81 for investments in plant and equipment to comply with environmental standards. Additional assistance was given to Hoogovens in 1981 for building a blast furnace waste water pulp thickener.

We have determined the Air and Water Pollution assistance programs do not confer benefit since they are funded through the collection of environmental control charges on all industries in the Netherlands.

G. *Investment Incentives—WIR.* The Wet op de Investeringsrekening (WIR) became effective May 24, 1978 and provides investment credits and incentives for all commercial investments in the Netherlands. This scheme is implemented through the Dutch tax system, and applicants have a legal right to WIR receipts.

The Ministries of Economic Affairs, Finance and Social Affairs concurrently set the schedules for WIR payments. The four categories of investments associated with the WIR program are: new buildings, modifications to buildings, independent installation, and other equipment and machines. These investments are reported on a firm's fiscal balance sheet. Only investments of goods and equipment with a useful life of more than one year are eligible for these tax credits.

The Secretary of Economic Affairs reviews applications for WIR payments and forwards those that qualify to the tax department for a final decision. Each investment accepted for tax purposes automatically receives a credit. Approved requests receive a tax credit in the following year. If a firm has losses and does not pay taxes in the year of a WIR receipt, a direct payment equal to the amount of the tax credit is paid to the firm. Such was the case in 1980 and 1981, when Hoogovens paid no corporate income tax. There is no administrative discretion in the WIR scheme to favor any individual company, group or companies or industry sector.

The GPT allowance (Large Scale Investment Program) is an additional premium, under the WIR, for investment projects greater than 30 million guilders. The conditions of award with regard to the GPT are public and fixed. The allowance is related to the number of jobs created by the investment. Hoogovens received a GPT allowance in 1980/81 for the installation of a continuous caster.

Assistance received by Hoogovens under this WIR program is not a countervailable benefit since these investment tax credits are available on all commercial investments. Preferance is not given to exports, to specific industries or enterprises, or to particular regions. Certain provisions of WIR include regional incentives for investments in underdeveloped areas in the Netherlands. Hoogovens is located in the Randstad, the most heavily industrialized and populated region in the Netherlands, and is not eligible for such regional incentive benefits.

In a prior investigation, financial assistance conferred under the WIR regional program to a Dutch exporter of corn starch and/or derivatives, Cooperatieve Verkoop-en Produkti-everening van Aardappelmeel en Derivaten AVEBE G.A. (AVEBE), was deemed a subsidy because of its regional nature. That determination is distinguished from the present case which does not involve any regional preference. (For information on the AVEBE case, see "Dextrines and Soluble or Chemically Treated Starches Derived from Corn Starch from the European Community," 45 Fed. Reg. 18414.)

H. *ECSC Housing Loans.* In our preliminary determinations we assumed that the availability of preferential funding for steelworkers' housing enabled steel companies to pay lower wages than they would have otherwise paid in the absence of ECSC housing assistance. As explained in Appendix 3, we have developed additional information on this program and have determined that no steel company benefits from this program.

I. *ECSC Research and Development.* For the reasons described in Appendix 3, we have determined that ECSC R & D funds do not confer any benefits which are subsidies within the meaning of the law.

J. *Indirect Benefits from Aid Given to German Coal Mining Companies.* For the reasons described in Appendix 3, we have determined that German subsidization of German coking coal producers does not confer a subsidy on Dutch steel companies, which purchase that coal in arm's length transactions.

III. Programs Determined Not To Be Used

We have determined that the following programs which were listed in the notice of "Initiation of Countervailing Duty Investigations" are not used by the manufacturers, producers, or exporters in the Netherlands of hot-rolled carbon steel sheet and strip and cold-rolled carbon steel sheet:

A. *Regional Development.* Hoogovens has not participated in regional industrial incentive programs designed to stimulate economic development in priority zones in the Netherlands.

B. *Dutch Energy Development Company.* This organization was founded by the government of the Netherlands in 1976 for the purpose of conserving and diversifying the use of energy. Results of these demonstration projects are generally available and used by all industries in the Netherlands. Hoogovens has not received any funds pursuant to this program.

C. *Labor Programs.*

Employment of Workers from Surinam and Netherlands Antilles. Hoogovens has received no assistance during 1981 pursuant to this program.

Experimental Early Retirement Plan. This program was terminated in 1980. Hoogovens received no funds in 1981.

D. *Export Loans/Credits.*

Matching Funds. Funds from this program can only be used when exporting capital goods to an area where competitors are trading unfairly. Hoogovens exports steel, a consumption item, and is not eligible to receive funds under this program.

Subordinated Loans for Exporting Companies. These loans are available for exports of capital goods. The Ministry of Finance considers steel a consumption item, not a capital good, and will not issue a steel company the additional insurance required to meet the eligibility requirements of this program.

Export Financing Arrangement. Only captial goods qualify for insurance by a credit insurance company. Steel, a consumption items, does not meet the eligibility criteria for this program. Consequently, Hoogovens was not eligible to participate in this program.

IV. Petitioners' Comments

Comment 1

Petitioners argue that housing loans at an interest rate of 1 percent create more disposable income for the workers receiving these loans. Under different circumstances, workers would have to spend a larger percentage of their salary on living costs, and perhaps an employer would be expected to pay its employees a larger salary.

DOC Position

As stated in the section "Programs Determined Not To Confer Subsidies," we found ECSC housing loans to be a benefit to the worker alone. We found no evidence of an effect on wage demands due to this program. Refer to Appendix 3 for further details.

Comment 2

Petitioners state that the weighted cost of capital data in Hoogovens' balance sheet is only an historical cost of selected debt instruments, does not account for the cost of equity capital, and ignores the function of the countervailing duty law to determine the commercial benefit received by a company from a particular loan, grant or equity infusion.

Petitioners content that the proper method of valuing the commercial and competitive benefit to the recipient of grant and loan subsidies is to examine the cost of capital (weighted average of both equity and debt for grants; and debt capital for loans) for the individual company at the time at which the loan or grant was made.

It was proposed that the highest effective short-term interest rate available at the time of the loan guarantee should be used as a comparable interest rate without government intervention.

DOC Position

On the basis of the verified information available to use, the DOC determined that the annual averages of the latest three long-term issues of central government bonds in the secondary market in the Netherlands (OECD Financial Statistics Report) were the most appropriate figures to use as discount rates in our present value calculations. Rates for private sector bonds in the secondary market (OECD Financial Statistics Report) were used as benchmark figures based on the currency in which the funds were given. Monthly rates were used for all benchmark rates since the Department had specific information relative to the date of receipt of such loans. For further explanation of the DOC's position regarding use of discount rates and the present value methodology see Appendix 2.

Comment 3

Petitioners stated that because Hoogovens has been unable to earn an adequate profit on its sales during the last seven years, it is an uncreditworthy company. They cite losses during 1975–81 as being dfl 700 million for Hoogovens, and more than dfl 2.3 billion losses for ESTEL during the same period. As a result of such losses, shareholders equity of ESTEL has been decreased by approximately 60 percent.

DOC Position

Since Hoogovens has obtained loans from private commercial sources at prevailing commercial rates, at arm's length and without government intervention, the Department considers that, for purposes of these investigations, Hoogovens was not uncreditworthy.

Comment 4

Petitioners contend that the discount rate used by the DOC in calculations for loans to uncreditworthy companies was incorrect.

DOC Position

For purposes of these investigations, the Department has determined that Hoogovens is not uncreditworthy. This point is moot.

The Department supports the theory that money today is much more valuable than the same amount of money received over time. However, the present value (in the year of receipt) of the amounts allocated over time must not exceed the face value of the grant. This methodology is consistent with both U.S. law and international obligations because the amount countervailed will not exceed the total net subsidy. Refer to Appendix 2 for additional information.

Comment 5

Petitioners contend that benefits bestowed upon any foreign steel company, general or industry specific, are countervailable benefits within the meaning of "bounty or grant."

DOC Position

For a full explanation of the Department's position, see Appendix 4.

V. Respondents' Comments

Comment 1

Counsel for Hoogovens maintains that the Program for Introducing New Technology is generally available to all industries in the Netherlands, and that industries such as medical technology and automotive engineering have also received funds. In addition, they note that such assistance is intended to stimulate the economy as a whole. Also, since appeals can be made to a court, they view the program as being administered in a nondiscretionary manner.

DOC Position

As discussed above in the section titled "Programs Determined to Confer Subsidies," the Department found this program countervailable in part because it is aimed at high technology industries. Moreover, the Administration of an informal pre-screening process has insured to date that formal denials have never been required. Consequently, there is no judicial record establishing what standards, it any, govern the administration of this program. Finally, such information as the Department has available to it indicates the steel industry has been a major beneficiary of the benefits available under the program. In view of the evidence of the program's preferentiality, and the lack of information regarding the identity of recipients and the standards of administration, respondents were unable to rebut the reasonable presumption that the program is not generally available and is administered in a discriminatory manner. Therefore, we find the benefits available under this program constitute a subsidy within the meaning of the Act.

Comment 2

Counsel for the respondent concedes that ECSC housing loans are industry-specific, but contends that it is speculative for the Department to assume the economic effect resulting from the elimination of ECSC housing loans. Further, counsel for the respondent contends that programs for the health, safety and well-being of individuals are the legitimate and normal function of government.

DOC Position

We found no evidence of an effect on wage demands due to this program. For additional information regarding the Department's reasoning in reversing its perliminary finding regarding the countervailability of ECSC housing loans, refer to Appendix 3.

Comment 3

Counsel for Hoogovens states that the effective rather than the nominal interest rate should be used when calculating the countervailable benefit of ECSC loans. The effective rate takes into account the terms of interest repayment. Further, the Department should use a principal repayment basis when calculating the benefit of preferential interest rates because all of Hoogovens' ECSC loans provide for a constant principal repayment. The respondent regards the mortgage basis, which features a flat amount of total repayment, as inappropriate.

Counsel for Hoogovens also contends that the benchmark rates used in the preliminary were arbitrary and that a long-term government bond rate plus 0.75 percent would be more representative.

Counsel for Hoogovens noted that information contained in Hoogovens' consolidated balance sheet reflects the average rate of interest on the company's long-term debt—the actual cost of money to Hoogovens. Hoogovens asserts this information should be used, and to include return on equity in the cost of capital would not be arbitrary in light of the multitude of factors to be considered in such a choice.

DOC Position

We normally seek to compare the loan at issue with a loan made on terms consistent with commercial considerations and comparable to the loan at issue. To derive precise effective rates is a task of financial interpolation which cannot be accomplished within the deadlines imposed by statute.

The principal basis was used in order to allocate the preferential loan subsidy to the future in a constant nominal stream because all of Hoogovens' ECSC loans provide for a constant principal repayment.

Rates for private sector bonds in the secondary market (OECD Financial Statistics Report) were used as the benchmark figures, based on the currency in which the loan was given. Monthly rates were used since the Department had specific information relative to the date of receipt of these loans.

The DOC determined that the annual averages of the latest three long-term issues of central government bonds in the secondary market in the Netherlands (OECD Financial Statistics Report), were the most appropriate figures to use as discount rates in our present value calculations.

For reasons stated in Appendix 2, the Department has determined that, for purposes of these investigations, the methodology described above remains appropriate because it is both reasonable and administrable.

Comment 4

Counsel for Hoogovens maintains that the present value methodology employed by the DOC in calculating the benefit received through certain subsidies results in assessing countervailing duties which exceed the legal maximum. Counsel further maintains that the term "bounty or grant" defines a subsidy as the amount given rather than the benefit or the apparent benefit received. The subsidy rate cannot be based on a theoretical calculation of the future income which results in assessment of amounts greater than those actually received.

DOC Position

The Department supports the theory that money today is more valuable that the same amount of money received over time. In our present value calculations, the amount allocated over time does not exceed the face value of the grant. This methodology is consistent with both U.S. law and our international obligations because the amount countervailed will not exceed the total net subsidy. Refer to Apendix 2 for additional information.

Comment 5

Counsel for Hoogovens contends that in adopting the present value methodology the DOC has ignored past precedent which was confined to amortization over time.

DOC Position

As previously noted, so long as the calculation of the present value in the year of receipt of the amount allocated over time does not exceed the face value of the grant, this methodology is consistent with both U.S. laws and our international obligations. The amount countervailed will not exceed the total net subsidy. Refer to Appendix 2 for additional details.

Critical Circumstances

Counsel for Bethlehom Steel Corporation and counsel for the Five alleged that imports of hot-rolled carbon steel sheet and strip and cold-rolled carbon steel sheet under investigation present "critical circumstances." Since our countervailing duty determinations, with regard to the Netherlands, are negative, the allegation is moot.

Verificaton

In accordance with section 776(a) of the Act, we verified the data used in making our final determinations. During this verification, we followed normal procedures, including inspection of documents, discussions with government officials, and on-site inspection of the manufacturer's operations and records.

Administrative Procedures

The Department has afforded interested parties an opportunity to present oral views in accordance with its regulations (19 CFR 355.35). A public hearing was held on July 8, 1982. In accordance with the Department's regulations (19 CFR 355.34(a)) written views have been received and considered.

Suspension of Liquidation

The suspension of liquidation ordered in our preliminary affirmative countervailing duty determinations shall be terminated upon publication of this notice. All estimated countervailing duties shall be refunded and all appropriate bonds shall be released in accordance with section 355.33(g) of the Department of Commerce Regulations (19 CFR 355.33(g)).

ITC Notifications

In accordance with section 705(d) of the Act, we will notify the ITC of our determinations.

This notice is published pursuant to section 705(d) of the Act and § 355.13 of the Department of Commerce Regulations (19 CFR 355.33).

Dated: August 24, 1982.

William T. Archey,

Acting Assistant Secretary for Trade Administration.

[FR Doc. 82-23878 Filed 8-31-82; 8:45 am]

BILLING CODE 3510-25-M

Final Affirmative Countervailing Duty Determinations and Countervailing Duty Orders; Certain Steel Products From South Africa

AGENCY: International Trade Administration, Commerce.

ACTION: Final affirmative countervailing duty determinations and countervailing duty orders.

SUMMARY: We have determined certain benefits which counstitute bounties or grants within the meaning of the countervailing duty law are being provided to manufacturers, producers, or exporters in South Africa of certain steel products, as described in the "Scope of Investigations" section of this notice. The estimated net bounty or grant for each firm and for each product is indicated under the "Suspension of Liquidation" section of this notice.

EFFECTIVE DATE: September 7, 1981.

FOR FURTHER INFORMATION CONTACT: Joseph A. Black or Paul Thran, Office of Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230, telephone: (202) 377-1774 or 377-1766.

SUPPLEMENTARY INFORMATION:

Final Determinations and Orders

Based upon our investigations, we have determined that certain benefits which constitute bounties or grants within the meaning of section 303 of the Tariff Act of 1930, as amended (the Act), are being provided to manufacturers, producers, or exporters in South Africa of certain steel products, as described in the "Scope of Investigations" section of this notice. The following programs are found to be bounties or grants:

- Export incentive program—category C and D.
- Assumption of financing charges.
- Railroad rate differential.
- Central government rail rebate.

We determine the net bounties or grants to be the amount indicated for each firm and for each product in the "Suspension of Liquidation" section of this notice.

Case History

On January 11, 1982, we received petitions from United States Steel Corporation; and counsel for Republic Steel Corporation, Inland Steel Company, Jones & Laughlin Steel, Inc., National Steel Corporation, and Cyclops Corporation (the Five), filed on behalf of the U.S. industry producing carbon steel structural shapes, hot-rolled carbon steel plate, hot-rolled carbon steel sheet, cold-rolled carbon steel sheet, galvanized carbon steel sheet hot-rolled carbon steel bars, hot-rolled alloy steel bars and cold-formed carbon steel bars. United States Steel Corporation only petitioned against hot-rolled carbon steel plate. The petitions alleged that certain benefits which constitute bounties or grants within the meaning of section 303 of the Act are being provided, directly or indirectly, to the manufacturers, producers or exporters in South Africa of the steel products listed above.

We found the petitions sufficient, and on February 1, 1982, we initiated countervailing duty investigations (47 FR 5751). We stated that we expected to issue preliminary determinations by April 6, 1982. We subsequently determined that the investigations are "extraordinarily complicated," as defined in section 703(c) of the Act, and postponed our preliminary determinations for 65 days, until June 10, 1982 (47 FR 11733).

On June 10, 1982, we preliminarily determined that there was reason to believe or suspect that benefits which constitute bounties or grants within the meaning of the countervailing duty law were being provided to manufacturers, producers, or exporters in South Africa of certain steel products (47 FR 26340). Hearings were held on July 15 and 27, 1982, to provide an opportunity for the public to comment on the preliminary determinations.

Since South Africa is not a "country under the Agreement" within the meaning of section 701(b) of the Act and the certain steel products at issue here are dutiable, the domestic industry is not required to allege that, and the U.S. International Trade Commission is not required to determine whether, imports of these products cause or threaten material injury to the U.S. industry in question.

Scope of Investigations

The products covered by these investigations are:

- Carbon steel structural shapes.
- Hot-rolled carbon steel plate.
- Hot-rolled carbon steel sheet.
- Cold-rolled carbon steel sheet.
- Galvanized carbon steel sheet.
- Hot-rolled carbon steel bars.
- Hot-rolled alloy steel bars.
- Cold-formed carbon steel bars.

The products are fully described in Appendix 1, which accompanies the notice of "Final Affirmative Countervailing Duty Determinations, Certain Steel Products from Belgium", in this issue of the **Federal Register**. The product definitions of hot-rolled carbon steel bars, hot-rolled alloy steel bars, and cold-formed carbon steel bars were amended on June 29, 1982 (47 FR 28121), by deleting the phrase "and not coated or plated with metal" from each of those product definitions. On August 10, 1982 (47 FR 34609), the amended product definition of hot-rolled carbon steel bars was corrected by reinserting the deleted phrase.

The South African Iron and Steel Industrial Corporation (ISCOR) and the Highveld Steel and Vanadium Corporation (Highveld) are the only known producers in South Africa of the subject products exported to the United States.

The period for which we are measuring subsidization is corporate

fiscal year 1981, which runs from July 1, 1980 through June 30, 1981 for both companies.

Analysis of Programs

In its response, the government of South Africa provided data for the applicable periods. Additionally, we received information from ISCOR, which produced and exported carbon steel structural shapes, hot-rolled carbon steel plate, hot-rolled carbon steel sheet, cold-rolled carbon steel sheet, galvanized carbon steel sheet, and hot-rolled carbon steel bars to the United States during 1981; and Highveld, which produced and exported carbon steel structural shapes and hot-rolled carbon steel plate to the United States during 1981. However, both companies stated that they did not produce or export to the United States either hot-rolled alloy steel bars or cold-formed carbon steel bars. After examining production records and U.S. Commerce Department special steel summary invoices, we have determined that neither Highveld nor ISCOR exported these products to the United States during 1981.

Throughout this notice, general principles applied by the Department of Commerce to the facts of the current investigations concerning certain steel products are described in detail in Appendices 2 and 4 which accompany the notice of "Final Affirmative Countervailing Duty Determinations, Certain Steel Products from Belgium", in this issue of the **Federal Register**. Based upon our analysis to date of the petitions and responses to our questionnaires, we determine the following.

I. Programs Determined To Be Bounties or Grants to Manufacturers, Producers, or Exporters of Certain Steel Products

We determine that bounties or grants are being provided to manufacturers, producers, or exporters in South Africa of the certain steel products included in these investigations under the programs listed below:

A. *Export Incentive Program.* The South African Department of Industries, Commerce and Tourism has a four-part general export incentive program, of which Highveld took advantage of one part in 1981. It is described below.

Category D (Export Marketing Assistance Program). We find that this program consists of a deduction from taxable income of between 175 and 200 percent of export market development expenses rather than the normal 100 percent. Therefore, we have determined that, through this Category D tax deduction program, the government of South Africa provides benefits which constitute bounties or grants.

In our preliminary determinations, we used the extra deduction taken for this program in Highveld's 1981 income tax return as the benefit. We have since concluded that as the benefit received under this program can only be calculated after the close of the company's books, the benefit based on 1981 expenses is received in the 1982 tax year. Therefore, in order to determine the benefit of this program in 1981, we looked to the extra deduction taken and received in 1981 reflecting 1980 marketing expenses. We then divided this amount by the total value of exports of the products to the United States during Highveld's 1981 fiscal year, the period for which we are measuring subsidization, to obtain the value of the benefit.

We obtained and verified the 1980 information needed to calculate the benefit received in 1981. The results are benefits of 0.16 percent *ad valorem* for both carbon steel structural shapes and hot-rolled carbon steel plate.

ISCOR did not benefit from this program during the period for which subsidization is being measured.

B. *Assumption of Finance Charges.* In 1978 the government of South Africa assumed R70 million of ISCOR's finance charges. Under the grants methodology described in Appendix 2, we treated this payment as a grant, and allocated the amount over 15 years, the average life of capital assets in integrated steel mills. Using this methodology, we calculated a benefit of 0.35 percent *ad valorem* for each steel product under investigation produced by ISCOR.

In our "Preliminary Affirmative Countervailing Duty Determinations—Certain Steel Products from South Africa" (47 FR 26340), we calculated the benefit of this program as though the grant were given in 1977, using the discount rate for that year, following our then existing methodology. Since the grant was actually given in 1978, we are now using the appropriate discount rate for 1978, which is lower. This results in a benefit of 0.35 percent instead of 0.5 percent. (The benefit, using a discount rate based on our original methodology, would have been 0.4 percent.)

C. *Railroad Rate Differential.* The South African Transport Services (SATS), a government-owned corporation, maintains a rate schedule that generally provides railroad rates for shipments destined for export that are lower than domestic rates.

Both ISCOR and Highveld used rail transport for their exports of certain steel products. The export rates are approximately 50 percent of the domestic rates. In our preliminary determinations, we found this program to be a bounty or grant, and we calculated its benefit by dividing the differential per ton by the per ton value of the appropriate product.

As stated in our preliminary notice, SATS maintains that its export rates are "cost justified," and that the difference between the domestic and export rates reflects the difference in the cost of handling the two types of traffic.

SATS has demonstrated that rate differentials between domestic and export steel shipments are generally cost justified. It has shown that the ratio of revenues to costs in export shipments of steel is greater than the similar ratio for most domestic shipments. The exception was certain domestic steel shipments railed under the same conditions as exports. Prior to April 1, these were charged higher rates than exports. Necessarily, the revenue-to-cost ratio for these shipments exceeded the normal ratio for domestic shipments.

During our verification we found that steel for export is shipped in "full-truck loads" (full cars) and 39-car trains. The mill is charged for a fully loaded car whether or not it is able to fill the car completely. These trains are moved to the harbors as complete units. The only handling required is the changing of locomotives on various parts of the lines. At the ports the harbor administration unloads the train and loads the ships; for this service a separate fee is charged.

In contrast, domestic shipments are charged rates on a per ton basis. The railroad moves the cars from the mill to a marshalling yard where they are transferred to other trains for hauling to their destination. (Marshalling may occur more than once during any shipment.) At the destination the railroad is responsible for unloading the train.

SATS has made available to domestic steel shippers, effective April 1, 1982, the same rates export shipments enjoy if the domestic shipments meet the same loading and point-to-point conditions imposed on export shipments.

Based on the availability of the lower rates to all domestic steel shippers meeting the conditions imposed on export shipments of steel. We determine that the rates afforded by SATS to exporters of certain steel products are not provided on terms more favorable than those for domestic shippers and that they do not constitute a bounty or grant in these cases for shipments

exported after April 1, 1982. For shipments prior to April 1, 1982, we calculated the following rates based on the difference in the full truckload rate available to exporters and the per ton rate available to domestic shippers.

Manufacturer/producer/exporter	Ad valorem rate (percent)
ISCOR:	
Carbon steel structural shapes	11.4
Hot-rolled carbon steel plate	9.4
Hot-rolled carbon steel sheet	10.0
Cold-rolled carbon steel sheet	8.4
Galvanized carbon steel sheet	6.9
Hot-rolled carbon steel bars	3.9
Hot-rolled alloy steel bars	3.9
Cold-formed carbon steel bars	3.9
Highveld:	
Carbon steel structural shapes	8.0
Hot-rolled carbon steel plate	8.0

D. *Export Incentive Program—Category C (Finance Charges Aid Scheme).* The South African government provided for a tax-free rebate to certain firms increasing the value of their exports of manufactured goods. The rebate was equal to 25 percent of the interest costs for financing exports. Both ISCOR and Highveld benefited from this program in 1981. However, as this program was terminated on April 1, 1982, we are not including this benefit in our calculation of the bounties or grants on shipments after that date. For shipments prior to April 1, 1982, we calculated benefits of 1.2 percent *ad valorem* for ISCOR and 1.9 percent *ad valorem* for Highveld.

E. *Central Government Rebate.* The government of South Africa offered a "Central Government Rebate" of up to 25 percent of the railroad charges on products shipped in open railway cars for export. Both ISCOR and Highveld benefited from this program in 1981. However, as this program was terminated on April 1, 1982, we are not including this benefit in our calculation of the bounties or grants on shipments after that date. For shipments prior to April 1, 1982, we calculated the following benefits.

Manufacturer/producer/exporter	Ad valorem rate (percent)
ISCOR:	
Carbon steel structural shapes	2.3
Hot-rolled carbon steel plate	2.2
Hot-rolled carbon steel sheet	2.4
Cold-rolled carbon steel sheet	2.0
Galvanized carbon steel sheet	1.6
Hot-rolled carbon steel bars	1.4
Hot-rolled carbon steel bars	1.0
Cold-formed carbon steel bars	1.0
Highveld:	
Carbon steel structural shapes	2.0
Hot-rolled carbon steel plate	2.0

II. Programs Determined Not To Be Bounties or Grants to Manufacturers, Producers, or Exporters of Certain Steel Products

Based upon our verification, we determine that bounties or grants are not being provided to manufactures, producers, or exporters in South Africa of certain steel products under the following programs:

A. *Government Equity Participation in ISCOR.* The government of South Africa owns over 99 percent of the outstanding shares of ISCOR. The remaining shares are not publicly traded. The petitioners alleged that the purchase of equity by the government represents a bounty or grant. In our preliminary determinations, we made the tentative judgment, based on ISCOR's financial statements, that the purchase of share capital in ISCOR by the government was inconsistent with commerical considerations, and therefore potentially a bounty or grant.

We then measured the value of the bounty or grant by comparing the government's rate of return in 1981 on its equity investment in ISCOR with the national average rate of return in 1981 on equity investments in South Africa as evidence by the report of the South African Reserve Bank. We then multiplied this difference by the amount of the government equity infusions since 1974. We preliminarily found the value of the benefit, allocated over total ISCOR sales, to be 3.7 percent *ad valorem.*

ISCOR has provided additional information to suggest that the government's equity infusions were consistent with commerical considerations, and therefore not a bounty or grant. ISCOR's income statements in it s annual reports are based on an inflation-based accounting system which charges to production costs the increased replacement cost of fixed assets. This expense item is in addition to normal depreciation. While approved and recommended, this practice is not followed by most South African companies. However, ISCOR has been using it since 1952.

The effect of this practice on ISCOR is to understate its profit performance *vis-a-vis* companies not using the inflation-based system. When the provisions for increased replacement costs are added back to profits, ISCOR's performance changes dramatically. Instead of two profitable years in the last eight, ISCOR showed profits in six to those years.

Moreover, we have found that ISCOR's non-payment of taxes in those years is not related to a poor profit performance, but instead to significiant write-offs for major capital expenditures made during earlier periods. These write-offs are not preferential under South African tax law.

For these reasons we determine that the South African government's purchase of ISCOR's share capital was not inconsistent with commercial considerations, and therefore is not potentially a bounty or grant under the Act.

B. *ISCOR Loan Guarantees.* The petitioners alleged that the South African government's ownership of ISCOR allows the company to receive loans at interest rates lower than if the company were privately held. In our preliminary determinations, we estimated the benefit from loan guarantees based on the best information available. ISCOR has since presented information on all its loans outstanding during the period for which subsidization is being measured.

Government ownership of a firm does not implicitly guarantee the debt of the firm, and thus does not confer *per se* a bounty or grant. An explicit loan guarantee by the state, on the other hand, bestows a benefit to the extent that the recipient of the guaranteed loan pays less for the debt than it would have absent the guarantee. In ISCOR's case we found that only certain of the company's loans obtained in foreign countries were guaranteed by the government. Those loans of ISCOR's which were guaranteed carried rates generally higher than the rates for long-term corporate bonds in the countries in which they were received. The long-term corporate bond rate is the rate we selected as our measure of debt incurred solely on the basis of commercial considerations. Therefore, we determine that the guarantee of ISCOR's loans by the government did not provide a benefit which is a bounty or grant in this case.

C. *Export Credit Insurance.* The Credit Guarantee Insurance Company (CGIC) offers export credit insurance to qualifying export companies. Both ISCOR and Highveld participated in this program. No other insurance company is known to provide similar coverage. According to its annual reports, CGIC's insurance premium rates cover the long-term costs and losses of the program. Therefore, respondents' purchase of export credit insurance did not provide a benefit which is a bounty or grant.

D. *Employee Training Programs.* The South African Department of Manpower certifies a company's training programs to the taxing authority, which allows that company to deduct 200 percent of its qualified training expenses from its taxable income. Both ISCOR and

Highveld qualified for the 200 percent deduction. The Department of Manpower has demonstrated that all qualified training programs are available to all companies and industries, and that they are not restricted to certain sectors of the economy or to exporters. In view of the general availability of this tax benefit, we do not consider it to be a bounty or grant under the Act.

F. *Reduced Ocean Freight Rates.* The petitions alleged that South African shippers benefited from reduced ocean freight rates. We could find no evidence of such a program. We did find evidence of variable ocean freight rates due to rate negotiation between shippers and carriers; however, this variability does not constitute a bounty or grant under the Act.

III. Programs Determined Not To Be Used by Manufacturers, Producers, or Exporters of Certain Steel Products

We determine that the following programs, which were alleged by the petitioners to confer bounties or grants, are not being used by the manufacturers, producers or exporters in South Africa of certain steel products.

- Pre- and post-shipment financing,
- Export incentive program—category A and B,
- Beneficiation allowances for base mineral processing,
- Homeland development, and
- Iron/steel export promotion scheme.

Additionally, we determine that ISCOR does not use Category D of the Export Incentive Scheme.

New Allegations

In its pre-hearing brief (July 12, 1982), submitted after the preliminary determinations and after the verification, Bethlehem Steel Corporation presented new allegations regarding two of ISCOR's mining operations. (Bethlehem is a party to the proceeding, but not a petitioner, in these cases.) The first is called the "Sishen-Saldanha scheme" which involves a railway line from ISCOR's Sishen mines to harbor facilities at Saldanha Bay. The line transports iron ore for export. Bethlehem argues that the financing of the line and its subsequent transfer of ownership from ISCOR to SATS provide a benefit to ISCOR's steel production. Since none of the iron ore that is shipped over this line goes into ISCOR's steel production, we find that the alleged benefits do not confer a bounty or grant on ISCOR's steel production.

Bethlehem's second allegation is based on statements contained in ISCOR's annual reports concerning a new mine that the company developed during the late 1970's. These statements indicate that SATS built a new railway line to the facility and several government departments cooperated in developing the nearby town. However, nowhere in the report is there any indication that SATS' contribution was not commercially sound or that the government preferentially subsidized this infrastructure development.

Bethlehem presents no evidence that the railroad line or town involved a countervailable bounty or grant. Given the late date of this allegation and the fact that it does not present a credible *prima facie* case for a bounty or grant, we will not investigate this allegation further.

Additionally, Bethlehem, in its hearing statement (July 27, 1982), alleged that ISCOR's exemption from an undistributed profits tax represented a bounty or grant. The information available to the Department indicates that the tax applies to investment companies in South Africa. Industrial concerns such as ISCOR are not subject to the tax. Therefore, we find that the company's exemption is not preferential and does not constitute a bounty or grant.

Further, in the same hearing statement, Bethlehem quoted an ISCOR publication which stated that the ISCOR "may apply for exemption from the payment of non-residence tax on interest in respect of overseas loans made for its expansion programs" and alleged that this is a bounty or grant. This language does not suggest preferential treatment. Again, given the late date of this allegation and the lack of evidence indicating a *prima facie* bounty or grant, we will not investigate it further.

Petitioners' and Bethlehem's Comments

Comment 1

The petitioners and Bethlehem argue that the magnitude of the railway rate differential cannot be explained by difference in cost experience, and therefore, exports of steel products are railed at rates more favorable than domestic shipments. This constitutes a bounty or grant.

DOC Position

During our verification we were presented with data that demonstrates that export shipments of all of the subject products return a higher percentage of revenues relative to cost than do domestic shipments of the same products. The data which we examined were the railroad's standard costs applied against its work performance factors. These latter numbers reflected the railroad's actual experience in moving steel from the mills to the ports. The ratio of revenues to cost generated from that traffic results in a larger number than the similar ratio for traffic moved under domestic conditions. As explained above, generally the conditions under which domestic and export traffic move are significantly different. Additionally, the railroad has provided us with information that indicates it now offers the lower rates to domestic shippers who meet the same conditions that export shippers must meet to obtain the lower rates. This provision is effective April 1, 1982. With this change, there is no further question that export shipments of steel in open cars do not receive rates more favorable than similar domestic shipments.

Comment 2

The Five cite the 1978–79 Annual Report of the railroad which states that the government of South Africa subsidizes export rates.

DOC Position

The subsidies referred to were those given by the South African Department of Industries, Commerce and Tourism under the Central Government Rebate program which was terminated on April 1, 1982.

Comment 3

The Five maintain that a refund made to ISCOR of rail and harbor tariffs of overpayments on export shipments of iron ore is a bounty or grant.

DOC Position

These refunds were for export shipments of iron ore which do not affect ISCOR's production of steel. Therefore, they do not confer a bounty or grant on the products subject to these investigations.

Comment 4

The Five alleged that the Department is bound by *Macalloy Corp. v. United States*, 1 CIT ——, Slip Op. 81–23 (March 10, 1981), in which the Court of International Trade held that SATS' preferential export rail rates constitute a bounty or grant.

DOC Position

In *Macalloy*, the Court decided that, based on the facts of that case, preferential railroad freight rates charged by SATS upon shipments of ferrochrome constitute the payment or bestowal of a bounty or grant. In conducting new investigations, the law, regulations, and legislative history

require an independent review of the alleged bounties or grants. Based upon the substantially different facts presented in these cases, the Department is not required by *Macalloy* to consider SATS' rates a bounty or grant in these investigations.

Comment 5

The petitioners and Bethlehem argue that adjustment to ISCOR's financial statements to reflect its use of a replacement cost inflation factor is improper. They also quote from ISCOR's annual reports and various financial and trade journals which suggest that investments in steel in general, and in ISCOR in particular, were not prudent in the period 1974 to 1980.

DOC Position

ISCOR's use of the replacement cost inflation factor in its accounts is a conservative accounting procedure. It understates the firm's profits relative to other firms not using the system. Therefore, in order to place ISCOR's performance in its proper perspective, an adjustment must be made. When that adjustment is made, ISCOR's profits, while not high, are in a range that could be expected to attract certain investors.

The quotations supplied are not sufficient to demonstrate that investment in ISCOR by the government was unreasonable. We do not find the government's purchases of equity in ISCOR to be based on terms inconsistent with commercial considerations.

Comment 6

The Five suggest that before evaluating ISCOR's performance, we should restate it by using a 15-year (the number of years over which we allocate grants) amortization base for depreciating the company's assets.

DOC Position

Other than the adjustment for the inflation factor, there is nothing about ISCOR's accounting principles that suggests that we should make further adjustments before we evaluate the commercial reasonableness of the government's equity participation.

Comment 7

U.S. Steel cites the eight years in which ISCOR did not pay taxes as proof of its unprofitable condition.

DOC Position

We have found that ISCOR's non-payment of taxes in those years was not related to poor profit performance, but instead to significant write-offs for major capital expenditures made during the early and mid-seventies. These write-offs can be carried forward until exhausted. They are not preferential under South African tax law.

Comment 8

The petitioners argue that the government's ownership of ISCOR provides an implied guarantee of all the company's loans.

DOC Position

Government ownership of a firm does not implicitly guarantee the debt of the firm, and thus does not confer *per se* a bounty or grant. Where ISCOR's loans *were* guaranteed by South African government, we found that those guarantees did not allow the company to obtain loans at interest rates lower than if the loans had not been guaranteed.

Comment 9

The Five argue that the benefit received in a homelands region by one of ISCOR's subsidiaries is a bounty or grant affecting ISCOR's steel production.

DOC Position

The subsidiary located in the homeland does not manufacture these steel products or produce any inputs for them. The steel that it handles is not exported to the United States. Therefore, the benefits received by the subsidiary do not constitute a bounty or grant on steel exports to the United States.

Comment 10

The Five disagree with our finding that ISCOR and Highveld did not benefit from a program involving pre- and post-shipment financing.

DOC Position

The petitioners did not supply us with any information that suggests that our verification was inadequate with regard to this program. As stated above we found that neither ISCOR nor Highveld received, or were carrying on their books, loans under this program during the period for which subsidization is being measured.

Comment 11

Petitioners allege that employee training allowances are provided only to specific groups of industries and not to all; therefore, training benefits are countervailable. Further, the petitioners argue that even if the benefits of this program are available to all, they are still bounties or grants.

DOC Position

The Department finds that the training benefits are available to any industry or group of industries on an equal basis and that the present participation in the program demonstrates this general availability. Eligibility requirements do not limit the benefits of the program to particular companies or industries. Any corporation which sets up a qualified training program is eligible for the 200 percent tax deduction. These training programs are generally available on equal terms to all companies. As explained in Appendix 2, our interpretation of the Act and past practice is that generally available benefits are not bounties or grants. Since we determine that this program is generally available, we find it does not confer countervailable benefits under the Act.

Comment 12

Bethlehem alleged that the effect of South African labor legislation is to subsidize labor costs in key industries, one of which is the iron and steel industry.

DOC Position

South African labor legislation is part of a system which is applicable to the economy as a whole. Governmental domestic programs which are adopted on a broad scale and without the intent or effect of promoting a specific enterprise or industry or group of enterprises or industries, do not constitute a bounty or grant within the meaning of section 771(5)(B) of the Act, as applied under sections 103(b) and 303(1)(B) of the Act. See Appendix 2.

Respondent's Comments

Comment 1

ISCOR maintains that when placing its accounts on a purely historical accounting system we should recognize that they currently use LIFO instead of FIFO and make an appropriate adjustment.

DOC Position

In adjusting ISCOR's financial statements to reflect historical cost, we added back the replacement cost inflation factor to profits. We did not add back the LIFO adjustment proposed by ISCOR because the adjustment to LIFO is a generally accepted accounting practice used by many companies using historical cost accounting.

Comment 2

Highveld argues that its receipt of tax benefits under Category D of the export incentive scheme is not a bounty or grant because they are received after the sale is made. They affect the profits and dividend policy of the company and not the price at which steel is sold.

DOC Position

For programs involving income tax benefits, the Department generally determines the value of the bounty or grant by the value of the benefit received during the period for which subsidization is being measured. In this case, the measure of the benefit is the deduction received for 1980 marketing expenses, which is known and accounted for in 1981.

In addition, major issues common to all or most of the countervailing duty investigations involving certain steel products are discussed in Appendices 2 and 4 attached to the notice of "Final Affirmative Countervailing Duty Determinations, Certain Steel Products from Belgium".

Verification

In accordance with section 776(a) of the Act, we verified the data relied upon in our final determinations. During this verification, we followed standard procedures, including inspection of documents, discussions with government officials and on-site inspection of manufacturers' operations and records.

Suspension of Liquidation

The suspension of liquidation ordered in our preliminary determinations shall remain in effect until further notice. The net bounty or grant for each company and each product is as follows:

For Products Exported Before April 1, 1982 and Entered, or Withdrawn from Warehouse, for Consumption on or after the Date of Publication of This Notice

Manufacturer/producer/exporter	Ad valorem rate (percent)
ISCOR:	
Carbon steel structural shapes	15.1
Hot-rolled carbon steel plate	13.1
Hot-rolled carbon steel sheet	13.0
Cold-rolled carbon steel sheet	11.8
Galvanized carbon steel sheet	9.9
Hot-rolled carbon steel bars	6.7
Hot-rolled alloy steel bars	6.7
Cold-formed carbon steel bars	6.7
Highveld:	
Carbon steel structural shapes	12.1
Hot-rolled carbon steel plate	12.1
All Others:	
Carbon steel structural shapes	15.1
Hot-rolled carbon steel plate	13.1
Hot-rolled carbon steel sheet	13.0
Cold-rolled carbon steel sheet	11.8
Galvanized carbon steel sheet	9.9
Hot-rolled carbon steel bars	6.7
Hot-rolled alloy steel bars	6.7
Cold-formed carbon steel bars	6.7

For Products Exported on or after April 1, 1982 and Entered, or Withdrawn from Warehouse, for Consumption on or after the Date of Publication of This Notice

Manufacturer/producer/exporter	Ad valorem rate (percent)
ISCOR: [1]	
Carbon steel structural shapes	0.0
Hot-rolled carbon steel plate	0.0
Hot-rolled carbon steel sheet	0.0
Cold-rolled carbon steel sheet	0.0
Galvanized carbon steel sheet	0.0
Hot-rolled carbon steel bars	0.0
Hot-rolled alloy steel bars	0.0
Cold-formed carbon steel bars	0.0
Highveld: [2]	
Carbon steel structural shapes	0.0
Hot-rolled carbon steel plate	0.0
All Others:	
Carbon steel structural shapes	0.0
Hot-rolled carbon steel plate	0.0
Hot-rolled carbon steel sheet	0.0
Cold-rolled carbon steel sheet	0.0
Galvanized carbon steel sheet	0.0
Hot-rolled carbon steel bars	0.0
Hot-rolled alloy steel bars	0.0
Cold-formed carbon steel bars	0.0

[1] The total bounty or grant that ISCOR received on steel products shipped after April 1, 1982 is 0.35 percent *ad valorem*. We consider this rate to be *de minimis*.
[2] The total bounty or grant that Highveld received on steel products shipped after April 1, 1982 is 0.16 percent *ad valorem*. We consider this rate to be *de minimis*.

As required by section 706(a)(3) of the Act, cash deposits of estimated countervailing duties in the amounts specified above of the f.o.b. invoice prices shall be required on shipments of the subject products entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice.

The Department intends to complete an administrative review of these determinations and orders under section 751 of the Act.

These determinations and orders are published in accordance with sections 705(d) and 706(a) of the Act.

Dated: August 23, 1982.

William T. Archey,

Acting Assistant Secretary for Trade Administration.

[FR Doc. 82-23877 Filed 8-31-82; 8:45 am]

BILLING CODE 3510-25-M

Final Affirmative Countervailing Duty Determinations: Carbon Steel Structural Shapes, Hot-Rolled Carbon Steel Plate, and Hot-Rolled Carbon Steel Bar From the United Kingdom; and Final Negative Countervailing Duty Determination: Cold-Formed Carbon Steel Bar From the United Kingdom

AGENCY: International Trade Administration, Commerce

ACTION: Final Affirmative Countervailing Duty Determinations and Final Negative Countervailing Duty Determination: Certain Steel Products from the United Kingdom.

SUMMARY: We have determined that certain benefits that constitute subsidies within the meaning of the countervailing duty law are being provided to two manufacturers, producers, or exporters in the United Kingdom of carbon steel structural shapes, hot-rolled carbon steel plate, and hot-rolled carbon steel bar, British Steel Corporation and Brymbo Steel Works, Ltd. We have found that certain manufacturers, producers, or exporters of these products have received zero or *de minimis* benfits, and have therefore excluded them from the determination. We have determined that manufacturers, producers, and exporters of cold-formed carbon steel bar in the United Kingdom are not receiving such benefits. The estimated net subsidy for each firm and for each product is indicated under the "Suspension of Liquidation" section of this notice. The U.S. International Trade Commission (ITC) will determine within 45 days of the publication of this notice whether these imports are materially injuring, or threatening to materially injure, a U.S. industry.

EFFECTIVE DATE: September 7, 1982.

FOR FURTHER INFORMATION CONTACT: Vincent P. Kane, Office of Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230, Telephone: (202) 377-5414.

SUPPLEMENTARY INFORMATION:

Final Determinations

Based upon our investigations, we have determined that certain benefits that constitute subsidies within the meaning of section 701 of the Tariff Act of 1930, as amended (the Act), are being provided to manufacturers, producers, or exporters in the United Kingdom of certain steel products, as described in the "Scope of Investigations" section of this notice. The following programs are found to confer subsidies:

- Public dividend capital and new capital.
- National Loans Fund loans and loan conversions.
- Industrial investment loans from the European Coal and Steel Community (ECSC).
- Loans from the European Investment Bank (EIB).
- Regional development grants.
- Interest relief grants.

- Iron & Steel Industry Training Board grants.
- Export Credit Guarantee Department loans.
- Industrial and Commercial Finance Corporation (ICFC) loans.
- Preferential rail rates.

The net subsidy is indicated for each firm and product in the "Suspension of Liquidation" section of this notice.

Case History

On January 11, 1982, we received petitions from United States Steel Corporation; Bethlehem Steel Corporation; and Republic Steel Corporation, Inland Steel Company, Jones & Laughlin Steel, Inc., National Steel Corporation, and Cyclops Corporation (the Five), filed on behalf of the U.S. industry producing carbon steel structural shapes and hot-rolled carbon steel plate. The Five also filed on behalf of the U.S. industry producing hot-rolled carbon steel bars and cold-formed carbon steel bars. The petitions alleged that certain benefits that constitute subsidies within the meaning of section 701 of the Act are being provided, directly or indirectly, to the manufacturers, producers, or exporters in the United Kingdom of the steel products listed above. Bethlehem Steel Corporation and the Five also alleged that "critical circumstances" exist, as defined in section 703(e) of the Act. We found the petitions to contain sufficient grounds upon which to initiate countervailing duty investigations, and we initiated such investigations on February 1, 1982 (47 FR 5748).

Since the United Kingdom is a "country under the Agreement" within the meaning of section 701(b) of the Act, injury determinations are required for these investigations. Therefore, we notified the ITC of our initiations. On February 26, 1982, the ITC determined that there is a reasonable indication that imports of carbon steel structural shapes, hot-rolled carbon steel plate, hot-rolled carbon steel bar, and cold-formed carbon steel bar are materially injuring, or threatening to materially injure, a U.S. industry.

We presented questionnaires concerning the allegations to the Delegation of the Commission of the European Communities and to the government of the United Kingdom in Washington, D.C. On April 30, 1982, we received responses to the questionnaires. Supplemental responses were received on May 17, 1982. On June 10, 1982, we issued our preliminary determinations in these investigations (47 FR 26343). These stated that the government of the United Kingdom was providing British manufacturers, producers, or exporters of certain steel products with benefits that constitute subsidies. The programs preliminarily determined to bestow countervailable benefits were:

- Public dividend capital and new capital.
- National Loans Fund loans and loan forgiveness.
- Government guaranteed loans.
- Regional development grants.

Scope of the Investigations

The products covered by these investigations are:

- carbon steel structural shapes.
- hot-rolled carbon steel plate.
- hot-rolled carbon steel bars.
- cold-formed carbon steel bars.

The products are fully described in Appendix 1, which appears with the notice of "Final Affirmative Countervailing Duty Determinations: Certain Steel Products from Belgium" in this issue of the **Federal Register.**

The only known British producers of the subject merchandise exported to the United States are listed below, together with their corporate fiscal year ends and the products under investigation that they produced and exported to the United States. The period of review is the most recent fiscal year for which information is available.

BRITISH PRODUCERS OF SUBJECT MERCHANDISE

Company	End of fiscal year	Products			
		Structurals	Plate	HR bar	CF bar
Bar Bright Usam	December 31				X.
Bedford Steel, Ltd	November 30			X	X.
Brasway Bright Bar	April 30				X.
Bright Steel, Ltd	December 31				X.
British Steel Corporation (BSC)	March 31	X	X	X	
Brymbo Steel Works, Ltd	December 31			X	
Darlington-Simpson Rolling Mills	March 31	X			
Dudley Port Rolling Mills, Ltd	June 30	X		X	
Eaton & Booth, Ltd	December 31	X		X	
Exors of James Mills, Ltd	December 31				X.
Flather Bright Steel, Ltd	March 31				X.
Glynwed Steels, Ltd	December 31			X	X.
Riveton Park Steel & Wireworks, Ltd	May 31				X
Lee Bright Bars, Ltd	September 30				X.
London Works Steel Co., Ltd	March 31			X	
Round Oak Steel Works, Ltd	March 31			X	X.
Spencer Clark Metal Industries, PLC	September 30	X		X	

Analysis of Programs

In their responses, the government of the United Kingdom and the Delegation of the Commission of the European Communities provided data for the applicable periods. Additionally, we received information from the firms listed.

Throughout this notice, general principles and conclusions of law applied by the Department of Commerce to the facts of the current investigations concerning certain steel products are described in detail in Appendices 2–4, which appear with the notice of "Final Affirmative Countervailing Duty Determinations: Certain Steel Products from Belgium" in this issue of the **Federal Register.** Unless otherwise noted, we allocated each compay's countervailable benefits as follows:

Where untied benefits were provided to a company, they were allocated over the revenue of that company; and

Where benefits were provided directly to specific divisions producing products under investigation, they were allocated over the revenue of that division.

Based upon our analysis of the petitions, responses to our questionnaires, our verification, and oral and written comments from interested parties, we determined the following:

Programs Determined To Confer Subsidies

We have determined that subsidies are being provided to producers in the

United Kingdom of carbon steel structural shapes, hot-rolled carbon steel plate, and hot-rolled carbon steel bars. We have determined that subsidies are not being provided under these programs to producers of cold-formed carbon steel bars.

A. *Equity Investment in BSC.* BSC was established by Parliament on March 22, 1967, under the provisions of the Iron and Steel Act of 1967. The 1967 Act combined 14 steel companies, creating the nationalized British Steel Corporation. The British government reimbursed stockholders of record at the time the companies were merged and absorbed the debts of the individual companies. The bulk of the debt was converted to government equity under the provisions of the Iron and Steel Act of 1969, which also authorized government payments to BSC.

Authority for the government to make payments to BSC was renewed in the Iron and Steel Act of 1975. Section 18(1) of this Act provided that "the Secretary of State may, with the approval of the Treasury, pay to the British Steel Corporation such sums as he thinks fit." In nine of the 15 years of its existence, the corporation has received such payments, known as public dividend capital or new capital (PDC or NC), from the government.

IN 1972 and in 1981 Parliament directed that portions of its capital investment be credited to accumulated revenue deficit. Neither of these transactions altered the potentially countervailable benefit of the original PDC or NC infusions. Two additional equity investments were made in 1972 and in 1981 when certain government loans were converted into equity.

As described in Appendix 2, the treatment of government equity investment in a company hinges essentially on the soundness of the investment. If the government investment was reasonably sound at the time it was made, we do not consider it a subsidy. If, on the contrary, the investment appears unsound, a subsidy may exist.

For the preliminary determinations we used the strength of BSC as reflected in its operating results as our primary criterion for evaluating the soundness of the U.K. government's investment in BSC. Operating results were defined as net income before interest costs.

Since the preliminary determinations, we have done additional analysis, primarily considering BSC's cash flow from operations, including interest but excluding grants. The analysis also included computing BSC's current assets divided by current liabilities (current ratio).

On the basis of these tests, we have reevaluated BSC's financial strength for the purpose of determining whether BSC represented a sound investment at the time that each equity investment was made by the U.K. government. Investment in BSC was considered inconsistent with commercial considerations from fiscal year 1977/78 through 1981/82.

Since we have determined that BSC was not a sound investment from April 1977 through March 1982, we examined the government's equity infusions during this period to determine whether they bestowed a subsidy. As described in greater detail in Appendix 2, we compared the rate of return the government received on its equity investment in BSC in a given year with the average rate of return on equity investment in the United Kingdom for that year, as estimated by the average earnings yield on U.K. industrial shares. BSC's return was measured by its net earnings (or losses) divided by owner's equity. During this period BSC's losses were large, resulting in substantial negative returns on owner's equity.

Comparing the average return with BSC's large negative return yielded an amount exceeding the amount we would have calculated had we treated the public dividend capital or new capital payments as outright grants rather than as equity. Consequently, we have limited the subsidy to the 1981/82 amount that would result if the equity investments were treated as grants. (See grants and equity methodologies described in Appendix 2.) Allocated over all BSC revenues, the subsidy amount for public dividend capital and new capital in the 1981/82 fiscal year was found to be 15.88 percent *ad valorem*.

For reasons described in Appendix 2, we allocated the subsidies arising from funds for loss coverage exclusively to the year during which they were received. The remainder of the subsidy was allocated using the equity methodology. Thus, subsidies from equity infusions in years in which BSC sustained losses were reduced. The allocation of funds to cover losses explains in part the significant difference between the preliminary and the final *ad valorem* subsidy rates attributable to equity infusions in BSC.

Payments of PDC and NC in excess of loss coverage from operations in the years 1977/78 to 1981/82 were treated as equity infusions inconsistent with commercial consideration and analyzed using the equity methodology. We determine that 9.75 percent of the 15.88 percent final *ad valorem* subsidy rate was due to such excess payments made through 1981/82; the remaining 6.13 percent is due to PDC received for loss coverage in 1981/82.

Extension of the period when investments were viewed as consistent with commercial considerations was also a factor in reducing the final subsidy rate. Another factor was the allocation of the subsidy amount for equity infusions over corporate revenue rather than the value of steel production. Finally, the use of verified 1981/82 information, the most recent data available for BSC, further reduced the rate.

B. *The National Loans Fund (NLF).* The NLF is a depository of money raised through government borrowings. Lending from the NLF is not generally available, but is limited to nationalized British companies. (Therefore, British Independent Steel Producer Association members (BISPA producers) do not qualify for NLF loans.) BSC was expressly authorized to borrow from NLF's predecessor fund (the Consolidated Fund) by the Iron and Steel Act of 1967, and from the NLF by the Iron and Steel Act of 1975.

Petitioners alleged that BSC was uncreditworthy. Based upon similar criteria used to determine whether equity infusions in BSC were consistent with commercial considerations, we have determined that BSC was creditworthy from its formation through its fiscal year 1976/77, and was uncreditworthy for fiscal years 1977/78 through 1981/82. As explained in Appendix 2, it is therefore necessary to consider whether the NLF loans were made to BSC during the period of creditworthiness or the period of uncreditworthiness.

During its creditworthy period (through March 1977), BSC received loans in substantial amounts from the NLF. If these loans had remained outstanding in fiscal year 1981/82, then we would have applied the methodology described in Appendix 2 for loans to companies considered creditworthy. However, all outstanding loans from the NLF were converted into equity: £ 150 million in 1971/72, and £ 509 million in 1981/82. We treated each conversion as an additional equity investment.

Since the first conversion occurred during the period in which we consider equity infusions to be consistent with commercial considerations, it does not confer a subsidy. Since the second conversion was made during the period that we consider equity infusions to be inconsistent with commercial considerations, it potentially confers a subsidy. Using the equity methodology described in Appendix 2, we determined

that a subsidy was in fact conferred. Pursuant to Appendix 2, we used the grants methodology to calculate the subsidy, since our comparison of rates of return for 1981/82 under the equity methodology resulted in a larger amount than if we had treated the 1981/82 conversion as an outright grant. Upon this basis, we calculated a subsidy for BSC of 2.21 percent *ad valorem.*

We note that our loss coverage allocation methodology does not apply to the 1981/82 conversion since there was no infusion of cash at that time.

C. *Industrial Investment Loans from the European Coal and Steel Community (ECSC).* For the reasons described in Appendix 3, we determine that ECSC industrial investment loans confer a subsidy insofar as they offer preferential interest rates to U.K. steel companies. BSC has received ECSC industrial investment loans.

As explained above and for the reasons described in Appendix 2, we considered loans made to BSC during its creditworthy period separately from loans made during its uncreditworthy period. We quantified the amount of the subsidy on loans made prior to April 1977 using the methodology described in Appendix 2 for loans to companies considered creditworthy. The commercial rate selected for comparison with the interest rate on ECSC loans (the period of which ranged from 5 to 20 years) was, for BSC, an average rate on 20-year industrial debentures. The debentures were chosen as being the most typical source of long-term debt for private British firms. For loans made on and after April 1, 1977, we quantified the subsidy to BSC using the methodology described in Appendix 2 for loans to companies considered uncreditworthy for purposes of these investigations. For the 1981/82 fiscal year, the subsidy arising from ECSC loans was 0.26 percent *ad valorem* for BSC.

D. *Loans from the European Investment Bank (EIB).* For the reasons described in Appendix 3, we determine that EIB loans are countervailable because they are, by charter, regional in character and thus preferential. From October 1973 through December 1977, BSC received eighteen EIB loans. Since we are treating BSC as creditworthy from March 1967 through March 1977, we have quantified the benefit to BSC from EIB loans made prior to April 1977 using the methodology described in Appendix 2 for loans to companies considered creditworthy. The commercial rate selected for comparison with the rates on EIB loans (the period of which ranged from 5 to 18 years) was an average rate on 10-year industrial debentures. For loans made on or after April 1, 1977, we calculated the benefit from EIB loans using the methodology described in Appendix 2 for loans to companies considered uncreditworthy for purposes of these investigations. On these bases, we calculated a subsidy amount of 0.59 percent *ad valorem* for fiscal 1981/82 on each of the products under investigation produced by BSC.

The BISPA producers did not receive EIB loans.

E. *Regional Development Grants (RDG's).* The Industry Act of 1972 established an RDG incentive program with the goal of eliminating certain social problems in specified regions of the United Kingdom. RDG's are not made generally available in the United Kingdom, but rather are available only to designated manufacturing sectors (*e.g.*, metals manufacture) and to "special development" and "development" regions. Therefore, we find the RDG program to be preferential in nature and to confer subsidies within the meaning of section 771(5) of the Act.

The Secretary of State for Industry, with the approval of the Treasury, is authorized to determine the activities that qualify for grants and the conditions of each grant. The grants are made toward the cost of capital expenditures on new buildings or works in development areas, the adaptation of existing buildings on qualifying premises in development areas, and new machinery and plants for use in qualifying premises in development areas. The grants pay for a fixed percentage of the cost for specific capital assets, depending on the type of region for which they are designated. The amount of a grant in a "development" area is 15 percent, and in a "special development" area 22 percent, of the capital asset. Grants are provided only after the asset has been purchased or the expenditure on it is incurred. We find these grants to be "tied" to (*i.e.*, bestowed expressly to purchase) specific capital assets.

In each case, the individual grants were for less than $50 million. In accordance with the methodology described in Appendix 2, we are therefore allocating them over 15 years. We calculated subsidy amounts as follows:

Company	Percent ad valorem
BSC	1.32
Bright Steels, Ltd.	0.26
Brymbo Steel Works, LTD.	1.88
Darlington & Simpson Rolling Mills, Ltd.	0.04
Glynwed Steels, Ltd.	0.02
Lee Bright Bars, Ltd.	0.07
Spencer Clark Metal Industries, Ltd.	0.07

We note that in our preliminary determinations we attributed RDG's to Lee Bright Bars, Ltd., and Riveton Park Steel & Wireworks, Ltd. Upon verification, we determined that neither company received RDG's, and that Lee Bright Bars, Ltd., producing cold-formed carbon steel bar, received RDG's.

F. *Interest Relief Grants.* During our verification, we found that Eaton & Booth, Ltd., had received an Interest Relief Grant. The interest relief program appears to be distinct from any of the other subsidies alleged and investigated. It is administered similarly to the RDG program, with grants being provided to offset interest charges on loans used to purchase capital equipment. Verification showed that no other firm received such grants. To the best of our knowledge, the qualifying criteria are similar to those for RDG's. Accordingly, we quantified the benefit in the same manner as for RDG's, which results in a subsidy in the amount of 0.03 percent *ad valorem* for Eaton & Booth.

G. *The Iron and Steel Industry Training Board (ISITB).* There are 24 industry training boards in the U.K. The ISITB sponsors various training programs aimed at maintaining the nation's pool of skills required by the iron and steel industry and increasing employee job versatility in the event that present employment is terminated. The Board receives annual levies of up to one percent of payroll from iron and steel producers and makes grants to those companies required by the government to conduct training programs. The grants normally are insufficient to cover the costs incurred by the companies providing the training. BSC received several training grants under this program.

Since the training may benefit BSC's employees in their employment with BSC, we have found the grants to be countervailable. Because the grants were less than 1 percent of revenue and were expensed in year of receipt, we considered only the grants received in 1981/82. Using this methodology, we calculated a subsidy of 0.01 percent *as valorem* for BSC.

H. *Export Credit Guarantee Department (ECGD) Loans.* The ECGD makes fixed rate loans only to exporters at public expense. Verified information indicates that only Bar Bright-Usam received these loans. Comparing the rate on its commercial loans with the ECGD export loans, we determined Bar Bright-Usam receives a subsidy of 0.05 percent *ad valorem.*

I. *Industrial and Commercial Finance Corporation (ICFC) Loans.* Several BISPA producers received ICFC loans

from the ECSC. These loans were medium-term loans at fixed rates which were found to be preferential when compared to rates on loans from normal commercial sources available to these producers. Both Eaton and Booth, Ltd., and Lee Bright Bars, Ltd., received loans for equipment used in the production of products under investigation. The subsidy benefits to Eaton and Booth, Ltd., and Lee Bright Bars, Ltd., were 0.09 and 0.02 percent *ad valorem*, respectively.

Spencer Clark Metal Industries, Ltd., received an ICFC loan for equipment in a plant that only produced an alloy product which was not subject to these investigations. Therefore, this loan did not provide a countervailable benefit.

J. *Preferential Rail Rates.* Petitioners alleged that BSC and BISPA producers receive transport assistance in the form of preferential rail rates charged by British Rail, a government-owned corporation. In response to our questionnaire, the government stated that no rate differentials exist between the rate charged for public transport provided to BSC and general users, and that BISPA producers do not use British Rail. The government also responded that no private transport firms have been subsidized for service rendered to BSC or BISPA producers. The latter point was confirmed on verification.

However, British Rail refused to allow us to examine freight contracts if had negotiated with customers other than BSC. Although it offered to supply a sworn statement confirming the government's response, we have determined that such a statement would not adequately satisfy the verification requirements of section 776(a) of the Act. Consequently, in the absence of verified informantion and in light of British Rail's refusal to cooperate, we must use as best information available the comparison of British Rail rates charged for freight traffic to all users as set forth in British Rail's 1981 annual report to the changes made to BSC for its freight traffic. Based on this comparison, we determined that BSC received a subsidy of 0.07 percent *ad valorem* from preferential rail rates.

II. Programs Determined Not To Confer Subsidies

We have determined that subsidies are not being provided under the following programs to manufacturers, producers, or exporters in the United Kingdom of carbon steel structural shapes, hot-rolled carbon steel plates, hot-rolled carbon steel bars, and cold-formed carbon steel bars.

A. *The British Government Redundancy Fund.* Redundant workers in the United Kingdom (those who have lost jobs due to plant closures or reductions in capacity) receive a redundancy payment that in 1981 averaged about L1,100 per worker. Fifty-nine percent of the payment is borne by the employer and forty-one percent by the government. Since the Redundancy Fund is available and used for the benefit of all employees made redundant, and since it is not restricted to particular sectors of the economy or regions of the country, we have determined that payments from the fund do not constitute a subsidy.

We have received no information from which we can conclude that the ECSC assists BSC or other British steel producers with contributions to redundant workers.

B. *Temporary Short-Time Working Compensation Scheme (TSTWCS).* When employees in any industry are forced to work less then full time because of threatened plant closures or reduction in capacity, they may receive compensation from the government through the TSTWCS. The scheme encourages employers to place workers on short time rather then make them redundant. The scheme is applied generally and is not restricted to workers in a particular industry, sector, or region. Consequently, we find that the scheme does not result in a subsidy to steel producers.

The possibility that the steel companies may be required by union contract to employ workers for a minimum number of hours and therefore may derive a benefit from the scheme was examined during verification. We found no evidence during verification that the TSTWCS relieved BSC or other producers from any statutory or contractual obligations to its workers.

C. *Assistance to the Coal Industry.* In our preliminary determinations, we found that subsidies to U.K. coal producers did not bestow a countervailable benefit upon the production, manufacture, or exportation of U.K. steel.

Between the preliminary determinations and these final determinations, we have analyzed and verified aspects of the U.K. coal subsidy program as it applies to steel. Based upon the verified information in the records of these investigations, we find that this program does not confer a countervailable benefit on U.K. steel producers for the following reasons.

Benefits bestowed upon the manufacturer of an input do not flow down to the purchaser of that input if the sale is transacted at arm's-length. In an arm's-length transaction, the seller generally attempts to maximize its total revenue by charging as high a price and selling as large a volume as the market will bear.

These principles apply to U.K. coal sales as follows. We find that the price charged for U.K. coal does not undercut the market price. Absent special circumstances warranting a contrary conclusion, then, U.K. steel producers apparently do not benefit from U.K. coal subsidies as long as the price for U.K. coal does not undercut the market price.

Further consideration is warranted, however, for one special circumstance. The National Coal Board and BSC are owned by the U.K. government. The issue arises whether transactions between them are conducted on an arm's-length basis. We do not believe that government ownership *per se* confers a subsidy, or that common government ownership of separate companies necessarily precludes arm's-length transactions between them. In determining whether coal sales between government-owned coal and steel producers appear to have been consummated on arm's-length terms, two factors are relevant: (1) whether the government-owned coal producer sold to the government-owned steel producers at the prevailing market price, and/or (2) whether the government-owned coal producer sold coal at the same prices to steel producers not owned by the government. We found that the NCB did charge the prevailing market prices. On this basis, we conclude that coal subsidies were not conferred on U.K. steel producers as a result of government ownership

Based upon the above considerations, we determine that U.K. coal subsidies do not confer upon U.K. steel producers a subsidy within the meaning of the Act.

D. *Electricity Generating Boards.* The electricity generating boards operate without government assistance. BSC and the BISPA producers purchase electric power from the boards on an arm's-length basis, paying the same rates as other large industrial users. Therefore, we determine that no subsidies are being conferred on steel production through preferential electric power rates.

E. *Research and Development Grants from the ECSC.* BSC and Round Oak Steel Works, Ltd., received research and development grants from the ECSC. For the reasons described in Appendix 3, we determine that these ECSC research and development grants are not countervailable.

F. *Export Credit Guarantee Department (ECGD) Insurance and Guarantees.* The ECGD insures exporters against non-payment by

overseas buyers by guaranteeing bank loans needed to finance export sales made on credit. Premium payments are collected for these services and the ECGD is required by the government to operate at no cost to public funds. In our preliminary determinations, we said that BISPA producers and BSC did not purchase ECGD services. During verification we found that several BISPA producers did purchase ECGD insurance. Since the rates paid by these producers were substantial and since we found upon verification that the ECGD was operating with a reserve (i.e., that the rates were sufficient to cover all long-term costs and expenses of the program), we determine that no subsidy was conferred.

G. *Manpower Services Commission.* The Manpower Services Commission provides employment services for the entire working population. Its services include aid for the employment of the disabled, and transfer allowances to the unemployed who must relocate to find work. The Manpower Services Commission also provides a range of training courses for the unemployed under the Training Opportunities Scheme. Arrangements can be made under the scheme to allow workers faced with redundancy to begin training for a new job before they have been discharged. BSC and the BISPA producers have indicated that they have received no financial aid under Manpower Services Commission programs.

However, during verification we found that the Manpower Services Commission contributed through industry training boards to apprentice training grants, which were received by steel producers. Since the apprentice training program was generally available and used by all sectors, we determined that it did not confer a subsidy.

H. *Iron and Steel Employees Readaptation Benefit Scheme (ISERBS).* Under Article 56 of the Treaty of Paris, the ECSC provides matching grants to member states under the Iron and Steel Employees Readaptation Benefit Scheme, which assists unemployed steelworkers. We verified that BSC and some BISPA producers have received benefits under the ISERBS program, and that these funds have been provided after workers were permanently released from the iron and steelmaking divisions of each company's workforce.

Assistance under the program takes several forms, including the reemployment and retraining of steelworkers for jobs outside the U.K. iron and steel industry and, for workers over 55, pensions that are paid in addition to benefits provided through a company's own retirement program. Basically, these benefits are used to permanently remove workers from the U.K's iron and steel industry. We find that benefits received by BSC nd BISPA producer workers under this program do not constitute a subsidy to steel producers within the meaning of the Act because the goal of this program is to reemploy redundant workers in sectors other than steel. At the same time, verified information indicates that this program does not relieve employers of any statutory or collective bargaining agreement obligations. As a result, the ISERBS program does not constitute a benefit with respect to the manufacture, production, or exportation of the products under investigation.

I. *Producers Related to BSC.* We have determined that subsidies are not being provided to three BSC subsidiaries—Round Oak, Flather Bright, and London Works—through the provision of concessional financing or low-priced material inputs by BSC. In our preliminary determinations, we published rates based on what appeared to be low-interest loans from BSC to Flather Bright and London Works. Verification and respondents' briefs have demonstrated that in fact no such loans occurred, and that the transactions between BSC and the three firms were on a commercial basis. Further, we have determined that the firms did not buy raw materials, either semi-finished steel or hot-rolled carbon steel bars, from BSC at prices lower than those available to other unrelated purchasers, and that the three firms in question could and did buy such raw materials from other unrelated sellers at the same or lower prices. None of the three firms received funds directly from the government. Therefore, we have determined that the firms have not received countervailable benefits of any kind.

J. *Dollar Bond Issues.* Bonds denominated in U.S. currency issued by BSC were sold on the world market during 1974. The bonds were guaranteed by the British government. Based upon our comparison of the Dollar Bond interest rates and the benchmark rates, we determined that no subsidy was conferred by virtue of the government guarantee.

III. Programs Determined Not To Be Used

We have determined that the following programs that were listed in the notice of "Initiation of Countervailing Duty Investigations of Certain Steel Products From the United Kingdom" are not used by the manufacturers, producers, or exporters in the United Kingdom of carbon steel structural shapes, hot-rolled carbon steel plate, hot-rolled carbon steel bars, and cold-formed carbon steel bars.

A. *Research and Development Grants from the British Government.* Verified information indicates that no research and development funds have been granted by the British government with respect to the products currently under investigation.

B. *ECSC Loan Guarantees.* Neither BSC nor the BISPA producers received loan guarantees from the ECSC.

C. *ECSC Worker Housing Loans.* In our preliminary determinations we stated that we would seek further information as to whether and to what extent BSC or BISPA producers or their employees received ECSC worker housing loans. There is no evidence that these loans have been paid to BSC or BISPA producer for disbursement to their workers, nor did we find any evidence that these loans have been paid directly to BSC or BISPA producer workers. Therefore, we find that these loans confer no benefit on the producers of products under investigation in the United Kingdom.

Petitioners' Comments

Comment Number 1

All petitioners argue that we should regard BSC as uncreditworthy since its formation in 1967/68 to the present. As evidence, they point to the condition of the 14 companies that in 1967 were joined to form BSC, and to the extensive need for rationalization.

A petitioner states that the British government could have obtained a higher return elsewhere at a comparable risk prior to 1975, but chose to invest instead in BSC, and that its investment is therefore inconsistent with commercial considerations. The Department erred in preliminary determining that BSC was creditworthy or a sound investment prior to 1975.

DOC Position

We disagree. For reasons described in detail in the "Equity Investment in BSC" section, we consider BSC to have been creditworthy through 1976/77. The general methodology is explained in Appendix 2.

Comment Number 2

One interested party argues that subsidies bestowed upon BSC for the manufacture or production of hot-rolled carbon steel bar indirectly provide a subsidy to British manufacturers of cold-formed carbon steel bar. The subsidy to BSC allows it to provide hot-rolled bars

at a lower price than it would otherwise offer, and therefore confers a subsidy on users of hot-rolled bars.

Moreover, the situation is unlike that of West German coal (in which the Department concluded that a subsidy on coal was not indirectly conferred on steel producers), in that there is no evidence that hot-rolled bar is sold above world prices in the U.K. Thus, an industry or group of industries, consumers of hot-rolled bar, is benefitting by a subsidy passed on through lower prices.

DOC Position

We disagree that the subsidy on hot-rolled bars leads to a benefit specifically conferred upon an industry or group of industries including the cold-formed bar producers. While the effect of the subsidy to BSC may or may not be to lower its hot-rolled bar prices, the bar is available at the same price to all BSC customers. Any benefit realized by British cold-formed bar producers is also realized by other buyers of hot-rolled bar, both in the United Kingdom and ther countries. Benefits passed on to purchasers are not specific to an industry or group of industries in the United Kingdom.

Further, we verified that cold-formed bar producers can and did purchase hot-rolled bar from producers other than BSC at roughly the same price. Therefore, BSC is not undercutting the market price for hot-rolled bar.

Comment Number 3

Petitioners disagree with the interest rate used by the Department as a benchmark during BSC's creditworthy period, the average yield on 20-year industrial debentures. Petitioners maintain that even if BSC were creditworthy in some years, the industrial debenture rate would be available in the capital market only to firms of unquestionable soundness and solvency. Petitioners contend that the high risk nature of an investment in BSC, assuming it even had access to commercial capital markets, would have forced it to offer yields substantially higher than the benchmark identified by the Department.

One petitioner added that the Department's estimate of the cost of capital for the uncreditworthy period was incorrect. The estimate should be adjusted to reflect more accurately the cost of capital to uncreditworthy companies. A more accurate estimate for determining the cost of capital would be a 2 percent risk premium over the highest rate of interest charged to a creditworthy company in the United Kingdom—19 percent. The proper cost of capital should therefore be at least 21 percent.

Another petitioner contends that our benchmark rates are too low because our reliance upon BSC's actual credit experience at a given time does not account for the fact that the cost of capital to BSC actually depends on the extent of subsidization. Government backing allows BSC to borrow on the open market at lower rates than would exist absent such support. Without government backing, BSC's actual credit experience would not equal any "average" or "national" rate.

For these reasons petitioners urge the Department to add a risk premium to the benchmark rate used to measure the extent to which loans to BSC are preferential.

DOC Position

We disagree. Our reasons for using national benchmarks are explained in Appendix 2.

We note that the second argument asks us to double count a subsidy; petitioner would have us countervail not only the original subsidy, but also the secondary effect of that subsidy. For the reasons indicated in Appendix 2, we disagree with the contention.

Comment Number 4

Petitioners contend that we erred in finding that particular programs of general applicability and availability within a country do not give rise to domestic subsidies. They assert that subsidies are conferred by government programs providing benefits, regardless of whether those programs are generally available, and that we are unjustified in interpreting the definition of subsidy contained in section 771(5) of the Act so narrowly.

DOC Position

See Appendix 4.

Comment Number 5

A petitioner asserts that BSC's obligation to make redundancy payments to its workers terminated as a result of the restructuring. A formal indicator of this obligation, according to petitioner, is statute, contract, or actual practice. The government's assumption of this burden reduced BSC's operating expenses, relieved BSC of the need to borrow or secure other funds, and provided the working capital for the firm to continue operations.

DOC Position

We disagree. The redundancy payment scheme, because of its universal application among British industry, is not peculiar to, or a special benefit bestowed exclusively upon, employers or former employees in the iron and steel industry.

Comment Number 6

A petitioner argues that a subsidy necessarily results whenever suppliers extend credit terms to an uncreditworthy company receiving government assistance. These credit terms confer a subsidy because the supplier would not have agreed to them but for the fact that government backing diminishes the risk of lending to an otherwise uncreditworthy enterprise.

DOC Response

We disagree for the reasons set forth in Appendix 2.

Comment Number 7

A petitioner contends that with regard to the provision of Public Dividend Capital (PDC), the conversion of debt to equity mandated by the Iron and Steel Act of 1972 of £ 150 million in NLF loans to BSC during fiscal 1972/73 was clearly on terms inconsistent with commercial considerations. REsultant interest savings were estimated to be £ 13.4 million annually. Also, in 1969, £ 700 million of Commencing Capital Debt to the U.K. Government was converted to equity—Public Dividend Capital. Petitioner argues that this conversion would, in effect, have equaled an interest saving of about £ 145 million per annum had the debt remained in the form of fixed interest debt. Consequently, BSC's profitability was greatly exaggerated. Petitioner also notes that losses would be even greater if we consider that BSC's coal and railway transportation were heavily subsidized. In assessing the government's rate of return on its funding, these subsidies should be subtracted.

DOC Response

We disagree. Petitioner's statement concerning BSC's net income is not based upon BSC's reported results, but rather upon numbers created by petitioner. Specifically, the petitioner restates BSC's reported net income to include an imputed interest charge for BSC's initial capital of £ 700 million and for a conversion of debt to equity of £ 150 million in 1971/72. Neither adjustment is appropriate.

Interest is not paid on equity investments in normal commercial practice.

Even if petitioner's analysis were based upon fact, petitioner's conclusion would not necessarily follow. Profit is only one indication of whether an

investment is consistent with commercial considerations. Investments in companies showing losses are frequently made when investors believe that the future cash flow of the investment warrants the commitment. New companies, restructured companies, and companies that suffer economic vicissitudes could show losses and still represent sound investments.

Comment Number 8

A petitioner claims that political, rather than commercial, considerations determined government funding and management of BSC.

DOC Position

In determining whether an investment was consistent with commercial considerations, we do not investigate the motives underlying the government's action, but rather examine objective financial characteristics of the firm at the time of the investment. These have been described in the "Equity Investment in BSC" section, above. Whether the British government was politically motivated in its actions is not in itself relevant to our determination.

Comment Number 9

A petitioner cited evidence that the British government has granted the Central Electricity Generating Board and BSC substantial subsidies to buy coal from the National Coal Board. The cost to the taxpayer from these coal subsidies was estimated at £ 231 million.

DOC Position

On verification, we found no evidence of British government subsidies to the Central Electricity Generating Board or BSC to buy NCB coal.

Comment Number 10

A petitioner challenges our preliminary determinations regarding several ECSC programs (discussed in Appendix 3) that we determined were not countervailable. We preliminarily determined that these programs are funded by levies paid by ECSC coal and steel producers, and that these funds exceed the cost of the ECSC programs. Accordingly, since the benefits did not exceed the levies, we preliminarily concluded that the benefits were not subsidies. The petitioner argues that: (1) Our factual conclusions as to the extent to which the levies cover the cost of the programs are based on faulty information, (2) our decision not to countervail against the programs because they were funded by producer levies constitutes an illegal offset, and (3) an across-the-board determination that all ECSC benefits are not countervailable fails to account for situations in which a given enterprise or member state receives a benefit that is disproportionate *vis-a-vis* the levies collected from that enterprise or state.

DOC Position

See Appendix 3.

Comment Number 11

One petitioner argues that we should look at the effects of government provisions of funds to BSC, not the motivation behind those provisions. (See Petitioners' Comment Number 10, which argues the contrary point of view.) Moreover, funds used for restructuring and to cover operating losses must be countervailed, for they allowed BSC to maintain export prices at competitive levels, which would have been impossible otherwise.

DOC Position

For reasons stated above, we should not look at the government's motivation for bestowing a subsidy. As indicated in Appendix 2, funds otherwise considered to be a subsidy do not escape such consideration simply because the recipient expended them for loss coverage or restructuring. With the exceptions noted for tied funds such as regional development grants, we believe that the subsidies conferred on BSC benefitted its entire operation, and we have treated the funds accordingly. For example, when a government buys equity in a company, it is providing funds for the corporation as a whole, not for particular divisions or projects.

Comment Number 12

Petitioner claims that BSC's claim that operating losses should be expensed in the year received ignores economic reality. Were it not for government subsidies, firms suffering operating losses would have to borrow funds or sell assets to cover losses. Thus, an operating loss in one year has an effect on the firm in subsequent years in the form of reduced assets or additional interest payments. The petitioner argues that the Department's methodology is not concerned with what was done with funds, but with the difference between what the firm paid for the funds compared with what it would have paid for commercial funds. In addition, operating losses reduce retained earnings, leaving less of an investment reserve in subsequent years. Government funds to cover loss allow retained earnings to be available for future investment.

DOC Position

See Appendix 2.

Comment Number 13

One petitioner alleges that BSC is the recipient of countervailable benefits conferred through transportation services supplied by British Rail by virtue of the fact that British Rail is both subsidized by the government and provides transportation to BSC at rates which do not cover operating costs.

DOC Position

As discussed above, we have concluded that, on the basis of the best information available, the rates British Rail charges BSC are preferential and confer a subsidy. It appears, however, that these rates are the result of active negotiations, which demonstrates that British Rail is otherwise maximizing its rate and is not passing through any subsidy from which BSC might benefit.

Petitioner's allegation that the rail rates charged BSC are below British Rail's operating costs is irrelevant to our investigation. We are concerned with whether a benefit is being conferred upon the British steel industry. Once we examine, as we have, whether BSC receives preferential treatment from British Rail, and whether any subsidy to British Rail is passed through to BSC, our inquiry ends.

Comment Number 14

Petitioner notes that in 1980/81 and in 1981/82, BSC workers received substantial payments from the Iron and Steel Employees Readaptation Benefits Scheme (ISERBS). Petitioner asserts that these payments result in a subsidy, since they relieve BSC from obligations to its redundant workers.

DOC Position

We disagree. The program does not confer a subsidy. Benefits are distributed directly to the redundant workers through regional offices of the U.K. government's Department of Industry, not through BSC. Further verification revealed that ISERBS payments were not required of steel companies as a matter of law, nor was BSC relieved of any obligation to provide similar funds to redundant workers.

Respondent's Comments

Comment Number 1

The British government and BSC challenge our conclusion that investment in BSC in the period from 1975 to the present was on terms inconsistent with commercial considerations. The British government distinguishes between two periods of investment in BSC: (1) from 1973 to 1977,

the capital investment period; and (2) from 1978 to the present, the reorganization period. During both periods, investment funds were allegedly provided fully in accord with industry views of reasonable investment, such as U.S. industry forecasts as late as 1977 that predicted a high steel demand in the mid-1980's. BSC also argues that: (1) The Department's focus on only past earnings as the basis for creditworthiness is unrealistic, (2) the application of more reasonable criteria shows that investment in BSC was commercially reasonable during this period, and (3) even by our criterion, investment in BSC was commercially reasonable in 1975/76 and 1976/77. Most importantly, BSC believes that if a given investment were commercially reasonable at the time it was made, we should conclude that there is no subsidy, rather than judge the reasonableness of the investment with hindsight.

BSC also claims that funds provided for restructuring are not countervailable. It points out that U.S. policy generally supports attempts to restructure. BSC contends that at the very least, funds used for closure and redundancy costs are not countervailable because they do not contribute to the manufacture, production, or export of steel.

DOC Position

We have broadened the criteria for judging whether equity infusions were consistent with commercial considerations to those described in the "Equity Investment in BSC" section. Using these criteria, we have determined that investments in BSC were consistent with commercial considerations through 1976/77. We need not consider the relevance of contemporary industry forecasts to that determination. We also disagree that funds used for closure and redundancy are not countervailable. In measuring a subsidy, we are concerned with the difference between what, if anything, the firm paid for government funds and what it would have paid on the private market. Regardless of their application, consessional funds benefit the firm as a whole. This is the subsidy element; the use that a company makes of a particular infusion of funds is not relevant except in a few carefully defined circumstances.

Comment Number 2

Flather Bright, London Works, and Round Oak argue that should we find zero or *de minimis* margins for them and that they should be excluded from any order that might result from these investigations. They argue that the three firms, while subsidiaries of BSC, are wholly separate from BSC, and therefore could not be used by BSC to avoid the effects of any order. To assure that such avoidance cannot occur, they suggest that the Department may wish to exclude products "produced and sold" by the firms, an exclusion that would not apply to BSC products exported by the firms.

DOC Position

We agree. The firms act autonomously from BSC, and we have determined that they should be excluded because they receive either no subsidy or a *de minimis* subsidy. Since BSC does not produce cold-formed carbon steel bar, there is not possibility of avoidance by transshipment through these firms of this product. The three subsidiaries cannot be used to avoid the order on hot-rolled bars because the BSC rate for hot-rolled bars applies to all merchandise produced or manufactured by BSC, regardless of who exports it. Therefore, we will exclude products produced by Flather Bright, London Works, and Round Oak from any order that may be issued in these investigations.

Comment Number 3

The U.K. Government and BSC maintain that the valuation method used by the Department in its preliminary determinations implicitly allocates subsidies by revenue. They argue that other methods of allocation, particularly by expenditures, provide a more appropriate basis for allocating subsidies.

DOC Position

We disagree. How the Corporation chooses to spend subsidies is in general not of concern in the determination of countervailing duty margins. We are not convinced that an allocation by expenditures approximates the value of the subsidy to BSC's products. Allocation by revenue permits a more definite distribution of subsidy which involves none of the myriad of speculative tracing problems an expenditure distribution would entail and avoids arbitrary decisions as to how specific we must become in determining which expenditures are attributable to specific products.

Comment Number 4

BSC believes that the benchmark rate we used—the national average rate of return for all industrial enterprises in the U.K.—Overstates the expectation of equity investors who invest money in firms in the steel sector. Except in 1974, investment yields in the U.S. iron and steel industry for the years 1969 through 1978 consistently fell below the average return for all U.S. manufacturing. BSC argues that our standard of commercial reasonableness of the government's investment decision is thus one that private investors themselves rarely meet.

DOC Position

The Department's benchmark enables comparison between subsidized companies' performance versus the market average, presumably the government's (or any other reasonable investor's) alternative to investing in subsidized companies.

Comment Number 5

BSC claims that its expenditures for training its employees usually exceeded the amount of grants received from the ISITB. It further contends that the program provided training in excess of what BSC would have provided otherwise to meet its own needs and therefore constitutes a contribution to the nations's pool of skills.

DOC Position

We disagree. Although the training grants were insufficient to cover expenses received in conducting the training programs, the grants partially defrayed training expenses and resulted in a subsidy. Respondent's further contention concerning a contribution to the nation's pool of skills is irrelevant.

Comment Number 6

BSC claims that special sections are a separate class or kind of merchandise and should not be subject to these determinations.

DOC Position

In our "Preliminary Affirmative Antidumping Duty Determinations: Certain Steel Products from the United Kingdom" (47 FR 35668), we indicated that we are considering the establishment in our final determinations of a separate margin for special sections, as a distinct subclass of the class or kind of merchandise called carbon steel structural shapes. For the purpose of these determinations, we have treated, consistent with our preliminary dumping determinations, special sections as the same class or kind of merchandise as structural shapes. Should we determine that they are a distinct subclass of structural shapes, we will publish an amended estimated countervailing duty rate for special sections if that rate would differ from the rate for structural shapes (e.g., for receipt of RDG's by a division

producing only special sections, or by a division producing products other than special sections).

Comment Number 7

BSC believes that the Department's method of valuing loan funds is erroneous because the forgiveness of NLF funds was part of a recapitalization of overvalued assets, and is therefore not countervailable. The 1981 forgiveness should be expensed in the year received. It argues this method would be in accordance with generally accepted accounting principles. It also contends that ECSC and EIB loans are not provided by a government body, are tied to specific assets, and therefore should not be spread over 15 years. Accordingly, such loans should not be treated like equity during the uncreditworthy period.

DOC Position

Both the 1971/72 and 1981/1982 loan "forgivenesses" have been regarded as conversions of debt to equity by BSC's sole shareholder, the U.K. government. The equity conversions were treated as described in "Equity Investment in BSC" and in Appendix 2. Loans granted during uncreditworthy periods are treated as discussed in Appendix 2. Finally, we have determined that the ECSC and EIB loans are benefits provided or required by government action.

Negative Determinations of Critical Circumstances

Bethlehem Steel and the Five have alleged that imports of the products under investigation present "critical circumstances." Under §§ 355.29 and 355.33(b) of the Department's regulations, critical circumstances exist when the alleged subsidies include an export subsidy inconsistent with the Agreement and there have been massive imports of the class or kind of merchandise which is the subject of the investigation over a relatively short period.

Of the British steel producers found to receive more than *de minimis* subsidies, none are recipients of export subsidies. Therefore, "critical circumstances" do not exist.

Verification

In accordance with section 776(a) of the Act, we verified the data used in making our final determinations. During this verification, we followed normal procedures, including inspection of documents, discussions with government officials and on-site inspection of manufacturers' operations and records.

Administrative Procedures

The Department has afforded interested parties an opportunity to present oral views in accordance with its regulations (19 CFR 355.35). A public hearing was held on July 15, 1982. In accordance with the Department's regulations (19 CFR 355.34(a)), written views have been received and considered.

Suspension of Liquidation

The suspension of liquidation ordered in our "Preliminary Affirmative Countervailing Duty Determinations" shall remain in effect until further notice for carbon steel structural shapes, hot-rolled carbon steel plate, and hot-rolled carbon steel bars, except with respect to products produced by the following firms, which are excluded from these determinations: Darlington-Simpson Rolling Mills; Round Oak Steel Works, Ltd.; Flather Bright; London Works Steel Co., Ltd.; Exors of James Mills, Ltd.; Bright Steel, Ltd.; Eaton & Booth, Ltd.; Bar Bright Usam; Brasway Bright Bar; Glynwed Steels, Ltd.; Spencer Clark Metal Industries, PLC.; Lee Bright Bars, Ltd.; Dudley Port Rolling Mills, Ltd.; Kiveton Park Steel & Wireworks, Ltd.; and Bedford Steel, Ltd. Moreover, we are immediately lifting the suspension of liquidation for cold-formed carbon steel bars. All estimated countervailing duties deposited subsequent to the preliminary determinations on entries of cold-formed carbon steel bars, and on entries of merchandise produced by the firms listed immediately above, shall be refunded and the appropriate bonds shall be released. The net subsidy for each firm and product is as follows:

Manufacturer/producer/exporter	Ad valorem rate (percent)
British Steel Corporation:	
Carbon Steel Structural Shapes	20.33
Hot-Rolled Carbon Steel Plate	20.33
Hot-Rolled Carbon Steel Bar	20.33
Brymbo Steel Works, Ltd.: Hot-Rolled Carbon Steel Bar	1.88
All other manufacturers/producers/exporters:	
Carbon Steel Structural Shapes	20.33
Hot-Rolled Carbon Steel Plate	20.33
Hot-Rolled Carbon Steel Bar	20.33

We are directing the United States Customs Service to require a cash deposit or bond in the amount indicated above for each entry of the subject merchandise entered on or after the date of publication of the notice in the **Federal Register**. Where the manufacturer is not the exporter, and the manufacturer is known, the rate for that manufacturer shall be used in determining the amount of cash deposit or bond. If the manufacturer is unknown, the rate for all other manufacturers/producers/exporters shall be used. Where a company specifically listed above has not exported a particular product during the period for which we are measuring subsidization, the cash deposit or bond amount shall be based on the highest rate for products that were exported by that company.

ITC Notifications

In accordance with section 705(d) of the Act, we will notify the ITC of our determinations. In addition, we are making available to the ITC all non-privileged and non-confidential information relating to these investigations. We will allow the ITC access to all privileged and confidential information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order, without the written consent of the Deputy (for Policy) to the Deputy assistant Secretary for Import Administration. The ITC will determine within 45 days of the publication of this notice whether these imports are materially injuring, or threatening to materially injure, a U.S. industry. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated and all securities posted as a result of the suspension of liquidation will be refunded or cancelled. If, however, the ITC determines that such injury does exist, within 7 days of notification by the ITC of that determination, we will issue a countervailing duty order, directing Customs officers to assess countervailing duty on certain steel products from the United Kingdom entered, or withdrawn from warehouse, for consumption after the suspension of liquidation, equal to the net subsidy determined or estimated to exist as a result of the annual review process prescribed by section 751 of the Act. The provisions of section 707(a) of the Act will apply to the first directive for assessment.

This notice is published pursuant to section 705(d) of the Act and § 355.33 of the Department of Commerce Regulations (19 CFR 355.33).

Dated: August 24, 1982.

William T. Archey,

Acting Assistant Secretary for Trade Administration.

[FR Doc. 82-23876 Filed 8-31-82; 8:45 am]

BILLING CODE 3510-25-M

Carbon Steel Plate From Brazil; Suspension of Investigation

AGENCY: International Trade Administration, Commerce.

ACTION: Notice of Suspension of Investigation.

SUMMARY: The Department of Commerce has decided to suspend the countervailing duty investigation involving carbon steel plate from Brazil. The basis for the suspension is an agreement by the government of Brazil to offset with an export tax all benefits which we find to be subsidies on exports of the subject product to the United States.

EFFECTIVE DATE: September 7, 1982.

FOR FURTHER INFORMATION CONTACT: Paul J. McGarr, Office of Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230, telephone: (202) 377–2786.

SUPPLEMENTARY INFORMATION:

Case History

On January 11, 1982, we received petitions from United States Steel Corporation, and counsel for Republic Steel Corporation, Inland Steel Company, Jones & Laughlin Steel, Inc., National Steel Corporation, and Cyclops Corporation filed on behalf of the U.S. industry producing carbon steel plate. The petitions alleged that certain benefits which constitute subsidies within the meaning of section 701 of the Tariff Act of 1930, as amended (the Act), are being provided, directly or indirectly, to the manufacturers, producers, or exporters in Brazil of carbon steel plate.

We found the petitions to contain sufficient grounds upon which to initiate a countervailing duty investigation, and on February 1, 1982, we initiated a countervailing duty investigation (47 FR 5751). We stated that we expected to issue a preliminary determination by April 6, 1982. We subsequently determined that the investigation is "extraordinarily complicated," as defined in section 703(c) of the Act, and postponed our preliminary determination for 65 days until June 10, 1982 (47 FR 11738).

We presented a questionnaire concerning the allegations to the government of Brazil in Washington, D.C. On April 22, 1982, we received the response to the questionnaire. A supplemental reponse was received on June 7, 1982. During July 5–9, 1982, we verified this information by a review of government documents and company books and records of Companhia Siderurgica Paulista (COSIPA) and Usinas Siderurgicas de Minas Gerais S.A. (USIMINAS), the only known exporters in Brazil of carbon steel plate to the United States.

On June 10, 1982, we preliminarily determined that the government of Brazil is providing subsidies to manufacturers, producers,or exporters of carbon steel plate under three programs. The programs preliminarily found to confer subsidies were IPI rebates for capital investment, the IPI export credit premium, and preferential working capital financing for exports. Based upon verification, we also found benefits constituting subsidies were received on machinery imported under the Industrial Development Council (CDI) program. This program is countervailable because it allows an exemption of 80 percent of the customs duties and 80 percent of the IPI tax on certain imported machinery for projects approved by the CDI.

Notice of the preliminary affirmative countervailing duty determination was published in the **Federal Register** on June 17, 1982 (47 FR 26310). We directed the U.S. Customs Service to suspend liquidation of all entries of the subject merchandise, entered or withdrawn from warehouse, for consumption on or after June 17, 1982, and to require a cash deposit or bond in the amount of 8.58 percent of the f.o.b. value of the merchandise.

On July 23, 1982, the Department of Commerce (the Department) initialed a proposed agreement to suspend the countervailing duty investigation involving carbon steel plate from Brazil. The basis for the suspension is an agreement between the Department and the government of Brazil that the latter will offset by an export tax the entire amount of benefits we find to confer subsidies on exports of carbon steel plate to the United States.

On the same date, in compliance with the procedural requirements of section 704(e) of the Act, we called counsel for the petitioners and counsel for Bethlehem Steel informing them of the proposed agreement. At that time, we read them the essential points of the proposed agreement and offered to answer any questions. Each of these parties also received a copy of the proposed agreement on that date.

Scope of the Investigation

The product covered by this investigation is hot-rolled carbon steel plate manufactured in Brazil and exported, directly or indirectly, from Brazil to the United States. The term "carbon steel plate" covers hot-rolled carbon steel products, whether or not corrugated or crimped; not pickled; not cold-rolled; not in coils; not cut, not pressed, and not stamped to non-rectangular shape; 0.1875 inch or more in thickness and over 8 inches in width; as currently provided for in items 607.6615, or 607.94, of the *Tariff Schedules of the United States Annotated (TSUSA);* and hot- or cold-rolled carbon steel plate which has been coated or plated with zinc including any material which has been painted or otherwise covered after having been coated or plated with zinc, as currently provided for in items 608.0710 or 608.11 of the TSUSA. Semi-finished products of solid rectangular cross section with a width at least four times the thickness in the as cast condition or processed only through primary mill hot rolling are not included.

The period for which we are measuring subsidization is calendar year 1981.

Suspension of the Investigation

The Department consulted with the petitioners and has considered the comments submitted with respect to the proposed suspension agreement. We have determined that the agreement will offset the subsidies completely with respect to the subject merchandise exported directly or indirectly to the United States, that the agreement can be monitored effectively, and that the agreement is in the public interest. We find, therefore, that the criteria for suspension of an investigation pursuant to section 704 of the Act have been met. The terms and conditions of the agreement, signed August 24, 1982, are set forth in Annex 1 to this notice.

Pursuant to section 704(f)(2)(A) of the Act, the suspension of liquidation of all entries, entered or withdrawn from warehouse, for consumption of carbon steel plate from Brazil effective June 17, 1982, as directed in our notice of "Preliminary Affirmative Countervailing Duty Determination, Carbon Steel Plate from Brazil" is hereby terminated. Any cash deposits on entries of carbon steel plate from Brazil pursuant to that suspension of liquidation shall be refunded and any bonds shall be released.

The Department intends to conduct an administrative review within twelve months of the anniversary date of publication of this suspension as provided in section 751 of the Act.

Notwithstanding the suspension agreement, the Department will continue the investigation if we receive such a request in accordance with section 704(g) of the Act within 20 days after the date of publication of this notice.

This notice is published pursuant to section 704(f)(1)(A) of the Act.

Dated: August 24, 1982.

Gary N. Horlick,

Deputy Assistant Secretary for Import Administration.

Annex I.—Suspension Agreement

Carbon Steel Plate From Brazil

Pursuant to section 704 of the Tariff Act of 1930, as amended ("the Act"), and section 355.31 of the Commerce Regulations, the United States Department of Commerce ("the Department") and the government of Brazil enter into the following suspension agreement ("the agreement") on the basis of which the Department shall suspend its countervailing duty investigation initiated on February 1, 1982 (47 FR 5751) with respect to carbon steel plate from Brazil. The agreement shall be in accordance with the terms and provisions set forth below.

A *Scope of the Agreement.* The agreement applies to all carbon steel plate manufactured in Brazil and exported, directly or indirectly, from Brazil to the United States (hereinafter referred to as the "subject product"). The term "carbon steel plate" covers hot-rolled carbon steel products, whether or not corrugated or crimped; not pickled; not cold-rolled; not in coils; not cut, not pressed, and not stamped to non-rectangular shape; 0.1875 inch or more in thickness and over 8 inches in width; as currently provided for in items 607.6615, or 607.94, of the *Tariff Schedules of the United States Annotated ("TSUSA");* and hot- or cold-rolled carbon steel plate which has been coated or plated with zinc, including any material which has been painted or otherwise covered after having been coated or plated with zinc, as currently provided for in items 608.0710 or 608.11 of the TSUSA. Semifinished products of solid rectangular cross section with a width at least four times the thickness in the as cast condition or processed only through primary mill hot rolling are not included.

B. *Basis of the Agreement.* 1. The government of Brazil hereby agrees to offset completely the amount of the net subsidy determined by the Department to exist with respect to the subject product. The offset shall be accomplished by an export tax applicable to the subject product exported on or after September 30, 1982. The export tax shall be utilized to offset completely any benefits found to exist with respect to the following programs:

(a) The IPI export credit premium,

(b) Resolution 674 financing,

(c) Decree Law 1547 rebates for investment,

(d) Benefits on imported machinery received under the CDI program,

(e) The income tax exemption for export earnings, and

(f) Any other program subsequently determined by the Department in this proceeding to constitute a subsidy under the Act to the subject product.

The Department shall officially notify the government of Brazil of any determination made under item (f) above.

2. The government of Brazil certifies that no new or equivalent benefits shall be granted on the subject product as a substitute for any benefits offset by the agreement.

3. The offset of these benefits does not constitute an admission by the government of Brazil that such benefits are subsidies within the meaning of the U.S. countervailing duty law.

4. The government of Brazil agrees that from the effective date of the suspension of the investigation and until the imposition of an export tax no later than September 30, 1982 that completely offsets the net subsidy determined by the Department to exist, the rate of exports of the subject product will not exceed the average monthly rate of exports to the U.S. in 1981. The Department will monitor the exports of the subject product to the United States from the effective date of the suspension of the investigation until the imposition of the export tax and will issue instructions to the Customs Service to deny entry, or withdrawal from warehouse, for consumption of the subject product exported in excess of the average monthly rate in 1981.

5. The Department will continue to monitor the volume of exports of the subject product to the United States during the six-month period following the effective date of the imposition of the export tax. The government of Brazil agrees to report to the Department by January 15, 1983 and April 15, 1983, the monthly volume of exports of the subject product for the preceding three-month period.

C. *Monitoring of the Agreement.* 1. The government of Brazil agrees to supply to the Department such information as the Department deems necessary to demonstrate that it is in full compliance with the agreement.

2. The government of Brazil shall notify the Department if any exporters of the subject product transship the subject product through third countries or apply for or receive, directly or indirectly, the benefits of the programs described in paragraph B(1) regarding the manufacture of the subject product.

3. The government of Brazil shall certify to the Department within 15 days after the first day of each three-month period beginning on January 1, 1983 whether it continues to be in compliance with the agreement by offsetting the net subsidy referred to in paragraph B(1) and whether it has substituted any new or equivalent benefits for the benefits offset by the agreement. Failure to supply such information or certification in a timely fashion may result in the immediate resumption of the investigation or issuance of a countervailing duty order.

4. The government of Brazil shall permit such verification and data collection as is requested by the Department in order to monitor the agreement. The Department will request such information and perform such verification periodically pursuant to administrative reviews conducted under section 751 of the Act.

5. The government of Brazil shall promptly notify the Department, with appropriate documentation, of any change in the amount of benefits to the subject product, of any change in the rate of the export tax, or if it decides to alter or terminate its obligations with respect to any of the terms of the agreement.

D. *Violation of the Agreement.* If the Department determines that the agreement is being or has been violated or no longer meets the requirements of section 704(b) or (d) of the Act, then section 704(i) shall apply.

E. *Effective Date.* The effective date of the agreement is September 7, 1982.

Signed on this 24th day of August 1982.

For the Government of Brazil

Luiz Felipe P. Lampreia,

Minister-Counselor, Brazilian Embassy.

I have determined that the provisions of paragraph B completely offset the subsidies that the government of Brazil is providing with respect to carbon steel plate exported directly or indirectly from Brazil to the United States and that the provisions of paragraph C ensure that this agreement can be monitored effectively pursuant to section 704(d) of the Act. Furthermore, I have determined that the agreement meets the requirements of section 704(b) of the Act and suspension of the investigation is in the public interest.

U.S. Department of Commerce.

Gary N. Horlick,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 82-23874 Filed 8-31-82; 8:45 am]

BILLING CODE 3510-25-M

federal register

Tuesday
September 7, 1982

Part III

Department of Transportation

Federal Railroad Administration

Track Safety Standards; Miscellaneous Amendments

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 213

[Docket No. RST-3, Notice No. 4]

Track Safety Standards; Miscellaneous Amendments

AGENCY: Federal Railroad Administration (FRA), DOT.

ACTION: Final rule.

SUMMARY: This document amends the Federal Railroad Administration (FRA) Track Safety Standards. It clarifies existing rules and eliminates certain rules no longer considered necessary for safety. This action is taken by FRA in an effort to improve its safety regulatory program.

EFFECTIVE DATE: This regulation will become effective on November 1, 1982.

FOR FURTHER INFORMATION CONTACT:

Principal Program Person: Edward R. English, Office of Safety Programs, Federal Railroad Administration, Washington, D.C. 20590. Phone 202–426–9252

Principal Attorney: Lawrence I. Wagner, Office of the Chief Counsel, Federal Railroad Administration, Washington, D.C. 20590. Phone 202–426–8836.

SUPPLEMENTARY INFORMATION:

I. Background

On February 18, 1982, FRA published a notice of proposed rulemaking (NPRM) in the **Federal Register** (47 FR 7275) to amend the Track Safety Standards. The specific objectives of the proposed changes included clarification of existing rules and elimination of certain rules no longer considered necessary for safety.

As announced in the NPRM, FRA held a public hearing on March 16, 1982. At the hearing, FRA received testimony from state agencies, the Association of American Railroad (AAR) and the Railway Labor Executives' Association (RLEA). In addition, written comments were submitted by a number of state agencies, one railroad, and private individuals who did not testify at the hearing. All the comments and testimony have been reviewed and fully considered during the formulation of the final rule set forth in this document.

The representatives of rail labor and rail management expressed support for the proposed changes. The state agencies and individual commenters generally responded with a mixture of support and opposition to particular aspects of the proposal.

One commenter, the National Transportation Safety Board (NTSB), objected to the fact that the FRA proposal was limited in scope. It was the view of NTSB that an extensive set of changes to the standards is needed. The NTSB urged FRA to undertake the total revision contemplated by the NPRM issued by FRA in 1979. The NTSB further suggested that FRA prepare and make available detailed technical reports to support each of the particular regulatory changes that FRA is proposing in this NPRM. Specific concerns about particular changes to individual section changes and a suggestion that FRA provide more economic information were also included in the NTSB comments.

The FRA proposed extensive changes in an NPRM that was published in the **Federal Register** on September 9, 1979 (44 FR 52104) (1979 NPRM). The 1979 NPRM proposal contained a virtual total revision of these standards. That proposal generated extensive commentary and considerable controversy. Those comments questioned the technical basis for many aspects of the contemplated changes, expressed sincere doubts about the feasibility of complying with the provisions if the changes were adopted, and indicated that severe adverse financial consequences would result if that proposal were adopted.

After analyzing and reviewing the comments, FRA concluded that many of the concerns raised in response to the 1979 NPRM were valid; that significant provisions of the 1979 NPRM, which addressed a variety of the concerns reflected in the current NTSB recommendations, required long term study and analysis; and that it was not feasible to develop an appropriate final rule on the basis of the 1979 NPRM. Accordingly, by notice in the **Federal Register** on June 25, 1981, FRA withdrew the 1979 NPRM.

There remained, however, a pressing need to address promptly certain identified problems with the Track Safety Standards, FRA had been contemplating technical changes to the regulation at the time it received letters jointly submitted by the AAR and RLEA, the two groups upon whom any changes would have the most extensive and immediate impact. It was their unified judgment that FRA should proceed immediately to make specific changes to the regulation concurrently with a study of extensive alteration or revision. The joint recommendations of AAR and RLEA paralleled FRA's judgment. Therefore, FRA elected to use these recommendations as the basis for this NPRM and to address the remaining areas in the future in a different proceeding, as part of the evolving process of revision of the Track Safety Standards.

The NTSB suggestion that FRA prepare and make available detailed technical reports prior to making regulatory changes addresses a problem that has concerned all parties that have an interest in rail safety. Unlike some industries, such as the aircraft industry, the railroad industry does not have the benefit of extensive, all encompassing research and detailed technical experiments concerning the myriad of variables and component interactions involved in its operations. Therefore, it is not feasible to predict with precision the impact of changes in particular aspects of one subsystem. The inability to predict the growth of an internal flaw in a rail length from the point of detectability to the point of in-service failure is illustrative of this type of problem. Many widely varying factors, such as temperature fluctuations, wheel and axle loadings, total tonnage, speed, type of train operations, and multiple maintenance practices, may significantly affect that growth.

Despite the best efforts of all parties over many years involving the expenditure of untold sums of money, no clear answers exist. Faced with the lack of reliable data on this problem and many others, FRA and all parties in the rail industry have been forced to rely on the seasoned judgment of experienced technical personnel in making regulatory and practical decisions about rail operations. Adoption of the NTSB suggestion would effectively preclude FRA or any regulatory body from establishing totally defensible standards. In this proceeding, as in many others, the FRA relies on the technical judgment of its staff. The FRA's judgment on the particular matters addressed in this proceeding are buttressed by the consensus opinion of a multitude of senior rail engineers and every day rail workers that is reflected in the joint AAR/RLEA recommendations. While the FRA appreciates the NTSB suggestion, it is precluded from adopting it for the reasons stated.

The specific comments furnished by NTSB on particular proposed changes to individual sections of the regulation are reflected in the summary of the comments received from all commenters. This summary, which also includes FRA's response to the comments, has been organized in a section-by-section format.

II. Section-by-Section Analysis

The following paragraphs discuss the major points raised by the commenters.

Additionally, the FRA has made minor editorial changes to some sections of the regulation without specific explanation.

Section 213.3 Application.

The FRA proposed to delete the existing language of subparagraph (b)(3) concerning the effective dates for various provisions and to replace that subparagraph with a cross reference to § 213.4. Some commenters who had concerns about the concept of "excepted track" as set forth in § 213.4, expressed those concerns in their comments on this section. FRA has responded to those concerns in the discussion of § 213.4 below.

Two commenters suggested that FRA make more extensive changes in this section. The FRA has not adopted these suggestions because they are beyond the scope of this proceeding. Moreover, their comments encompass a variety of topics totally unrelated to track safety, which should be resolved in other contexts.

In adopting the final rule, the FRA has decided not to incorporate the proposed cross reference to "excepted track" in this section. Instead, the FRA has moved the cross reference to "excepted track" to § 213.5. This change has been made to eliminate any possible confusion about the scope of the FRA regulations based on the section heading.

Section 213.4 Excepted track.

The FRA proposal to permit portions of certain low density branch lines and related yard tracks to be excepted from compliance with the substantive provisions of the standards generated considerable comment. Some commenters objected to the concept of excepted track because that provision could adversely impact existing contractual relationships for the maintenance of track or hinder economic valuation determinations in pending and future abandonment proceedings. Other commenters objected to the basic concept of allowing any track to be used that does not meet the standards. The remaining commenters either objected to or questioned particular aspects of the specific provisions of this section.

The decision of various entities to use the existing track regulations as a reference tool for their individual purposes is a matter that is totally beyond the scope of relevant safety concerns. Although FRA is sympathetic to the plight of state agencies and other parties, their potential need to revise documents or procedures is not an appropriate basis for altering the proposal.

The commenters who objected to the basic concept of excepted track generally indicate a greater concern for the potential abandonment implications of this provision than for the safety implications. As indicated in the preamble to the NPRM, safety considerations have been addressed by the imposition of the operational limitations contained in this section.

The commenters objecting to or questioning particular aspects of operational constraint provisions focused most frequently on the ability of a railroad to haul hazardous materials over excepted track. A blanket prohibition against the movement of hazardous materials was suggested by most of these commenters. The FRA has not adopted this suggestion because the administration of the current standards has shown that such a blanket prohibition is not realistic. This decision is based upon FRA's experience in resolving various waiver petitions involving limited slow speed operations over substandard track. In those proceedings, FRA repeatedly has encountered situations where it is necessary to move occasional shipments of commodities that require placarding as hazardous materials. In many instances, the commodities involved were shipments of diesel fuel and bagged fertilizer.

Several commenters expressed intense concern about the potential for movement of tank cars containing commodities such as liquified petroleum gases or anhydrous ammonia over such track. The FRA believes that such concern is misplaced. The regulatory actions of the Materials Transportation Bureau (MTB) of the DOT have resulted in the redesign and retrofitting of the tank cars that carry these commodities. Head shields and shelf couplers to prevent tank head puncture and lading loss in a derailment, and high temperature thermal protection systems to prevent violent rupture in tank cars exposed to a fire at a derailment, both serve to minimize the potential consequences of any accidental derailment. The train placement requirements of the MTB rules and the slow speed of any train carrying such a commodity further reduce the risks for operations over this track. These factors, in combination with the requirements to maintain the track to Class 1 standards in areas where geographical considerations (such as bridges or public roadways) might introduce additional safety hazards, and to continue inspecting such track for the purpose of determining whether additional safeguards are necessary, add another level of safety. The individual railroad's interest in avoiding liability and in providing prompt and efficient service for such valuable commodities militates against any railroad using this provision on any track other than on lines where there is infrequent service. Finally, the adoption of this section or any section in this part is not construed by FRA as precluding the use of FRA's statutory authority to abate a particular hazard.

In deciding to adopt this provision as proposed, the FRA has rejected the suggestion of one commenter that this section impose movement restrictions only in those instances when a train had moved beyond the confines of a yard or yard limit area. The term "yard", however, lacks precise definition. The term "yard limit" is equally objectionable because it refers to a shifting operational concept that is related to individual operating rules. Followed to its logical conclusion, the suggestion would permit the movement of large volumes of hazardous materials or revenue passenger trains over substandard track at speeds of up to 20 miles per hour. Neither the language of the joint AAR/RLEA letters nor the FRA's proposal supports such a concept.

Section 213.5 Responsibility of track owners.

The FRA proposed to change this section to provide a clearer regulatory link between this section and other provisions of the standards. A number of commenters who had concerns about the proposed changes to section 213.9 addressed their remarks to both sections. Two commenters who focused specifically on this section, expressed support for the proposed change. No commenters offered substantive objection to this proposal.

In adopting the final rule, the FRA has decided to incorporate the cross reference to excepted track that was proposed as an amendment to § 213.3. The FRA has made this change to improve the logic of the regulatory text and to avoid any possible confusion about the scope or applicability of these regulations and their preemptive effect. This change has necessitated rewording of the existing paragraph (a) to accommodate the new language of paragraph (b). The new paragraph (b) contains the logical cross reference point for the "excepted track" provisions of § 213.4, and the remaining paragraphs have been sequentially redesignated to reflect the new paragraph (b).

This change should also help resolve some interpretive problems noted by commenters. These commenters indicated confusion about the effect of a single instance or even repeated

instances of a railroad's failure to adhere to the operational constraints provided in § 213.4. The relocation of the cross reference point to this section would clearly permit the FRA to address such failures in an enforcement context under § 213.4 and other applicable sections of Part 213. If the circumstances warrant enforcement activity, the FRA's general posture would be to treat the movement of a single train as a single violation of § 213.4. That approach would not preclude responding to an egregious situation in a different manner.

Section 213.9 Class of track: Operating speed limits.

The FRA proposal to provide a 30 day period during which operations may continue over substandard track was addressed by several commenters. Some felt that immediate restoration or rehabilitation should be required; others urged that the period be altered; and a final group sought more information on FRA's intentions in proposing this change.

The existing requirement to institute immediate restoration work under the supervision provisions of section 213.11 has proven to be too inflexible a response to deteriorated track. Compliance with that provision has frequently hindered or impaired the performance of planned maintenance activities. Consequently, FRA is amending this section to give railroads a reasonable period to muster needed resources to resolve the defect while maintaining both vital rail service over that track and the performance of planned maintenance work.

The amended section would limit operations over the defective conditions to a period of not more than 30 days. That 30-day period would commence on the date the railroad learns or has notice of the defective condition. The section also requires that a qualified person inspect the defective condition to determine whether trains can continue to operate safely over that track segment and, if necessary, impose appropriate safety restrictions in addition to the 10 miles per hour speed limitation.

Several commenters questioned the need to provide specific guidance to the qualified person on the latitude of his discretion in determining the appropriateness of continued operations. They suggested that FRA increase the qualification requirements or provide detailed parameters similar to those in § 213.113. The FRA has not adopted these suggestions because administration of the standards has shown that the current qualifications in § 213.7 are sufficient and that these individuals normally have the required skills to make the appropriate decisions in response to highly individual factual settings.

Two commenters expressed concern about the interpretation of the 30-day provision. Their concerns involved instances where a railroad had either actual notice of a sub-Class 1 defective condition that was noted on its inspection reports or constructive notice of such a condition that was not so noted. Under § 213.9(b), a railroad has 30 days from the date of notice to remedy the defective condition and thereby bring the track into compliance. However, if the railroad does not adhere to the conditions prescribed in § 213.9(b) during that period, it would be subject to enforcement action by FRA.

Section 213.11 Restoration or renewal of track under traffic conditions.

No substantive comments were received on this section and no changes have been made. However, some commenters did express reservations about potential problems if railroads attempt to abuse the application of the revised section in specific factual settings.

The FRA's intent is to allow train operations to occur on track that is being renewed if a qualified person determines that a train can safely traverse that track. His presence to observe the changing conditions and to supervise the work is necessary if he is to make the appropriate judgments. Clearly, if a work project is broken into too many segments or scattered over too many miles, that person could not be considered to be present and continually supervising.

Section 213.53 Gage.

The existing provisions of this section specify the maximum and minimum permissible distance between the heads of the rails. The maximum distance varies according to the class of track and the existence of curvature in the track. The FRA proposed to eliminate the existing distinction between the maximum permissible gage distances in tangent track and curved track and to increase the maximum allowable distances in certain instances.

The commenters who addressed this section generally opposed any change or suggested alternate dimensions. Neither the opponents nor those recommending alternatives have provided any information which suggests that the proposed changes are inadequate or inappropriate resolutions to the compliance problems generated by factors such as rail wear. Consequently, FRA has adopted the section as proposed.

Section 213.109 Crossties.

The FRA proposed to reword, restructure, and revise this section. Most commenters agreed with the proposed deletion of the prohibition against using interlaced crossties. However, a number of commenters opposed the proposed deletion of specific requirements on the allowable distance between crossties that are without defective conditions. Many of these commenters expressed a concern that the required number of effective crossties might be clustered in a particular location. Some commenters suggested alternate distances which could be substituted for those prescribed in the existing regulation.

The FRA has decided to adopt this section as proposed. The primary function of crossties is to provide effective support for the rails so that gage, surface, and alignment are maintained within prescribed limitations. If the only crossties that are capable of effectively supporting the rails are clustered at one location, it is doubtful that the entire 39 foot segment will have sufficient support to stay within the prescribed tolerances. However, if other crossties, although in marginal condition, can cumulatively provide enough additional support to supplement the better crossties, the entire segment will still have sufficient support. Given the potential support capability, FRA has decided to focus on the need for a required number of observably good crossties to perform the necessary function, either in isolation or in combination with other deteriorating crossties, rather than continue the explicit measurement requirements for the spacing of crossties.

In adopting this final rule, the FRA has slightly revised the diagrams showing correct placement of crossties at joint locations. This revision should resolve difficulties with this portion of the section noted by some commenters.

Section 213.113 Defective rails.

The FRA proposed to revise this section to alter the remedial action that must be taken once a rail flaw has been identified. The commenters who addressed this section generally opposed the concept of giving railroads any flexibility to tailor their remedial action to reflect operational factors on the line where the defect was discovered. These commenters indicate generally a concern that local supervisors will abuse the discretion afforded by the proposed change; they urge that the FRA retain the existing

provisions. Other commenters, including two state agencies, concur with the FRA proposal.

The FRA provided its rationale for changing this section in the preamble to the proposed rule. While appearing to harbor some doubts about localized implementation, none of the commenters refuted that explanation. Consequently, FRA has adopted the proposed section without change.

Section 213.127 Rail fastenings.

The FRA proposed to recaption this section and to revise it in terms of a performance requirement applicable to all types of fastenings. Most commenters agreed with the proposal to expand the types of devices covered by the section, but cautioned that the lack of precision inherent in a performance oriented requirement may prove to be a problem in an interpretation or enforcement context.

The FRA was alert to these potential difficulties in proposing the change and recognizes that implementation of this section will require the sound judgment of experienced personnel. The FRA believes that this language is appropriate and workable. Consequently, the FRA has adopted the section as proposed.

The FRA proposed the deletion of eight sections that have no demonstrable effect on rail safety. The commenters who expressed any opposition to these deletions indicated that a particular provision should be retained because it was helpful in some vague sense. None of these commenters attempted to refute FRA's assessment that deletion of these provisions would not have any adverse safety impact.

III. Regulatory Impact

This final rule has been evaluated in accordance with existing regulatory policies including Executive Order 12291 issued on February 17, 1981 (46 FR 1391). The final rule primarily contains technical revisions to the existing standards.

In general, the final rule serves to reduce the economic burdens of the existing regulation by exempting some tracks from full compliance with these standards. Additionally, a reduction in recordkeeping burdens and their associated costs may produce some savings. The FRA has not been able to quantify these economic impacts because it is not clear how extensively the railroads will utilize these changes.

Because the final rule is primarily technically oriented, the FRA has concluded that the revision does not constitute a major rule under the terms of Executive Order 12291 or a significant rule under DOT's regulatory policies and procedures.

The final rule has a direct economic impact only on railroads. Its primary impact is on large railroads which own hundreds of miles of track. It does not place any new requirements or burdens on the public, and to some extent it is deregulatory in nature. The only commenter directly addressing this subject indicated that railroads generally will not reduce their budgeted track expenditures in response to this revision, but will allocate their funding somewhat differently because of the increased discretion permitted by this revision. The final rule will not have a significant economic impact on any small entity. Based on these facts, it is certified that the final rule will not have a significant economic impact on a substantial number of small entities under the provisions of the Regulatory Flexibility Act (Pub. L. 96–354, 94 Stat. 1164, September 19, 1980).

The final rule contains provisions concerning the collection of information that are subject to the Paper Work Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*, Pub. L. 96–511). The information collection requirements contained in this amendment will not become effective until they have been approved by the Office of Management and the Budget.

Additionally, the final rule has also been reviewed in light of the FRA procedures for ensuring full consideration of the environmental impacts of FRA actions as required by the National Environmental Policy Act ("NEPA," 42 U.S.C. 4321 *et seq.*), other environmental statutes, Executive orders, and DOT Order 5610.113.

These FRA procedures require that an "environmental assessment" be performed prior to all major FRA actions. The procedures contain a provision that enumerates seven criteria which, if met, demonstrate that a particular action is not a "major" action for environmental purposes. These criteria involve diverse factors, including environmental controversiality; the availability of adequate relocation housing; the possible inconsistency of the action with Federal, state, or local law; the possible adverse impact on natural, cultural, recreational, or scenic environments; the use of properties covered by section 4(f) of the DOT Act; and the possible increase in traffic congestion. This revision of the track requirements meets the seven criteria that establish an action as a nonmajor action.

For the reasons above, the FRA has determined that this revision of Part 213, Track Safety Standards, does not constitute a major FRA action requiring an environmental assessment.

For indexing purposes there is only one entry—Railroad Safety—in the list of subjects covered in 49 CFR Part 213 on the basis of this document.

List of Subjects in 49 CFR Part 213

Railroad safety.

PART 213—TRACK SAFETY STANDARDS

For the reasons set out in the preamble, Part 213 of Chapter II of Title 49, Code of Federal Regulations, is amended as set forth below:

1. Section 213.3 is revised to read as follows:

§ 213.3 Application.

(a) Except as provided in paragraph (b) of this section, this part applies to all standard gage track in the general railroad system of transportation.

(b) This part does not apply to track—

(1) Located inside an installation which is not part of the general railroad system of transportation; or

(2) Used exclusively for rapid transit, commuter or other short-haul passenger service in a metropolitan or suburban area.

2. A new § 213.4 is added to read as follows:

§ 213.4 Excepted track.

A track owner may designate a segment of track as excepted track provided that:

(a) The segment is identified in the timetable, special instructions, general order, or other appropriate records which are available for inspection during regular business hours;

(b) The identified segment is not located within 30 feet of an adjacent track which can be subjected to simultaneous use at speeds in excess of 10 miles per hour;

(c) The identified segment is inspected in accordance with § 213.233(c) at the frequency specified for Class 1 track;

(d) The identified segment of track is not located on a bridge including the track approaching the bridge for 100 feet on either side, or located on a public street or highway, if railroad cars containing commodities required to be placarded by the Hazardous Materials Regulations (49 CFR Part 172), are moved over the track; and

(e) The railroad conducts operations on the identified segment under the following conditions:

(1) No train shall be operated at speeds in excess of 10 miles per hour;

(2) No revenue passenger train shall be operated; and

(3) No freight train shall be operated that contains more than five cars required to be placarded by the Hazardous Materials Regulations (49 CFR Part 172).

3. Section 213.5 is revised to read as follows:

§ 213.5 Responsibility of track owners.

(a) Except as provided in paragraph (b) of this section, any owner of track to which this part applies who knows or has notice that the track does not comply with the requirements of this part, shall—

(1) Bring the track into compliance;

(2) Halt operations over that track; or

(3) Operate under authority of a person designated under § 213.7(a), who has at least one year of supervisory experience in railroad track maintenance, subject to conditions set forth in this part.

(b) If an owner of track to which this part applies designates a segment of track as "excepted track" under the provisions of § 213.4, operations may continue over that track without complying with the provisions of subparts B, C, D, and E.

(c) If an owner of track to which this part applies assigns responsibility for the track to another person (by lease or otherwise), any party to that assignment may petition the Federal Railroad Administrator to recognize the person to whom that responsibility is assigned for purposes of compliance with this part. Each petition must be in writing and include the following:

(1) The name and address of the track owner;

(2) The name and address of the person to whom responsibility is assigned (assignee);

(3) A statement of the exact relationship between the track owner and the assignee;

(4) A precise identification of the track;

(5) A statement as to the competence and ability of the assignee to carry out the duties of the track owner under this part; and

(6) A statement signed by the assignee acknowledging the assignment to him of responsibility for purposes of compliance with this part.

(d) If the Administrator is satisfied that the assignee is competent and able to carry out the duties and responsibilities of the track owner under this part, he may grant the petition subject to any conditions he deems necessary. If the Administrator grants a petition under this section, he shall so notify the owner and the assignee. After the Administrator grants a petition, he may hold the track owner or the assignee or both responsible for compliance with this part and subject to penalties under § 213.15.

(e) A common carrier by railroad which is directed by the Interstate Commerce Commission to provide service over the track of another railroad under 49 U.S.C. 11125 is considered the owner of that track for the purposes of the application of this part during the period the directed service order remains in effect.

4. Section 213.9 is amended by revising paragraph (b) to read as follows:

§ 213.9 Class of track: operating speed limits.

* * * * *

(b) If a segment of track does not meet all of the requirements for its intended class, it is reclassified to the next lowest class of track for which it does meet all of the requirements of this part. However, if the segment of track does not at least meet the requirements for Class 1 track, operations may continue at Class 1 speeds for a period of not more than 30 days without bringing the track into compliance, under the authority of a person designated under § 213.7(a), who has at least one year of supervisory experience in railroad track maintenance, after that person determines that operations may safely continue and subject to any limiting conditions specified by such person.

* * * * *

5. Section 213.11 is revised to read as follows:

§ 213.11 Restoration or renewal of track under traffic conditions.

If during a period of restoration or renewal, track is under traffic conditions and does not meet all of the requirements prescribed in this part, the work on the track must be under the continuous supervision of a person designated under § 213.7(a) who has at least one year of supervisory experience in railroad track maintenance. The term "continuous supervision" as used in this section means the physical presence of that person at a job site. However, since the work may be performed over a large area, it is not necessary that each phase of the work be done under the visual supervision of that person.

6. Section 213.53 is amended by revising of paragraph (b) to read as follows:

§ 213.53 Gage.

* * * * *

(b) Gage must be within the limits prescribed in the following table:

Class of track	The gage must be at least—	But not more than
1	4'8"	4'10"
2 and 3	4'8"	4'9¾"
4 and 5	4'8"	4'9½"
6	4'8"	4'9¼"

7. Section 213.109 is revised to read as follows:

§ 213.109 Crossties.

(a) Crossties shall be made of a material to which rail can be securely fastened.

(b) Each 39 foot segment of track shall have:

(1) A sufficient number of crossties which in combination provide effective support that will:

(i) Hold gage within the limits prescribed in § 213.53(b);

(ii) Maintain surface within the limits prescribed in § 213.63; and

(iii) Maintain alignment within the limits prescribed in § 213.55.

(2) The minimum number and type of crossties specified in paragraph (c) of this section effectively distributed to support the entire segment; and

(3) At least one crosstie of the type specified in paragraph (c) of this section that is located at a joint location as specified in paragraph (d) of this section.

(c) Each 39 foot segment of: Class 1 track shall have five crossties; Classes 2 and 3 track shall have eight crossties; Classes 4 and 5 track shall have 12 crossties; and Class 6 track shall have 14 crossties, which are not:

(1) Broken through;

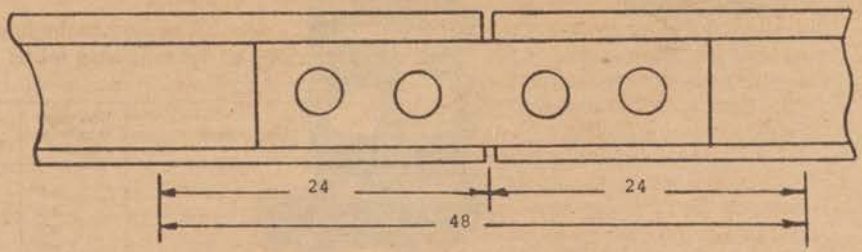
(2) Split or otherwise impaired to the extent the crossties will allow the ballast to work through, or will not hold spikes or rail fasteners;

(3) So deteriorated that the tie plate or base of rail can move laterally more than ½ inch relative to the crossties; or

(4) Cut by the tie plate through more than 40 percent of a tie's thickness.

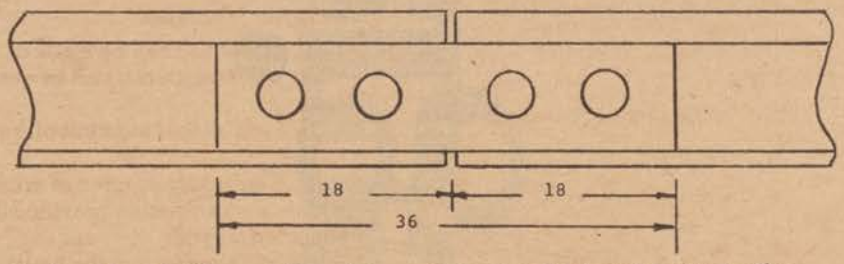
(d) Class 1 and Class 2 track shall have one crosstie whose centerline is within 24 inches of the rail joint location, and Classes 3 through 6 track shall have one crosstie whose centerline is within 18 inches of the rail joint location. The relative position of these ties is described in the following table.

Classes 1 and 2



Each rail joint in Classes 1 and 2 track shall be supported by at least one crosstie specified in paragraph (c) of this section whose centerline is within the 48" shown above.

Classes 3 through 6



Each rail joint in Classes 3 through 6 track shall be supported by at least one crosstie specified in paragraph (c) of this section whose centerline is within the 36" shown above.

8. Section 213.113 is revised to read as follows:

§ 213.113 Defective rails.

(a) When an owner of track to which this part applies learns, through inspection or otherwise, that a rail in that track contains any of the defects listed in the following table, a person designated under § 213.7 shall determine whether or not the track may continue in use. If he determines that the track may continue in use, operation over the defective rail is not permitted until—

(1) The rail is replaced; or

(2) The remedial action prescribed in the table is initiated:

REMEDIAL ACTION

Defect	Length of defect (inch)		Percent of rail head cross-sectional area weakened by defect		If defective rail is not replaced, take the remedial action prescribed in note
	More than	But not more than	Less than	But not less than	
Transverse fissure			20		B.
			100	20	B.
				100	A.
Compound fissure			20		B.
			100	20	B.
				100	A.
Detail fracture			20		C.
Engine burn fracture			100	20	D.
Defective weld				100	A or E and H.
Horizontal split head	0	2			H and F.
	2	4			I and G.
Vertical split head	4				B.
	(1)	(1)	(1)		A.
Split web	0	½			H and F.
Piped rail	½	3			I and G.
Head web separation	3				B.
	(1)	(1)	(1)		A.
	0	½			H and F.
Bolt hole crack	½	1½			G.
	1½				B.
	(1)	(1)	(1)		A.
Broken base	0	6			E.
	6				A, or E and I.
Ordinary break					A or E.
Damaged rail					C.

[1] Break out in rail head.

Notes:

A. Assigned person designated under § 213.7 to visually supervise each operation over defective rail.

B. Limit operating speed over defective rail to that as authorized by a person designated under § 213.7(a), who has at least one year of supervisory experience in railroad track maintenance.

C. Apply joint bars bolted only through the outermost holes to defect within 20 days after it is determined to continue the track in use. In the case of Classes 3 through 6 track, limit operating speed over defective rail to 30 mph until angle bars are applied; thereafter limit speed to 60 mph or the maximum allowable speed under § 213.9 for the class of track concerned, whichever is lower.

D. Apply joint bars bolted only through the outermost holes to defect within 10 days after it is determined to continue the track in use. In the case of Classes 3 through 6 track, limit operating speed over the defective rail to 30 mph or less as authorized by a person designated under § 213.7(a), who has at least one year of supervisory experience in railroad track maintenance, until angle bars are applied; thereafter, limit speed to 60 mph or the maximum allowable speed under § 213.9 for the class of track concerned, whichever is lower.

E. Apply joint bars to defect and bolt in accordance with § 213.121 (d) and (e).

F. Inspect rail 90 days after it is determined to continue the track in use.

G. Inspect rail 30 days after it is determined to continue the track in use.

H. Limit operating speed over defective rail to 60 mph or the maximum allowable speed under § 213.9 for the class of track concerned, whichever is lower.

I. Limit operating speed over defective rail to 30 mph or the maximum allowable speed under § 213.9 for the class of track concerned, whichever is lower.

(b) As used in this section—

(1) "Transverse Fissure" means a progressive crosswise fracture starting from a crystalline center or nucleus inside the head from which it spreads outward as a smooth, bright, or dark, round or oval surface substantially at a right angle to the length of the rail. The distinguishing features of a transverse fissure from other types of fractures or defects are the crystalline center or nucleus and the nearly smooth surface of the development which surrounds it.

(2) "Compound Fissure" means a progressive fracture originating in a horizontal split head which turns up or down in the head of the rail as a smooth, bright, or dark surface progressing until substantially at a right angle to the length of the rail. Compound fissures require examination of both faces of the fracture to locate the horizontal split head from which they originate.

(3) "Horizontal Split Head" means a horizontal progressive defect originating inside of the rail head, usually one-quarter inch or more below the running surface and progressing horizontally in all directions, and generally accompanied by a flat spot on the running surface. The defect appears as a crack lengthwise of the rail when it reaches the side of the rail head.

(4) "Vertical Split Head" means a vertical split through or near the middle of the head, and extending into or through it. A crack or rust streak may show under the head close to the web or pieces may be split off the side of the head.

(5) "Split Web" means a lengthwise crack along the side of the web and extending into or through it.

(6) "Piped Rail" means a vertical split in a rail, usually in the web, due to failure of the shrinkage cavity in the ingot to unite in rolling.

(7) "Broken Base" means any break in the base of a rail.

(8) "Detail Fracture" means a progressive fracture originating at or near the surface of the rail head. These fractures should not be confused with transverse fissures, compound fissures, or other defects which have internal origins. Detail fractures may arise from shelly spots, head checks, or flaking.

(9) "Engine Burn Fracture" means a progressive fracture originating in spots where driving wheels have slipped on top of the rail head. In developing downward they frequently resemble the compound or even transverse fissures with which they should not be confused or classified.

(10) "Ordinary Break" means a partial or complete break in which there is no sign of a fissure, and in which none of the other defects described in this paragraph are found.

(11) "Damaged Rail" means any rail broken or injured by wrecks, broken, flat, or unbalanced wheels, slipping, or similar causes.

9. Section 213.127 is revised to read as follows:

§ 213.127 Rail fastenings.

Each 39 foot segment of rail shall have a sufficient number of fastenings which, in the determination of a qualified Federal or State track inspector, effectively maintain gage within the limits prescribed in § 213.53(b). The term "qualified State track inspector" as used in this section means a track inspector who meets the qualification requirements of 49 CFR 212.203. (Formerly § 212.75).

§ 213.123 [Amended]

10. Section 213.123 *Tie Plates* is amended by removing paragraph (b) in its entirety.

§ 213.205 [Amended]

11. Section 213.205 *Derails* is amended by removing paragraph (b) in its entirety.

§§ 213.61, 213.105, 213.117, 213.119, 213.125, 213.129, 213.131, 213.207 [Removed]

12. The following sections are removed in their entirety:

Section 213.61 *Curve data for Classes 4 through 6 track;*

Section 213.105 *Ballast disturbed track;*

Section 213.117 *Rail end batter;*

Section 213.119 *Continuous welded rail;*

Section 213.125 *Rail anchoring;*

Section 213.129 *Track shims;*

Section 213.131 *Planks used in shimming;* and

Section 213.207 *Switch heaters.*

(Secs. 202 and 209, 84 Stat. 971, 975 (45 U.S.C. 431 and 438) and 49 CFR 1.49(n))

Issued in Washington, D.C. on August 31, 1982.

Robert W. Blanchette,

Administrator.

[FR Doc. 82-24190 Filed 9-3-82; 8:45 am]

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federal register

Tuesday
September 7, 1982

Part IV

Department of Health and Human Services

Food and Drug Administration

Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Establishment of a Monograph; and Reopening of Administrative Record

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 333

[Docket No. 75N-0183]

Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Establishment of a Monograph; and Reopening of Administrative Record

AGENCY: Food and Drug Administration.

ACTION: Advance notice of proposed rulemaking and reopening of administrative record.

SUMMARY: The Food and Drug Administration (FDA) is issuing an advance notice of proposed rulemaking that would establish conditions under which over-the-counter (OTC) topical antimicrobial drug products used for the treatment of diaper rash are generally recognized as safe and effective and not misbranded. This notice relates to the development of a monograph for topical antimicrobial drug products in general, which is part of the ongoing review of OTC drug products conducted by FDA. This notice also reopens the administrative record for OTC topical antimicrobial drug products to allow for consideration of a statement on drug products for the treatment of diaper rash that has been received from the Advisory Review Panel on OTC Miscellaneous External Drug Products.

DATES: Written comments by December 6, 1982 and reply comments by January 5, 1983.

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

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In accordance with Part 330 (21 CFR Part 330), FDA received on December 14, 1980 a statement from the Advisory Review Panel on OTC Miscellaneous External Drug Products relating to OTC drug products intended for use in the treatment of diaper rash. FDA regulations (21 CFR 330.10(a)(6)) provide that the agency issue in the **Federal Register** a proposed rule containing (1) the monograph recommended by the Panel, which establishes conditions under which these OTC drug products are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph because the Panel determined that they would result in the drugs not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph because the Panel determined that the available data are insufficient to classify these conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel.

Because some ingredients in drug products for the treatment of diaper rash are marketed in OTC drug products for topical antimicrobial use, FDA has determined that the Miscellaneous External Panel's recommendations on OTC drug products for the treatment of diaper rash should be included as part of the proposed rulemaking for topical antimicrobial drug products. Development of this rulemaking has been ongoing for some time.

In the **Federal Register** of September 13, 1974 (39 FR 33103), FDA issued an advance notice of proposed rulemaking to establish a monograph for OTC topical antimicrobial drug products. In the **Federal Register** of January 6, 1978 (43 FR 1210), FDA issued a tentative final monograph (notice of proposed rulemaking) for OTC topical antimicrobial drug products. In the **Federal Register** of March 9, 1979 (44 FR 13041), FDA reopened the administrative record and announced its intent to publish an updated (amended) tentative final monograph (amended notice of proposed rulemaking) for OTC topical antimicrobial drug products. FDA advises that it is again reopening the administrative record for OTC topical antimicrobial drug products only as it pertains to drug products for the treatment of diaper rash in order to allow for the consideration of the Miscellaneous External Panel's recommendations on these products. Comments received on this advance notice of proposed rulemaking will be addressed in a future issue of the **Federal Register.** Also, the proceeding to develop a monograph for drug products for the treatment of diaper rash will be merged with the general proceeding to establish a monograph for OTC topical antimicrobial drug products.

The Panel did not recommend any Category I conditions for topical antimicrobial ingredients contained in drug products for the treatment of diaper rash. Therefore, no new sections to Part 333 (as set forth in the notice of proposed rulemaking that was published in the **Federal Register** of January 6, 1978 (43 FR 1210)) are included in this advance notice of proposed rulemaking for this drug category.

The unaltered statement of the Panel relating to OTC topical antimicrobial ingredients contained in drug products for the treatment of diaper rash is issued to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. This statement has been prepared independently of FDA, and the agency has not yet fully evaluated the Panel's recommendations. The Panel's findings appear in this document to obtain public comment before the agency reaches any decision on the Panel's statements. This statement represents the best scientific judgment of the Panel members, but does not necessarily reflect the agency's position on any particular matter contained in it.

After reviewing all comments submitted in response to this document, FDA will issue in the **Federal Register** an amended tentative final monograph for OTC topical antimicrobial drug products, to include drug products for the treatment of diaper rash. Under the OTC drug review procedures, the agency's position and proposal are first stated in the tentative final monograph, which has the status of a proposed rule. Final agency action occurs in the final monograph, which has the status of a final rule.

The agency's position on OTC topical antimicrobial drug products will be restated when the amended tentative final monograph is published in the **Federal Register** as an amended notice of proposed rulemaking. In that amended notice of proposed rulemaking, the agency also will announce its initial determination whether the proposed rule is a major rule under Executive Order 12291 and will consider the requirements of the Regulatory Flexibility Act (5 U.S.C. 601-612). The present notice is referred to as an advance notice of proposed rulemaking to reflect its actual status and to clarify that the requirements of the Executive Order and the Regulatory Flexibility Act will be considered in the amended notice of proposed rulemaking. At that time FDA also will consider whether the proposed rule has a significant impact on the human environment under 21 CFR Part 25 (proposed in the **Federal Register** of December 11, 1979; 44 FR 71742).

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC topical antimicrobial drug products used for the treatment of diaper rash. Types of impact may include, but are not limited

to, costs associated with product testing, relabeling, repacking, or reformulating. Comments regarding the impact of this rulemaking on topical antimicrobial drug products for the treatment of diaper rash should be accompanied by appropriate documentation. Comments will not be accepted at this time on any portion of the OTC topical antimicrobial rulemaking other than that relating to drug products for the treatment of diaper rash.

In accordance with § 330.10(a)(2), the Panel and FDA have held as confidential all information concerning OTC drug products for the treatment of diaper rash submitted for consideration by the Panel. All the submitted information will be put on public display in the Dockets Management Branch, Food and Drug Administration, after October 7, 1982, except to the extent that the person submitting it demonstrates that it falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Requests for confidentiality should be submitted to William E. Gilbertson, Bureau of Drugs and Biologics (HFD–510) (address above).

FDA published in the **Federal Register** of September 29, 1981 (46 FR 47730) a final rule revising the OTC procedural regulations to conform to the decision in *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). The Court in *Cutler* held that the OTC drug review regulations (21 CFR 330.10) were unlawful to the extent that they authorized the marketing of Category III drugs after a final monograph had been established. Accordingly, this provision is now deleted from the regulations. The regulations now provide that any testing necessary to resolve the safety or effectiveness issued that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph.

Although it was not required to do so under *Cutler*, FDA will no longer use the terms "Category I," "Category II," and "Category III" at the final monograph stage in favor of the terms "monograph conditions" (old Category I) and "nonmonograph conditions " (old Categories II and III). This document retains the concepts of Categories I, II, and III because that was the framework in which the Panel conducted its evaluation of the data.

The agency advises that the condition under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the **Federal Register**. In some advance notices of proposed rulemaking previously published in the OTC drug review, the agency suggested an earlier effective date. However, as explained in the tentative final monograph for OTC topical antimicrobial drug products (published in the **Federal Register** of July 9, 1982; 47 FR 29986), the agency has concluded that, generally, it is more reasonable to have a final monograph be effective 12 months after the date of its publication in the **Federal Register**. This period of time should enable manufacturers to reformulate, relabel, or take other steps to comply with a new monograph with a minimum disruption of the marketplace thereby reducing economic loss and ensuring that consumers have continued access to safe and effective drug products.

On or after the effective date of the monograph, no OTC drug products that are subject to the monograph and that contain nonmonograph conditions, i.e., conditions which would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce. Further, any OTC drug products subject to this monograph which are repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

A proposed review of the safety, effectiveness, and labeling of all OTC drugs by independent advisory review panels was announced in the **Federal Register** of January 5, 1972 (37 FR 85). The final regulations providing for this OTC drug review under § 330.10 were published and made effective in the **Federal Register** of May 11, 1972 (37 FR 9464). In accordance with these regulations, a request for data and information on all active ingredients used in OTC miscellaneous external drug products was issued in the **Federal Register** of November 16, 1973 (38 FR 31697). (In making their categorizations with respect to "active" and "inactive" ingredients, the advisory review panels relied on their expertise and understanding of these terms. FDA has defined "active ingredient" in its current good manufacturing practice regulations (§ 210.3(b)(7), (21 CFR 210.3(b)(7))), as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect." An "inactive ingredient" is defined in § 210.3(b)(8) as "any component other than an 'active ingredient.' ") In the **Federal Register** of August 27, 1975 (40 FR 38179), a notice supplemented the original notice with a detailed, but not necessarily all-inclusive, list of ingredients in miscellaneous external drug products to be considered in the OTC drug review. The list, which included "baby cream (diaper rash, rash, prickly heat)" active ingredients, was provided to give guidance on the kinds of active ingredients for which data should be submitted. The notices of November 16, 1973 and August 27, 1975 informed OTC drug product manufacturers of their opportunity to submit data to the review at those times and of the applicability of the monographs from the OTC drug review to all OTC drug products.

Under § 330.10(a) (1) and (5), the Commissioner of Food and Drugs appointed the following Panel to review the information submitted and to prepare a report on the safety, effectiveness, and labeling of the active ingredients in these OTC miscellaneous external drug products:

William E. Lotterhos, M.D., Chairman;
Rose Dagirmanjian, Ph. D.
Vincent J. Derbes, M.D. (resigned July 1976)
George C. Cypress, M.D. (resigned November 1978)
Yelva L. Lynfield, M.D. (appointed October 1977)
Harry E. Morton, Sc. D.
Marianne N. O'Donoghue, M.D.
Chester L. Rossi, D.P.M.
J. Robert Hewson, M.D. (appointed September 1978).

Representatives of consumer and industry interests served as nonvoting members of the Panel. Marvin M. Lipman, M.D., of Consumers Union served as the consumer liaison. Gavin Hildick-Smith, M.D., served as industry liaison from January until August 1975, followed by Bruce Semple, M.D., until February 1978. Both were nominated by the Proprietary Association. Saul A. Bell, Pharm. D., nominated by the Cosmetic, Toiletry, and Fragrance

Association, also served as an industry liaison since June 1975.

Two nonvoting consultants, Albert A. Belmonte, Ph. D., and Jon J. Tanja, R.Ph., M.S., have provided assistance to the Panel since February 1977.

The following FDA employees assisted the Panel: John M. Davitt served as Executive Secretary until August 1977, followed by Arthur Auer until September 1978, followed by John T. McElroy, J.D. Thomas D. DeCilllis, R.Ph., served as Panel Administrator until April 1976, followed by Michael D. Kennedy until January 1978, followed by John T. McElroy, J.D. Joseph Hussion, R.Ph., served as Drug Information Analyst until April 1976, followed by Victor H. Lindmark, Pharm. D., until March 1978, followed by Thomas J. McGinnis, R.Ph.

The Advisory Review panel on OTC Miscellaneous External Drug Products was charges with the review of many categories of drugs. Due to the large number of ingredients and varied labeling claims, the Panel decided to review and publish its findings separately for several drug categories and individual drug products. The Panel presents in this statement its conclusions and recommendations on OTC drug products containing topical antimicrobial ingredients for the treatment of diaper rash. The Panel's findings on other categories of miscellaneous external drug products are being published periodically in the **Federal Register.**

The panel was first convened on January 13, 1975 in an organizational meeting. Working meetings at which drug products for the treatment of diaper rash were discussed were held on November 12 and 13, 1976; June 5 and 6, 1977; October 5 and 6, November 7 and 8, and December 14, 1980.

The minutes of the Panel meetings are on public display in the Dockets Management Branch (HFA–305), Food and Drug Administration (address above).

No individuals requested to appear before the Panel to discuss topical antimicrobial ingredients contained in drug products for the treatment of diaper rash, not was any individual requested to appear by the Panel.

The Panel has reviewed the literature and data submissions, and has considered all pertinent information submitted through December 14, 1980 in arriving at its conclusions and recommendations.

Referenced OTC Volumes

The "OTC Volumes" cited in this document include submissions made by interested persons in response to the call-for-data notices published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179). All of the information included in these volumes, except for those deletions which are made in accordance with confidentiality provisions set forth in § 330.10(a)(2), will be put on Public display after October 7, 1982 in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

Statement on OTC Drug Products for the Treatment of Diaper Rash

A. Submissions of Data and Information

In an attempt to make this review as extensive as possible and to aid manufacturers and other interested persons, the agency compiled a list of ingredients recognized, either through historical use or use in marketed products, as baby cream (diaper rash, rash, prickly heat) active ingredients. Fifty ingredients were identified as follows: alkyldimethyl benzylammonium chloride, allantoin (5-ureidohydantoin), aluminum acetate, aluminum hydroxide, amylum, balsam peru, benzethonium chloride, benzocaine, bicarbonate of soda, bismuth subnitrate, boric acid, calamine, calcium carbonate, camphor, casein, cod liver oil, cysteine hydrochloride, dibucaine, diperodon hydrochloride, glycerin, hexachlorophene, 8-hydroxyquinoline, iron oxide, lanolin, menthol, methapyrilene, methionine, methylbenzethonium chloride, oil of eucalyptus, oil of lavender, oil of peppermint, oil of white thyme, panthenol, *para*-chloromercuriphenol, petrolatum, phenol, pramoxine hydrochloride, salicylic acid, silicone, sorbitan monosterate, talc, tetracaine, vitamin A, vitamin A palmitate, vitamin D, vitamin D_2, vitamin E, white petrolatum, zinc oxide, and zinc stearate. notices were published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) requesting the submission of data and informatin on these ingredients or any other ingredients used in OTC drug products for the treatment of diaper rash.

1. *Submissions.* Pursuant to the above notices, the following submissions were received:

Firms	Marketed products
Block Drug Co., Inc., Jersey City, NJ 07302.	Tashan Super Skin Cream.
Bristol-Myers Co., New York, NY 10022.	Ammens Powder.
Chesebrough-Pond's, Inc., Trumbull, CT 06611.	Vaseline Pure Petroleum Jelly.
Cooper Laboratories, Inc., Cedar Knolls, NJ 07927.	Aveeno Colloidal Oatmeal.
Corona Manufacturing Co., Atlanta, GA 30301.	Corona Ointment.
Macsil, Inc., Philadelphia, PA 19125.	Balmex Ointment.
Miles Laboratories, Inc., Elkhart, IN 46514.	Acid Mantle Creme, Acid Mantle Lotion.
Pennwalt Corp., Rochester, NY 14603.	Caldesene Powder, Caldesene Ointment, Proposed Product Containing Calcium Undecylenate and Hydrocortisone Acetate.
Pfizer Pharmaceuticals, New York, NY 10017.	Desitin Ointment.
Resinol Chemical Co., Baltimore, MD 21201.	Resinol Ointment, Resinol Greaseless Cream.
Sterling Drug, Inc., New York, NY 10016.	Diaparene Ointment, Diaparene Peri Anal, Diaparene Baby Lotion, Diaparene Medicated Baby Powder, Diaparene Diaper Rinse Solution, Diaparene Diaper Rinse (Tablets), Diaparene Diaper Rinse (Granules).
Stiefel Laboratories, Inc., Oak Hill, NY 12460.	Zeasorb Super Absorbent Medicated Power.
Syntex Laboratories, Inc., Palo Alto, CA 94304.	Methakote Diaper Rash Cream.
The Upjohn Co., Kalamazoo, MI 49001.	Clocream Skin Cream.
USV Pharmaceutical Corp., Tuckahoe, NY 10707.	Panthoderm Cream, Panthoderm Lotion.
Whitehall Laboratories, Inc., New York, NY 10017.	Sperti Healing Ointment.
Warren-Teed Pharmaceuticals, Inc., Columbus, OH 43215.	Talcin Diaper Rash Ointment.

2. *Related submissions.* The Panel received data on the role of corn starch as a nutrient for *Candida albicans* from the Department of Dermatology, University of Pennsylvania. Data on the safety of 100 percent corn starch as a dusting powder and an evaluation of the effectiveness of methylbenzethonium chloride in diaper rash remedies were received from Glenbrook Laboratories (a Division of Sterling Drug, Inc.).

3. *Ingredients.* The following list contains ingredients in marketed products submitted to the Panel or ingredients that appeared in the call-for-data notice published in the **Federal Register** of August 27, 1975 (40 FR 38179):

Alkyldimethyl benzylammonium chloride
Allantoin (5-ureidohydantoin)
Aluminum acetate
Aluminum hydroxide
Aluminum dihydroxy allantoinate
Amylum
Aromatic oils
Balsam peru
Balsam peru oil
Beeswax
Benzethonium chloride
Benzocaine
Bicarbonate of soda
Bismuth subcarbonate
Bismuth subnitrate
Boric acid
Calamine (prepared calamine)
Calcium carbonate
Calcium undecylenate
Camphor
Casein
Cellulose

Chloroxylenol (*p*-chloro-*m*-xylenol)
Cod liver oil
Corn starch
Cysteine hydrochloride
Dexpanthenol (*D*-panthenol)
Dibucaine
Diperodon hydrochloride
Eucalyptol
Glycerin
Hexachlorophene
Hydrocortisone acetate
8-Hydroxyquinoline
Iron oxide
Lanolin
Live yeast cell derivative
Magnesium carbonate
Menthol
Methapyrilene
Methionine
DL-Methionine
Methylbenzethonium chloride
Microporous cellulose
Mineral oil
Oil of cade
Oil of eucalyptus
Oil of lavender
Oil of peppermint
Oil of white thyme
Panthenol
Para-chloromercuriphenol
Petrolatum
Phenol
Phenylmercuric nitrate
Pramoxine hydrochloride
Protein hydrolysate (composed of *L*-leucine, *L*-isoleucine, *L*-methionine, *L*-phenylalanine, and *L*-tyrosine)
Resorcinol (resorcin)
Salicylic acid
Shark liver oil
Silicone
Sorbitan monostearate
Starch
Talc
Tetracaine
Vitamin A
Vitamin A palmitate
Vitamin D
Vitamin D_2
Vitamin E (*DL-alpha*-tocopheryl acetate)
White petrolatum
Zinc oxide
Zinc stearate

B. General Discussion

The Panel has determined that many of the ingredients contained in products with "diaper rash" claims submitted to this Panel (Ref. 1), or labeling claims related to diaper rash (skin irritation), have previously been reviewed by other OTC advisory review panels. In this statement, the Panel presents some general comments on OTC drug products for the treatment of diaper rash.

In the **Federal Register** of January 6, 1978 (43 FR 1210), FDA published a tentative final monograph (notice of proposed rulemaking) on OTC topical antimicrobial drug products. The OTC drug products subject to this rulemaking include antibacterial soaps, surgical scrubs, skin cleansers, and first aid preparations. The Miscellaneous External Panel believes that the use of these products to control bacteria may prevent further skin irritation associated with diaper rash. Furthermore, the Panel notes that the ingredients benzethonium chloride, chloroxylenol (*p*-chloro-*m*-xylenol), methylbenzethonium chloride, and phenol are included in the topical antimicrobial rulemaking and, therefore, recommends that the use of these ingredients for "diaper rash" be referred to that rulemaking.

The Panel recommends that the other ingredients listed above be referred to the rulemaking(s) that FDA considers most appropriate. (Note: In order to assure that these ingredients are referred to the most appropriate rulemakings, FDA is seeking public comment from any interested person. Written comments should be submitted in the manner described at the end of this document.) The Panel also recommends that FDA develop labeling for diaper rash drug products by reviewing the Category I labeling already developed in other rulemakings for possible modification to include "diaper rash." (Note: Elsewhere in this issue of the **Federal Register**, the Panel's statement on OTC drug products for the treatment of diaper rash is included in the rulemakings for topical antifungal drug products, external analgesic drug products, and skin protectant drug products.)

The Panel further notes that hexachlorophene is included in the above list of ingredients. However, the use of hexachlorophene as a component of OTC drug products is restricted by 21 CFR 250.250(d). Hexachlorophene is limited to situations where an alternative preservative has not yet been shown to be as effective or where adequate integrity and stability data for the reformulated product are not yet available. Use of hexachlorophene as a preservative at a level higher than 0.1 percent is regarded as a new drug use requiring an approved new drug application.

The Panel did not review any individual ingredients. Instead, the Panel presents the following general comments on the use of OTC diaper rash drug products.

Diaper rash is a common skin problem of infancy, caused by contact with urine and feces, worsened by occlusion with plastic pants, and often secondarily infected with *Candida albicans*. It has an excellent prognosis for permanent cure after an infant is toilet trained. Incontinent adults may get similar irritant contact dermatitis.

The skin under the diaper is macerated by prolonged wetness. Disposable diapers with a plastic backing, or plastic pants used over regular diapers, keep heat as well as moisture in, causing miliaria (prickly heat) as well as more maceration than occurs with the use of regular diapers alone. Bacteria proliferate in this warm, moist environment, thriving on nutrients in feces and metabolizing urine to produce ammonia, an irritant. *Candida albicans*, often present in feces, also proliferates to produce a characteristic bright red, sharply marginated rash with satellite pustules and erosions. Other exacerbating factors are mechanical irritation (chafing) from rough cloth or tight or stiff plastic, chemical irritation from detergent and bleach in diapers or from soap used to cleanse the baby, diarrhea, and heat.

Ordinary mild diaper rash, characterized by erythema of the buttocks, perineum, and lower abdomen, responds to very frequent diaper changes, cleansing with water, and removal of plastic occlusion (switching to cloth diapers, often two at the same time). Most treatments help by protecting the skin, acting as a physical barrier to irritants, and absorbing or adsorbing moisture. Examples are talc and zinc oxide ointment and paste.

The panel wished to point out that physicians treat severe diaper rash with topical antifungal and anticandidal drugs such as iodochlorhydroxyquin, nystatin, amphotericin B, miconazole nitrate, and clotrimazole, often in combination with a topical steroid nitrate (Refs. 2 and 3). Potent fluorinated steroids, such as 0.1 percent triamcinolone cream, should not be used on diaper rash because, when applied under occlusive dressings, these steroids can produce local thinning of the skin, with striae and easy bruising, but 0.5 to 1 percent hydrocortisone cream is recommended.

References

(1) OTC Volumes 160021, 160025, 160027, 160028, 160038, 160040, 160041, 160042, 160053, 160067, 160069, 160070, 160077, 160088, 160091, 160104, 160204, 160236, 160242 through 160247, 160271, 160272, 160277, 160357, 160362, and 160427.

(2) Weston, W. L., "Practical Pediatric Dermatology," Little, Brown and Co., Boston, pp. 51–53, 1979.

(3) Weinberg, S., and R. Hoekelman, "Pediatric Dermatology for the Primary Care Practitioner," McGraw Hill, New York, p. 121, 1979.

Interested persons may, on or before December 6, 1982, submit to the Dockets Management Branch (HAFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments on this advance

notice of proposed rulemaking. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of tis document. Comments replying to comments may also be submitted on or before January 5, 1983. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 333

Labeling, Over-the-counter drugs.

Mark Novitch,

Acting Commissioner of Food and Drugs.

Dated: August 27, 1982.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82-24419, Filed 9-3-82; 8:45 am]

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Tuesday
September 7, 1982

Part V

Department of Health and Human Services

Food and Drug Administration

External Analgesic Drug Products for Over-the-Counter Human Use: Establishment of a Monograph; and Reopening of Administrative Record

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 348

[Docket No. 78N-0301]

External Analgesic Drug Products for Over-the-Counter Human Use: Establishment of a Monograph; and Reopening of Administrative Record

AGENCY: Food and Drug Administration.

ACTION: Advance notice of proposed rulemaking and reopening of administrative record.

SUMMARY: The Food and Drug Administration (FDA) is issuing an advance notice of proposed rulemaking that would establish conditions under which over-the-counter (OTC) external analgesic drug products used (1) for the treatment of diaper rash; (2) for prevention of poison ivy, oak, and sumac; (3) for the treatment of fever blisters; (4) as male genital desensitizers; (5) as astringents; and (6) as insect bite neutralizers are generally recognized as safe and effective and not misbranded. This notice relates to the development of a monograph for external analgesic drug products in general, which is part of the ongoing review of OTC drug products conducted by FDA. This notice also reopens the administrative record for OTC external analgesic drug products to allow for consideration of recommendations on external analgesic drug products for the six drug categories listed above that have been received from the Advisory Review Panel on OTC Miscellaneous External Drug Products.

DATES: Written comments by December 6, 1982 and reply comments by January 5, 1983.

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

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In accordance with Part 330 (21 CFR Part 330), FDA received on April 21, or December 14 or 15, 1980 statements from the Advisory Review Panel on OTC Miscellaneous External Drug Products relating to OTC drug products intended for use (1) in the treatment of diaper rash; (2) for the prevention of poison ivy, oak, and sumac; (3) for the treatment of fever blisters; (4) as male genital desensitizers; (5) as astringents; and (6) as insect bite neutralizers. FDA regulations (21 CFR 330.10(a)(6)) provide that the agency issue in the **Federal Register** a proposed rule containing (1) the monograph recommended by the Panel, which establishes conditions under which these OTC drug products are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph because the Panel determined that they would result in the drugs' not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph because the Panel determined that the available data are insufficient to classify these conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel.

Because some ingredients in the six drug categories listed above are marketed in OTC drug products as external analgesics, FDA has determined that the Miscellaneous External Panel's recommendations on OTC drug products for these uses should be included as part of the proposed rulemaking for OTC external analgesic drug products. Development of this rulemaking has been ongoing for some time.

In the **Federal Register** of December 4, 1979 (44 FR 69768), FDA issued an advance notice of proposed rulemaking to establish a monograph for OTC external analgesic products. FDA advises that it is reopening the administrative record for OTC external analgesic drug products only as it pertains to drug products for the six drug categories listed above in order to allow for the consideration of the Miscellaneous External Panel's recommendations on these products. Comments received on this advance notice of proposed rulemaking will be addressed in a future issue of the **Federal Register**. Also, the proceedings to develop monographs for drug products for the treatment of diaper rash; for the prevention of poison ivy, oak, and sumac; for the treatment of fever blisters; and for insect bite neutralizers will be merged with the general proceeding to establish a monograph for OTC external analgesic drug products.

The Panel did not recommend any Category I conditions for external analgesic ingredients contained in drug products for the treatment of diaper rash; for thr prevention of poison ivy, oak, and sumac; for the treatment of fever blisters; or used as insect bite neutralizers. Therefore, no new sections to Part 348 (as set forth in the advance notice of proposed rulemaking for external analgesic drug products that was published in the **Federal Register** of December 4, 1979 (44 FR 69768)) are included in this advance notice of proposed rulemaking for these drug categories. The Panel did recommend Category I conditions for astringent drug products and male genital desensitizing drug products. Therefore, for these drug categories amendments to Part 348 are included in this advance notice of proposed rulemaking (§§ 348.3 (h) and (i); 348.10 (c) and (d); and 348.50(a)(3) and (4), (b)(4), (5), and (6), (c)(7), (8), and (9), and (d)(1), (2) and (3)).

The unaltered statements of the Panel relating to OTC external analgesic ingredients contained in drug products for the treatment of diaper rash; for the prevention of poison ivy, oak, and sumac; for the treatment of fever blisters; as male genital desensitizers; as astringents; and as insect bite neutralizers are issued to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The statements have been prepared independently of FDA, and the agency has not yet fully evaluated the Panel's recommendations. The Panel's findings appear in this document to obtain public comment before the agency reaches any decision on the Panel's statements. This document represents the best scientific judgment of the Panel members, but does not necessarily reflect the agency's position on any particular matter contained in it.

After reviewing all comments submitted in response to this document, FDA will issue in the **Federal Register** a tentative final monograph for OTC external analgesic drug products to include the six drug categories listed above. Under the OTC drug review procedures, the agency's position and proposal are first stated in the tentative final monograph, which has the status of a proposed rule. Final agency action occurs in the final monograph, which has the status of a final rule.

The agency's position on OTC external analgesic drug products will be stated when the tentative final monograph is published in the **Federal Register** as a notice of proposed rulemaking. In that notice of proposed rulemaking, the agency also will announce its initial determination whether the proposed rule is a major rule under Executive Order 12291 and will consider the requirements of the Regulatory Flexibility Act (5 U.S.C. 601-612). The present notice is referred to as an advance notice of proposed rulemaking to reflect its actual status

and to clarify that the requirements of the Executive Order and the Regulatory Flexibility Act will be considered in the amended notice of proposed rulemaking. At that time FDA also will consider whether the proposed rule has a significant impact on the human environment under 21 CFR Part 25 (proposed in the **Federal Register** of December 11, 1979; 44 FR 71742).

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC external analgesic drug products used for the treatment of diaper rash; for the prevention of poison ivy, oak, and sumac; for the treatment of fever blisters; as male genital desensitizers; as astringents; and as insect bite neutralizers. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on external analgesic drug products relating to the six drug categories listed above should be accompanied by appropriate documentation. Comments will not be accepted at this time on any portion of the OTC external analgesic rulemaking other than that relating to drug products for the six drug categories listed above.

In accordance with § 330.10(a)(2), the Panel and FDA have held as confidential all information concerning OTC drug products for the treatment of diaper rash; for the prevention of poison ivy, oak, and sumac; and as insect bite neutralizers submitted for consideration by the Panel. All the submitted information will be put on public display in the Dockets Management Branch, Food and Drug Administration, after October 7, 1982, except to the extent that the person submitting it demonstrates that it falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Requests for confidentiality should be submitted to William E. Gilbertson, Bureaus of Drugs and Biologics (HFD–510) (address above).

FDA published in the **Federal Register** of September 29, 1981 (46 FR 47730) a final rule revising the OTC procedural regulations to conform to the decision in *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). The Court in *Cutler* held that the OTC drug review regulations (21 CFR 330.10) were unlawful to the extent that they authorized the marketing of Category III drugs after a final monograph had been established. Accordingly, this provision is now deleted from the regulations. The regulations now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph.

Although it was not required to do so under *Cutler*, FDA will no longer use the terms "Category I," "Category II," and "Category III" at the final monograph stage in favor of the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III because that was the framework in which the Panel conducted its evaluation of the data.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the **Federal Register**. In some advance notices of proposed rulemaking previously published in the OTC drug review, the agency suggested an earlier effective date. However, as explained in the tentative final monograph for OTC topical antimicrobial drug products (published in the **Federal Register** of July 9, 1982; 47 FR 29986), the agency has concluded that, generally, it is more reasonable to have a final monograph be effective 12 months after the date of its publication in the **Federal Register**. This period of time should enable manufacturers to reformulate, relabel, or take other steps to comply with a new monograph with a minimum disruption of the marketplace thereby reducing economic loss and ensuring that consumers have continued access to safe and effective drug products.

On or after the effective date of the monograph, no OTC drug products that are subject to the monograph and that contain nonmonograph conditions, i.e., conditions which would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce. Further, any OTC drug products subject to this monograph which are repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

A proposed review of the safety, effectiveness, and labeling of all OTC drugs by independent advisory review panels was announced in the **Federal Register** of January 5, 1972 (37 FR 85). The final regulations providing for this OTC drug review under § 330.10 were published and made effective in the **Federal Register** of May 11, 1972 (37 FR 9464). In accordance with these regulations, a request for data and information on all active ingredients used in OTC miscellaneous external drug products was issued in the **Federal Register** of November 16, 1973 (38 FR 31697). (In making their categorizations with respect to "active" and "inactive" ingredients, the advisory review panels relied on their expertise and understanding of these terms. FDA has defined "active ingredient" in its current good manufacturing practice regulations (§ 210.3(b)(7), (21 CFR 210.3(b)(7))), as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect." An "inactive ingredient" is defined in § 210.3(b)(8) as "any component other than an 'active ingredient.' ") In the **Federal Register** of August 27, 1975 (40 FR 38179) a notice supplemented the original notice with a detailed, but not necessarily all-inclusive, list of ingredients in miscellaneous external drug products to be considered in the OTC drug review. The list, which included "baby cream (diaper rash, rash, prickly heat);" "poison ivy and oak remedies;" "cold sore, fever blister;" "premature ejaculation remedies;" "astringents (styptic pencil)," "astringents," and "wet dressing"' and "insect bites" active ingredients, was provided to give guidance on the kinds of active ingredients for which data should be submitted. The notices of November 16, 1973 and August 27, 1975 informed OTC drug product manufacturers of their opportunity to submit data to the review at those times and of the applicability of the monographs from the OTC drug review to all OTC drug products.

Under § 330.10(a)(1) and (5), the Commissioner of Food and Drugs appointed the following Panel to review the information submitted and to

prepare a report on the safety, effectiveness, and labeling of the active ingredients in these OTC miscellaneous external drug products:

William E. Lotterhos, M.D., Chairman
Rose Dagirmanjian, Ph. D.
Vincent J. Derbes, M.D. (resigned July 1976)
George C. Cypress, M.D. (resigned November 1978)
Yelva L. Lynfield, M.D. (appointed October 1977)
Harry E. Morton, Sc. D.
Marianne N. O'Donoghue, M.D.
Chester L. Rossi, D.P.M.
J. Robert Hewson, M.D. (appointed September 1978)

Representatives of consumer and industry interests served as nonvoting members of the Panel. Marvin M. Lipman, M.D., of Consumers Union served as the consumer liaison. Gavin Hildick-Smith, M.D., served as industry liaison from January until August 1975, followed by Bruce Semple, M.D., until February 1978. Both were nominated by the Proprietary Association. Saul A. Bell, Pharm. D. nominated by the Cosmetic, Toiletry, and Fragrance Association, also served as an industry liaison since June 1975.

Two nonvoting consultants, Albert A. Belmonte, Ph. D., and Jon J. Tanja, R.Ph., M.S., have provided assistance to the Panel since February 1977.

The following FDA employees assisted the Panel: John M. Davitt served as Executive Secretary until August 1977, followed by Arthur Auer until September 1978, followed by John T. McElroy, J.D. Thomas D. DeCillis, R.Ph., served as Panel Administrator until April 1976, followed by Michael D. Kennedy until January 1978, followed by John T. McElroy, J.D. Joseph Hussion, R.Ph., served as Drug Information Analyst until April 1976, followed by Victor H. Lindmark, Pharm. D., until March 1978, followed by Thomas J. McGinnis, R.Ph.

The Advisory Review Panel on OTC Miscellaneous External Drug Products was charged with the review of many categories of drugs. Due to the large number of ingredients and varied labeling claims, the Panel decided to review and publish its findings separately for several drug categories and individual drug products. The Panel presents in this document its conclusions and recommendations on OTC drug products containing external analgesic ingredients for the treatment of diaper rash; for the prevention of poison ivy, oak, and sumac; for the treatment of fever blisters; as male genital desensitizers; as astringents; and as insect bite neutralizers. The Panel's findings on other categories of miscellaneous external drug products are being published periodically in the **Federal Register.**

The Panel was first convened on January 13, 1975 in an organizational meeting. Working meetings at which OTC drug products for the treatment of diaper rash were discussed were held on November 12 and 13, 1976; June 5 and 6, 1977; October 5 and 6, November 7 and 8, and December 14, 1980. Working meetings at which OTC drug products for the prevention of poison ivy, oak, and sumac were discussed were held on April 2 and 3, May 16 and 17, October 8 and 9, and November 12 and 13, 1976; January 14 and 15, April 3 and 4, June 5 and 6, August 5 and 6, and September 30 and October 1, 1977; October 5 and 6, November 7 and 8, and December 14 and 15, 1980. Working meetings at which OTC drug products for the treatment of fever blisters were discussed were held on October 5 and 6, November 7 and 8, and December 14, 1980. Working meetings at which OTC male genital desensitizing drug products were discussed were held on April 20 and 21, June 27 and 28, September 28 and 29, 1975; July 11 and 12, November 12 and 13, 1976; April 3 and 4, 1977; April 16 and 17, October 29 and 30, 1978; March 11 and 12, May 18 and 19, September 28 and 29, October 28 and 29, December 9 and 10, 1979; January 27 and 28, March 7 and 8, and April 20 and 21, 1980. Working meetings at which OTC astringent drug products were discussed were held on September 28 and 29, and November 9 and 10, 1975; May 16 and 17, June 11 and 12, and October 8 and 9, 1976; February 27 and 28, and December 11 and 12, 1977; June 11 and 12, August 11 and 12, and October 29 and 30, 1978; May 18 and 19, and September 28 and 29, 1979; August 3 and 4, October 5 and 6, November 7 and 8, and December 14 and 15, 1980. Working meetings at which OTC insect bite neutralizer drug products were discussed were held on October 8 and 9, and November 12 and 13, 1976; April 3 and 4, and June 5 and 6, 1977; October 5 and 6, November 7 and 8, and December 14 and 15, 1980.

The minutes of the Panel meetings are on public display in the Dockets Management Branch (HFA–305), Food and Drug Administration (address above).

No individuals requested to appear before the Panel to discuss external analgesic ingredients contained in drug products used for the treatment of diaper rash; for the prevention of poison ivy, oak, and sumac; for the treatment of fever blisters; or as insect bite neutralizers, nor was any individual requested to appear by the Panel.

The following individuals were given an opportunity to appear before the Panel, either at their own request or at the request of the Panel, to express their views on male genital desensitizing drug products:

John Adriani, M.D.
William Jordan, M.D.
Adalbert Vajay, M.D.
Chalon Rodriguez, M.D.

No person who so requested was denied an opportunity to appear before the Panel to discuss male genital desensitizing drug products.

The following individuals were given an opportunity to appear before the Panel, either at their own request or at the request of the Panel to express their views on astringent drug products:

Steven Carson, Ph. D.
Edward Jackowitz
James Leyden, M.D.
Kenneth Klippel
Robert Scheuplein, Ph. D.

No person who so requested was denied an opportunity to appear before the Panel to discuss astringent drug products.

In accordance with the OTC drug review regulations in § 330.10, the Panel reviewed the OTC drug products discussed in this document with respect to the following three categories:

Category I. Conditions under which OTC drug products are generally recognized as safe and effective and are not misbranded.

Category II. Conditions under which OTC drug products are not generally recognized as safe and effective or are misbranded.

Category III. Conditions for which the available data are insufficient to permit final classification at this time.

Referenced OTC Volumes.

The "OTC Volumes" cited in this document include submissions made by interested persons in response to the call-for-data notices published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179). All of the information included in these volumes, except for those deletions which are made in accordance with confidentiality provisions set forth in § 330.10(a)(2), will be put on public display after October 7, 1982, in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

I. Statement on OTC Drug Products for the Treatment of Diaper Rash

A. Submission of Data and Information

In an attempt to make this review as extensive as possible and to aid manufacturers and other interested persons, the agency compiled a list of ingredients recognized, either through historical use or use in marketed products, as baby cream (diaper rash, rash, prickly heat) active ingredients. Fifty ingredients were identified as follows: alkyldimethyl benzylammonium chloride, allantoin (5-ureidohydantoin), aluminum acetate, aluminum hydroxide, amylum, balsam peru, benzethonium chloride, benzocaine, bicarbonate of soda, bismuth subnitrate, boric acid, calamine, calcium carbonate, camphor, casein, cod liver oil, cysteine hydrochloride, dibucaine, diperodon hydrochloride, hlycerin, hexachlorophene, 8-hydroxyquinoline, iron oxide, lanolin, menthol, methapyrilene, methionine, methylbenzethonium chloride, oil of eucalyptus, oil of lavender, oil of peppermint, oil of white thyme, panthenol, *para*-chloromercuriphenol, petrolatum, phenol, pramoxine hydrochloride, salicylic acid, silicone, sorbitan monostearate, talc, tetracaine, vitamin A, vitamin A palmitate, vitamin D, vitamin D_2, vitamin E, white petrolatum, zinc oxide, and zinc stearate. Notices were published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) requesting the submission of data and information on these ingredients or any other ingredients used in OTC drug products for the treatment of diaper rash.

1. *Submissions.* Pursuant to the above notices, the following submissions were received:

Firms	Marketed products
Block Drug Co., Inc., Jersey City, NJ 07302.	Tashan Super Skin Cream.
Bristol-Myers Co., New York, NY 10022.	Ammens Powder.
Chesebrough-Pond's, Inc., Trumbull, CT 06611.	Vaseline Pure Petroletum Jelly.
Cooper Laboratories, Inc., Cedar Knolls, NJ 07927.	Aveeno Colloidal Oatmeal.
Corona Manufacturing Co., Atlanta, GA 30301.	Corona Ointment.
Macsil, Inc., Philadelphia, PA 19125.	Balmex Ointment.
Miles Laboratories, Inc., Elkhart, IN 46514.	Acid Mantle Creme, Acid Mantle Lotion.
Pennwalt Corp., Rochester, NY 14603.	Caldesene Powder, Caldesene Ointment, Proposed Product Containing Calcium Undercylenate and Hydrocortisone Acetate.
Pfizer Pharmaceuticals, New York, NY 10017.	Desitin Ointment.
Resinol Chemical Co., Baltimore, MD 21201.	Resinol Ointment, Resinol Greaseless Cream.
Sterling Drug, Inc., New York, NY 10016.	Diaparene Ointment, Diaparene Peri Anal, Diaparene Baby Lotion, Diaparene Medicated Baby Powder, Diaparene Diaper Rinse Solution, Diaparene Diaper Rinse (Tablets), Diaparene Diaper Rinse (Granules).
Stiefel Laboratories, Inc., Oak Hill, NY 12460.	Zeasorb Super Absorbent Medicated Power.
Syntex Laboratories, Inc., Palo Alto, CA 94304.	Methakote Diaper Rash Cream.
The Upjohn Co., Kalamazoo, MI 49001.	Clocream Skin Cream.
USV Pharmaceutical Corp., Tuckahoe, NY 10707.	Panthoderm Cream, Panthoderm Lotion.
Whitehall Laboratories, Inc., New York, NY 10017.	Sperti Healing Ointment.
Warren-Teed Pharmaceuticals, Inc., Columbus, OH 43215.	Taloin Diaper Rash Ointment.

2. *Related submissions.* The Panel received data on the role of corn starch as a nutrient for *Candida albicans* from the Department of Dermatology, University of Pennsylvania. Data on the safety of 100 percent corn starch as a dusting powder and an evaluation of the effectiveness of methylbenzethonium chloride in diaper rash remedies were received from Glenbrook Laboratories (a Division of Sterling Drug, Inc.).

3. *Ingredients.* The following list contains ingredients in marketed products submitted to the Panel or ingredients that appeared in the call-for-data notice published in the **Federal Register** of August 27, 1975 (40 FR 38179):

Alkyldimethyl benzylammonium chloride
Allantoin (5-ureidohydantoin)
Aluminum acetate
Aluminum hydroxide
Aluminum dihydroxy allantoinate
Amylum
Aromatic oils
Balsam peru
Balsam peru oil
Beeswax
Benzethonium chloride
Benzocaine
Bicarbonate of soda
Bismuth subcarbonate
Bismuth subnitrate
Boric acid
Calamine (prepared calamine)
Calcium carbonate
Calcium undecylenate
Camphor
Casein
Cellulose
Chloroxylenol (*p*-chloro-*m*-xylenol)
Cod liver oil
Corn starch
Cysteine hydrochloride
Dexpanthenol (*D*-panthenol)
Dibucaine
Diperodon hydrochloride
Eucalyptol
Glycerin
Hexachlorophene
Hydrocortisone acetate
8-Hydroxyquinoline
Iron oxide
Lanolin
Live yeast cell derivative
Magnesium carbonate
Menthol
Methapyrilene
Methionine
DL-Methionine
Methylbenzethonium chloride
Microporous cellulose
Mineral oil
Oil of cade
Oil of eucalyptus
Oil of lavender
Oil of peppermint
Oil of white thyme
Panthenol
Para-chloromercuriphenol
Petrolatum
Phenol
Phenylmercuric nitrate
Pramoxine hydrochloride
Protein hydrolysate (composed of *L*-leucine, *L*-isoleucine, *L*-methionine, *L*-phenylalanine, and *L*-tyrosine)
Resorcinol (resorcin)
Salicylic acid
Shark liver oil
Silicone
Sorbitan monostearate
Starch
Talc
Tetracaine
Vitamin A
Vitamin A palmitate
Vitamin D
Vitamin D_2
Vitamin E (*DL-alpha*-tocopheryl acetate)
White petrolatum
Zinc oxide
Zinc stearate

B. General Discussion

The Panel has reviewed the literature and data submissions, and has considered all pertinent information submitted through December 14, 1980 in arriving at its conclusions and recommendations.

The Panel has determined that many of the ingredients contained in products with "diaper rash" claims submitted to this Panel (Ref. 1), or labeling claims related to diaper rash (skin irritation), have previously been reviewed by other OTC advisory review panels. In this statement, the Panel presents some general comments on OTC drug products for the treatment of diaper rash.

In the **Federal Register** of December 4, 1979 (44 FR 69768), FDA published a proposed monograph (advance notice of proposed rulemaking) on OTC external analgesic drug products. The OTC drug products subject to this rulemaking include products used as topical analgesics, anesthetics, antipruritics, or counterirritants. The Miscellaneous External Panel believes that the use of these products may also be useful for

the treatment of diaper rash. Furthermore, the Panel notes that the ingredients dibucaine, eucalyptol, hydrocortisone acetate, menthol, methapyrilene, oil of eucalyptus, oil of cade, phenol, pramoxine hydrochloride, resorcinol (resorcin), and tetracaine are included in the external analgesic rulemaking and, therefore, recommends that the use of these ingredients for "diaper rash" be referred to that rulemaking.

The Panel recommends that the other ingredients listed above be referred to the rulemaking(s) that FDA considers most appropriate.

Note.—In order to assure that these ingredients are referred to the most appropriate rulemakings, FDA is seeking public comment from any interested person. Written comments should be submitted in the manner described at the end of this document.

The Panel also recommends that FDA develop labeling for diaper rash drug products by reviewing the Category I labeling already developed in other rulemakings for possible modification to include "diaper rash." (Note: Elsewhere in this issue of the **Federal Register**, the Panel's statement on OTC drug products for the treatment of diaper rash is included in the rulemakings for topical antifungal drug products, topical antimicrobial drug products, and skin protectant drug products.)

The Panel further notes that hexachlorophene is included in the above list of ingredients. However, the use of hexachlorophene as a component of OTC drug products is restricted by 21 CFR 250.250(d). Hexachlorophene is limited to situations where an alternative preservative has not yet been shown to be as effective or where adequate integrity and stability data for the reformulated product are not yet available. Use of hexachlorophene as a preservative at a level higher than 0.1 percent is regarded as a new drug use requiring an approved new drug application.

The Panel did not review any individual ingredients. Instead, the Panel presents the following general comments on the use of OTC diaper rash drug products.

Diaper rash is a common skin problem of infancy, caused by contact with urine and feces, worsened by occlusion with plastic pants, and often secondarily infected with *Candida albicans*. It has an excellent prognosis for permanent cure after an infant is toilet trained. Incontinent adults may get similar irritant contact dermatitis.

The skin under the diaper is macerated by prolonged wetness. Disposable diapers with a plastic backing, or plastic pants used over regular diapers, keep heat as well as moisture in, causing miliaria (prickly heat) as well as more maceration than occurs with the use of regular diapers alone. Bacteria proliferate in this warm, moist environment, thriving on nutrients in feces and metabolizing urine to produce ammonia, an irritant. *Candida albicans*, often present in feces, also proliferates to produce a characteristic bright red, sharply marginated rash with satellite pustules and erosions. Other exacerbating factors are diarrhea, heat, mechanical irritation (chafing) from rough cloth or tight or stiff plastic, and chemical irritation from detergent and bleach in diapers or from soap used to cleanse the baby.

Ordinary mild diaper rash, characterized by erythema of the buttocks, perineum, and lower abdomen, responds to very frequent diaper changes, cleansing with water, and removal of plastic occlusion (switching to cloth diapers, often two at the same time). Most treatments help by protecting the skin, acting as a physical barrier to irritants, and absorbing or adsorbing moisture. Examples are talc and zinc oxide ointment and paste.

The Panel wishes to point out that physicians treat severe diaper rash with topical antifungal and anticandidal drugs such as iodochlorhydroxyquin, nystatin, amphotericin B, miconazole nitrate, and clotrimazole, often in combination with topical steroid (Refs. 2 and 3). Potent fluorinated steroids, such as 0.1 percent triamcinolone cream, should not be used on diaper rash because when applied under occlusive dressings these steroids can produce local thinning of the skin, with striae and easy bruising, but 0.5 to 1 percent hydrocortisone cream is recommended.

References

(1) OTC Volumes 160021, 160025, 160027, 160028, 160038, 160040, 160041, 160042, 160053, 160067, 160069, 160070, 160077, 160088, 160091, 160104, 160204, 160236, 160242 through 160247, 160271, 160272, 160277, 160357, 160362, and 160427.

(2) Weston, W. L., "Practical Pediatric Dermatology," Little, Brown and Co., Boston, pp. 51–53, 1979.

(3) Weinberg, S., and R. Hoekelman, "Pediatric Dermatology for the Primary Care Practitioner," McGraw Hill, New York, p. 121, 1979.

II. Statement on OTC Drug Products For the Prevention of Poison Ivy, Oak, and Sumac

A. Submission of Data and Information

In an attempt to make this review as extensive as possible and to aid manufacturers and other interested persons, the agency compiled a list of ingredients recognized, either through historical use or use in marketed products, as active ingredients in poison ivy and oak remedies. Forty-six ingredients were identified as follows: alcohol, allantoin (5-ureidohydantoin), beechwood creosote, benzethonium chloride, benzocaine, benzyl alcohol, bicarbonate of soda, bichloride of mercury, bithionol, calamine, camphor, cetyldimethyl-benzylammonium chloride, chloral hydrate, chloroform, chlorpheniramine maleate, dimethyl polysiloxane, diperodon hydrochloride, diphenhydramine hydrochloride, endothermic hectorite, ferric chloride, glycerin, hexachlorophene, hydrogen peroxide, hydrous zirconia, iron oxide, isopropyl alcohol, lanolin, lead acetate, lidocaine, menthol, merbromin, oil of eucalyptus, oil of turpentine, panthenol, parethoxycaine, phenol, phenyltoloxamine dihydrogen citrate, polyvinyl pyrrolidone, pyrilamine maleate, salicylic acid, tannic acid, tincture of impatiens bi-flora, triethanolamine, zinc acetate, zirconium oxide, and zyloxin. Notices were published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) requesting the submission of data and information on these ingredients or any other ingredients used in OTC poison ivy and oak remedy drug products.

Pursuant to the above notices, the following submissions were received:

Firms and Products

Marion Health and Safety, Inc., Rockford, IL 61101; Poison Ivy Wash, Ferric Chloride, and Zircreme

Unimed, Inc., Somerville, NJ 08876; Residerm

B. Classification of Ingredients

In this document, the Panel has reviewed only those ingredients with a claim for preventing poison ivy, oak, or sumac.

1. *Active ingredients.* Buffered mixture of cation and anion exchange resins.

2. *Other ingredient.* The Panel was not able to locate nor is it aware of data demonstrating the safety and effectiveness of ferric chloride when used as an OTC poison, ivy, oak, and sumac prevention active ingredient. The Panel, therefore, classifies ferric chloride as Category II for this use, and it will be briefly discussed later in this document. (See part II. paragraph C. below—*General Discussion.*)

3. *Ingredients deferred to other rulemakings.* The Panel has determined has determined that some of the ingredients that appeared in the **Federal Register** of August 27, 1975 (40 FR 38179) are contained in products usually associated with the symptomatic

treatment of poison ivy, oak, and sumac. These types of products have been previously reviewed by the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products as external analgesic drug products (for the temporary relief of minor skin irritations, itching, and rashes due to poison ivy, poison oak, and poison sumac) in the **Federal Register** of December 4, 1979 (44 FR 69768).

Note.—Elsewhere in this issue of the **Federal Register**, the Panel's statement on OTC drug products for the prevention of poison ivy, oak, and sumac is included in the rulemaking for skin protectant drug products.

The Panel did not receive any data on the following ingredients used for the prevention of poison ivy, poison oak, and poison sumac. These ingredients should be considered in other appropriate rulemakings for their use in treating poison ivy, poison oak, poison sumac, and their related symptoms.

Alcohol
Allantoin
Benzethonium chloride
Benzocaine
Benzyl alcohol
Bithionol
Calamine
Camphor
Cetalkonium chloride (cetyldimethylbenzylammonium chloride)
Chloral hydrate
Chlopheniramine maleate
Creosote (beechwood creosote)
Diperodon hydrochloride
Diphenhydramine hydrochloride
Endothermic hectorite
Eucalyptus oil (oil of eucalyptus)
Glycerin
Hydrogen peroxide
Iron oxide
Isopropyl alcohol
Lanolin
Lead acetate
Lidocaine
Menthol
Merbromin
Mercuric chloride (bichloride of mercury)
Oil of turpentine
Panthenol
Parethoxycaine hydrochloride (parethoxycaine)
Phenol
Phenyltoloxamine citrate (phenyltoloxamine dihydrogen citrate)
Polyvinylpyrrolidone (polyvinyl pyrrolidone)
Pyrilamine maleate
Salicylic acid
Simethicone (dimethyl polysiloxane)
Sodium bicarbonate (bicarbonate of soda)
Tannic acid
Tincture of impatiens bi-flora
Trolamine (triethanolamine)
Zinc acetate
Zirconium oxide (hydrous zirconia)
Zyloxin

4. *Ingredients subject to existing regulation.* The Panel notes that hexachlorophene and chloroform are restricted as components of OTC drug products under 21 CFR 250.250(d) and 21 CFR 310.513.

C. General Discussion

The Panel has reviewed the literature and data submissions and has considered all pertinent information submitted through December 5, 1980 in arriving at its conclusions and recommendations.

The Panel received three submissions for products claiming to prevent poison ivy, oak, or sumac by complexing with the plant antigen before it enters the skin (Refs. 1, 2, and 3). Two submissions contained no substantial data to establish the safety and effectiveness of the active ingredient (ferric chloride) contained in the product (Refs. 2 and 3). The Panel has therefore placed this ingredient in Category II. (See paragraph B.2. above—Other ingredients.) The third submission (Ref. 1) contained data on the use of a buffered mixture of cation and anion exchange resins in the prevention and treatment of poison ivy. The Panel addresses these data below. (See part II. paragraph D.3.a. below—*Category III ingredient—Buffered mixture of cation and anion exchange resins.*)

The Panel wishes to emphasize that claims for the relief of minor skin irritations, itching, and rashes due to poison ivy, oak, and sumac have been previously addressed by another OTC Advisory Review Panel. (See the report on OTC External Analgesic Drug Products published in the **Federal Register** of December 4, 1979 (44 FR 69768).) Therefore, this document only discusses the use of OTC drug products for the prevention of poison ivy, oak, and sumac. The Panel recommends that the agency defer to other appropriate rulemakings those ingredients and labeling claims submitted for treatment of the symptoms of poison ivy, oak, or sumac.

References

(1) OTC Volume 160103.
(2) OTC Volume 160132.
(3) OTC Volume 160152.

D. Categorization of Data

1. *Category I conditions.* None.

2. *Category II conditions.* (See part II. paragraph B.2. above—*Other ingredient.*)

3. *Category III conditions.* These are conditions for which available data are insufficient to permit final classfication at this time.

a. *Category III ingredient—Buffered mixture of cation and anion exchange resins.* The Panel concludes that there are insufficient data to establish the effectiveness of a buffered mixture of cation and anion exchange resins for the prevention of poison ivy, oak, and sumac.

This mixture is a resin bed that contains both acidic groups and basic groups, mixed intimately in definite ratios, and possesses the ability to remove cations and anions simultaneously from solution.

(i) *Safety.* Skin irritation studies submitted show insignificant degrees of irritation during the first 2 weeks of observation. During the fourth week of observation severe lesions with cellulitis were seen in the rabbit skin and the technician applying the test material. It was the conclusion of the investigators that the test material was safe for topical application if it were used for a period not exceeding 14 to 21 days (Ref. 1).

(ii) *Effectiveness.* The mechanism of action of the buffered mixture of anion and cation exchange resins is claimed to be that these ingredients react chemically with the plant irritants that cause poison ivy, oak, and sumac to inactivate them. The inactivated irritants can then be readily removed from the skin by washing. However, Fisher (Ref. 2) states that no topical measure is effective in preventing poison ivy dermatitis.

The data submitted included an unblinded, poison ivy efficacy study using 20 subjects to determine efficacy of the mixture and an unblinded, uncontrolled clinical study. The uncontrolled clinical study consisted of 32 case reports submitted by 13 different phsycians who claimed effective results from the product.

Twenty male subjects, who were sensitive to poison ivy, were chosen for the unblinded study to evaluate the efficacy of a buffered mixture of cation and anion exchange resin in the treatment of poison ivy. Ten subjects followed a therapeutic course, and ten of the subjects followed a prophylactic course. For purposes of this document only, the portion of the study dealing with dermatitis prevention properties of the active ingredient is relevant. In this portion, the placebo showed almost the same degree of efficacy as the mixture of resins (Ref. 1).

(iii) *Evaluation.* The Panel concludes that there are insufficient data to show the effectiveness of a buffered mixture of anion and cation exchange resins when used in the prevention of poison ivy dermatitis.

References

(1) OTC Volume 160103.

(2) Fisher, A. A. "Contact Dermatitis," 2d Ed., Lea and Febiger, Philadelphia, pp. 260–265, 1973.

b. *Category III labeling.* None.

III. Statement on OTC Drug Products for the Treatment of Fever Blisters

A. Submission of Data and Information

In an attempt to make this review as extensive as possible and to aid manufacturers and other interested persons, the agency compiled a list of ingredients recognized, either through historical use or use in marketed products, as "cold sore, fever blister" active ingredients. Eighteen ingredients were identified as follows: alcohol, allantoin (5-ureidohydantoin), ammonia, ammonium carbonate, benzalkonium chloride, benzocaine, camphor, lanolin, lanolin alcohol, menthol, mineral oil, paraffin, peppermint oil, petrolatum, phenol, sorbitan sequioleate, soya sterol, and tannic acid. Notices were published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) requesting the submission of data and information on these ingredients or any other ingredients used in OTC "cold sore, fever blister" drug products.

1. *Submissions.* Pursuant to the above notices, the following submissions were received:

Firms and Marketed Products

Blister, Inc., Oak Brook, IL 60521; Blistex Ointment, Blistik Medicate Lip Balm

Campbell Laboratories, Inc., Farmingdale, NY 10022; Herpecin-L

Commerce Drug Co., Inc., Farmingdale, NY 11735; Bio-Stik, Tanac Stik, Tanac

International Pharmaceutical Corp., Kansas City, MO 64114; Gly-Oxide

Oral Prophylactic Association, Inc., Duluth, MN 55812; Mouth Komfort

Sterling Drug, Inc., New York, NY 10016; Campho-Phenique

2. *Ingredients.* The following list contains labeled ingredients contained in marketed products submitted to the Panel or ingredients that appeared in the call-for-data notice published in the **Federal Register** of August 27, 1975 (40 FR 38179):

Alcohol
Allantoin (5-ureidohydantoin)
Ammonia
Ammonium carbonate
Amyl dimethyl-*p*-aminobenzoate
Amyl *para*-dimethylaminobenzoate
Anhydrous glycerol
Aromatic oily solution
Beeswax
Benzalkonium chloride
Benzocaine
BHA
Bismuth sodium tartrate
Calcium silicate
Camphor
Candleillia wax
Carbamide peroxide
Carnauba wax
Castor oil
Cetyl alcohol
Escalol 506
Glycerol
Homosalate
Lanolin
Lanolin alcohol
Menthol
Mineral oil
Octyldodecanol
Ozokerite
Paraffin
Pectin
Peppermint oil
Petrolatum
Phenol
Propyl *p*-benzoate
Pyridoxine hydrochloride
Sorbitan sesquioleate
Soya sterol
Sesame oil
Spermaceti
Talcum powder
Tannic acid
Thymol
Titanium dioxide
Wheat germ glycerides
White petrolatum

B. General Discussion

The Panel has reviewed the literature and data submissions, and has considered all pertinent information submitted through December 14, 1980 in arriving at its conclusions and recommendations.

The Panel has determined that many of the ingredients contained in products with "cold sore, fever blister" claims submitted to this Panel (Ref. 1), or labeling claims related to fever blisters (irritation and discomfort), have previously been reviewed by other OTC advisory review panels. In this statement, the Panel presents some general comments on OTC drug products for the treatment of fever blisters.

In the **Federal Register** of December 4, 1979 (44 FR 69768), FDA published a proposed monograph (advance notice of proposed rulemaking) on OTC external analgesic drug products. The OTC drug products subject to this rulemaking include products used as topical analgesics, anesthetics, antipruritics, or counterirritants. The Miscellaneous External Panel believes that the use of these products may also be useful for the treatment of fever blisters. Furthermore, the Panel notes that the ingredients benzocaine, camphor, menthol, phenol, and thymol are included in the external analgesic rulemaking and, therefore, recommends that the use of these ingredients for "fever blisters" be referred to that rulemaking.

The Panel recommends that the other ingredients listed above be referred to the rulemaking(s) that FDA consider most approrpriate.

Note.—In order to assure that these ingredients are referred to the most appropriate rulemaking(s), FDA is seeking public comment from interested person. Written comments should be submitted in the manner described at the end of this document.)

The Panel also recommends that FDA develop labeling for cold sore and fever blister drug products by reviewing the Category I labeling already developed in other rulemakings for possible modification to include "cold sore" and "fever blister" claims.

Note.—Elsewhere in this issue of the **Federal Register**, the Panel's statement on OTC drug products for the treatment of fever blisters is included in the rulemaking for skin protectant drug products.

The OTC remedies for treating fever blisters consist of internally taken (oral) and externally applied (topical) medications. Only those which are externally administered to the lips are considered in this document. Preparations to be taken internally have been considered by the Advisory Review Panel on OTC Miscellaneous Internal Drug Products and its recommendations were published in the **Federal Register** of January 5, 1982 (47 FR 502).

The Panel did not review any individual ingredients. Instead, the Panel presents the following general comments on the use of OTC externally applied cold sore and fever blister drug products.

"Fever blisters" and "cold sores" are common names for herpes simplex, an acute infectious disease caused by the filterable (capable of passing through filters) virus *Herpes simplex*, type 1. Herpes simplex viruses are deoxyribonucleic acid (DNA) viruses, sensitive to ethyl ether and of two antigenic types. The type 1 virus is usually, but not exclusively, associated with nongenital lesions. The usual site of the lesion is at the junction of the mucous membrane and skin on the lips or nose. Hence, the term *herpes labialis* is frequently used. Occasionally, the lesions may occur in the skin in various areas of the body. The virus is spread from person to person by the oral or respiratory route. On the other hand, the type 2 virus is usually, but not exclusively (a small percentage of fever blisters are caused by this type), associated with genital lesions and is

spread from person to person by sexual contact. Hence, the term *herpes genitalis* is frequently used for this type of infection, which, at the present time, is perhaps the third most common sexually transmitted disease.

A description of the development of a herpes simplex lesion provides the explanation why there are no adequate OTC measures currently available for specifically preventing or curing the infection. The assemblying of the virus capsid within the nucleus of an infected cell is the beginning of virus production. The envelope is assembled around the capsid when it passes through the membrane of the nucleus into the cytoplasm of the host cell. Later the virus is released from the host's cell.Thus it is believed that any locally applied drug is likely to be without direct action upon the intracellular virus and is not beneficial prophylactically or therapeutically.

The course of events during herpetic infections in man is well understood and occurs in a predictable order. The majority of adults have humoral immunity (antibodies) to the herpes simplex type 1 virus so the majority of infants are born with passive immunity comparable to the degree to active immunity of the mother. The inherited passive immunity of the infant disappears during the first few months of life and by about 5 years of age the child begins to develop active immunity by exposure to the virus. The first infection in the nonimmune individual due to exposure to the virus is designated primary herpes. It may be so mild as to be unnoticed, a subclinical infection, or it may be severe; the symptoms in the latter case may range from a severe localized infection to a generalized infection that occasionally is fatal.

Usually the primary herpetic infection in the nonimmune person manifests itself by vesicles (blisters) on the mucous membranes in the mouth. The gums and tonsils may be involved as well as the regional lymph nodes. There may be a constitutional reaction and high fever. The virus may gain entrance to the blood stream that may result in a generalized vesicular eruption on the skin (a herpeticum eczema). The eyes may become involved, which results in a keratoconjunctivitis, and the central nervous system may become involved, giving rise to meningoencephalitis. Severe primary herpetic infections require laboratory procedures for specific diagnosis in order to differentiate them from infections with other viruses which may produce similar symptoms. Fortunately, the primary herpetic infection usually is self-limited. It persists longer than the recurrent infections, possibly 2 weeks, the period during which the body develops antibodies to combat the infection. The virus is not eliminated from the body with recovery from the primary infection. Once infected an individual probably harbors the virus for the remainder of his or her lifetime (Ref. 2).

During the intervals between the primary infection and the first recurrent infection, and between subsequent recurrent infections, the herpes virus is thought to remain dormant in the neurons of the sensory ganglia serving the region of the primary infection (a latent infection). The current thinking is that the incomplete virus may be integrated into the host cell chromosomes. In any event, the humoral and cellular immunities of the host keep the infection under control until some event occurs to reduce the immunity (resistance) of the host. Such events as fever, chilling, sunburn, windburn, menstruation, upset stomach or gastrointestinal disturbance, emotional stress, or excitement may reduce the immune state sufficiently for the virus to become activated and again cause an infection, designated recurrent herpes (Ref. 2).

Recurrent herpes usually begins with a sensation of mild burning or itching and a feeling of firmness in the local area. Shortly thereafter, papules appear followed by vesicles. The sensation of firmness and the appearance of papules are due to the intra- and inter-cellular edema (accumulation of fluid). If erythema (redness) occurs in the area, it is due to the dilation of the blood capillaries. The vesicles may coalesce to form groups of thin-walled vesicles which may rupture. The vesicle fluid contains the complete virus and it is infectious. The stratum mucosum (prickle-cells) of the skin is involved and when the vesicles rupture and the overlying layers of the skin slough off, scabs form and healing takes place without scarring. If large denuded areas appear before scab formation occurs, bleeding may occur. If the scabs are large, cracking or separation may occur due to the movement of the lips. Necrosis does not occur. Occasionally, secondary bacterial infection may take place. Healing usually takes place in about 7 to 10 days. If healing does not take place within this time period, the consumer may have made a misdiagnosis of a fever blister and actually had something worse. Hence, the Panel recommends that labeling for fever blister drug products contain the warning "If the fever blister does not improve in one week, consult a doctor." Recurrent infections usually occur in the same general area. The only preventive measure is to avoid, where possible, the conditions that bring about activation of the virus, if such events are known and can be controlled (Ref. 2).

The Panel concludes that primary infections with herpes virus type 1 may be so mild as to go unnoticed or sufficiently serious as to require the attention of a physician. The recurrent herpetic infections are more annoying or embarrassing than they are serious. While these, too, may be sufficiently serious to justify the services of a physician, the recurrent local infections usually can be self-diagnosed and OTC preparations used for palliative or symptomatic treatment.

The Panel discussed a newly developed technique for evaluating herpes treatment (Ref. 3). This technique used a guinea pig model in which the immune system was stimulated by drying the herpes lesion. The quicker the drying of the herpes cell, the faster it can be controlled from spreading to surrounding epithelial cells. Once the spread of herpes is slowed, the antigen-antibody reaction starts to inactivate the herpes virus.

Astringents such as tannic acid have been used in products for the relief of fever blisters (Ref. 4). The Miscellaneous External Panel notes that the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products, in the **Federal Register** of August 4, 1978 (43 FR 34628), noted that tannic acid has little action on intact skin. When applied to abraded tissue, it precipitates a protein-tannate film that serves as a mechanical cover which may encourage bacterial growth under the protein-tannate crust (43 FR 34644). However, the Panel concludes that tannic acid in low concentrations applied to a small area such as a fever blister would be safe (Ref. 5), but the data submitted (Ref. 4) on the use of this ingredient in treating fever blisters are insufficient to establish effectiveness. Nevertheless, the Panel recommends that human studies be conducted because the use of astringents may be a rational treatment in shortening the healing time of fever blisters.

Only one human study (Ref. 6) was submitted to the Panel. The study employed carbamide peroxide 10 percent in anhydrous glycerin and a control of anhydrous glycerin. According to the researchers, the medication provided highly dependable relief of pain (the chief complaint from

subjects) and surprisingly frequent reduction in healing time.

There is no prophylactic OTC therapy of proven value. Vaccines are being evaluated and may be useful in the future. The repeated use of smallpox inoculations has never been reliably shown to inhibit recurrent herpes simplex (Ref. 7).

Although most viral infections cannot be cured by OTC drugs, fever blisters should not be neglected. Local anesthetics can relieve pain, anitbiotics can control secondary bacterial infections when they occur, and ointments (protectants) can soften crusts. Steriod hormone ointments are not recommended against infections and may spread the virus (Ref. 8). Drying agents such as alcohols, astringents, or skin protectant agents may be useful (Ref. 7).

References

(1) OTC Volumes 160008, 160012, 160013, 160048, 160096, 160136, 160177, 160197, 160213, 160218,and 160231.

(2) Dorsett, P. H., "Burrows Textbook of Microbiology," 21st Ed., W. B. Saunders Co., Philadelphia, pp. 972–989, 1979.

(3) Transcript of Proceedings of the Advisory Review Panel on OTC Miscellaneous External Drug Products, October 6, 1980 pp. 28–33..

(4) OTC Volume 160012.

(5) Transcript of Proceedings of the Advisory Review Panel on OTC Miscellaneous External Drug Products, November 8, 1980, p. 24.

(6) OTC Volume 160177.

(7) Arndt, K. A., "Manual of Dermatologic Therapeutics With Essentials of Diagnosis," 2nd Ed., Little, Brown and Co., Boston, pp. 103–10, 1978.

(8) "Canker Sores and Fever Blisters," National Institute of Dental Research, DHEW Publication No. (NIH) 79–247.

IV. Statement on OTC Male Genital Desensitizing Drug Products

A. Submission of Data and Information

In an attempt to make this review as extensive as possible and to aid manufacturers and other interested persons, the agency compiled a list of ingredients recognized, either through historical use or use in marketed products, as male genital desensitizing active ingredients. Four ingredients were identified as follows: benzocaine, benzyl alcohol, ephedrine hydrochloride, and passion fruit. Notices were published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) requesting the submission of data and information on these ingredients or any other ingredients used in OTC premature ejaculation remedies (male genital desensitizing drug products).

1. *Submissions.* Pursuant to the above notices, the following submissions were received:

Firms and *Marketed Products*

Commerce Drug Co., Inc., Division of Del Laboratories, Inc., Farmingdale, NY 11735; Detane

Pound International Corp., New York, NY 10022; Stud 100

A related submission on Culminal was received from Frederic Damrau, M.D., New York, NY 10023.

Ciba-Geigy Corp., Summit, NJ 07901, submitted an adverse reaction report for a marketed product containing dibucaine. Because the submission contained no effectiveness data, and because the product is not labeled for use in treating premature ejaculation, the Panel did not consider the use of dibucaine in this document.

2. *Ingredients Reviewed by the Panel*— a. *Labeled ingredients contained in marketed products submitted to the Panel.*

Benzocaine
Lidocaine
Passion fruit

b. *Other ingredients reviewed by the Panel.*

Benzyl alcohol
Ephedrine hydrochloride

3. *Classification of Ingredients*—a. *Active ingredients.*

Benzocaine
Lidocaine

b. *Inactive ingredient.* Passion fruit.

c. *Other ingredients.* The Panel was not able to locate nor is it aware of any data demonstrating the safety and effectiveness of the following ingredients when used as OTC male genital desensitizing active ingredients. The Panel, therefore, classified these ingredients as Category II for this use, and they will not be discussed further in this document.

Benzyl alcohol
Ephedrine hydrochloride

B. General Discussion

The panel has reviewed the literature and data submissions, has listened to additional testimony from interested persons, and has considered all pertinent information submitted theough April 21, 1980 in arriving at its conclusions and recommendations.

The Panel reviewed the labeling submitted for marketed OTC products used to prevent premature ejaculation and noted that the two call-for-data notices published in the **Federal Register** requested data and information on "premature ejaculation remedies." However, based upon a review of the currently marketed products and on the fact that these products contain anesthetics used for desensitization, the Panel concludes that a more reasonable and descriptive term is "male genital desensitizing drug products." The Panel believes that such a term would be an accurate description of the pharmacologic category of those drugs and would be understood by the layman. Therefore, throughout this document the Panel will refer to these products as male genital desensitizers.

In the **Federal Register** of December 4, 1979 (44 FR 69768), FDA published a proposed monograph (advance notice of proposed rulemaking) on OTC external analgesic drug products. The OTC drug products subject to this rulemaking include products used as topical analgesics, anesthetics, antipruritics, or counterirritants. The Panel believes that the topical anesthetics (enzocaine and lidocaine) discussed in this statement as male genital desensitizing ingredients should be included in the external analgesic rulemaking because they have been extensively reviewed as part of that rulemaking.

The act of ejaculation may be purely a reflex (Ref. 1). In the first stage of ejaculation, nerve impulses originating in the sensitive glans penis are carried to the spinal cord and then transmitted to the muscles of the vasa deferentia, ejaculatory ducts, and prostate gland, causing secretions to be forced into the urethra (Ref. 2). In fhe final stage of ejaculation, contractions of the penile urethra forcibly expel semen from the penis (Ref. 1).

In about 75 percent of men, orgasm occurs approximately 2 minutes after entry of the penis into the vagina. In a considerable number, the climax is reached with less than a minute or even within 10 or 20 seconds after entrance (Ref. 2).

Premature ejaculation, or ejaculatio procox, is a common abnormality in which the climax occurs on contact with the vulva or immediately after introduction of the penis into the vagina. According to Damrau (Ref. 2), premature ejaculation is generally attributed to three basic causes: (1) Hypersensitivity of the glans penis, resulting in excessive stimulation of the sexual center in the spinal cord with prompt initiation of the ejaculation reflex (physiological viewpoint); (2) inflammation of the verumontanum (colliculus seminalis), which is the trigger mechanism of the ejaculation reflex (urological viewpoint); (3) psychoneurosis related to the sex life (psychiatric viewpoint).

In addition, Damrau (Ref. 2) observes that the male orgasm may be normally timed but premature in relation to a

sexually unresponsive female partner, and that the man who ejaculates before his mate becomes sexually aroused is not necessarily impotent, neurotic, or abnormal. Kinsey, Pomeroy, and Martin (Ref. 3) state that the quick performance of the typical male partner in relation to the slower response of many women is a physiological fact established by scientific surveys. Altogether, taking into consideration the number of women who experience orgasm before or immediately on insertion of the penis into the vagina, it is estimated by Damrau (Ref. 2) that approximately 25 percent of married couples fail to reach the climax simultaneously.

In 1943, Thorne (Ref. 4) reported that premature ejaculation was commonly preceded by a long period of restraint, with gradually increasing excitement resulting in a low level of resistance to sexual stimulation and quick orgasm.

The reflex mechanism of ejaculation, together with the fact that the impulse originates in the hypersensitive mucous membrane of the glans penis, suggested to Damrau (Ref. 2) the use of such mucosal anesthetics as benzocaine to delay the climax and prolong coitus. In 1963, he reported that an effective mucosal anesthetic applied to the glans penis should raise the level of resistance of sexual excitation and thereby delay the climax.

The Panel is aware of the many different treatments of premature ejaculation described in the literature. There are publications that relate premature ejaculation to emotional causes and state that psychological counseling of the patient to alleviate fear and anxiety and to rebuild self-confidence may be the best treatment. Other papers cite the use of drugs, topical anesthetics such as benzocaine and lidocaine, or internal medications such as thioridazine and benzodiazepines, either alone or concurrently with psychological counseling in the treatment of premature ejaculation. Still other publications deal with reeducation of the ejaculatory reflex by mechanical means such as the "start stop" technique of Semans (Ref. 5) later modified to the "squeeze" technique by Masters and Johnson (Ref. 6). Good results have been reported from all of the above methods of treating premature ejaculation.

The Panel has carefully considered the anatomy and physiology of the penis and its mucosa and agrees that there is a rationale for the use of topical anesthetics to desensitize the nerve endings in the glans penis in order to prolong time between insertion of the penis into the vagina and ejaculation. The Panel has also concluded that there is a target population that could benefit from the use of such male genital desensitizers and that a simple form of medical treatment such as use of topical anesthetics, which have been reported to be satisfactory in many cases, deserves a trial by the consumer before more prolonged and expensive methods of psychiatric treatment are untertaken.

However, the Panel is concerned about the lack of data on the effect of benzocaine and lidocaine on the sperm and the ovum (female egg) and feels that the following warning statement is warranted: "The effect of this product on sperm and fertility has not been determined."

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(3) Kinsey, A. C., W. B. Pomeroy, and C. E. Martin, "Sexual Behavior in the Human Male," W. B. Saunders and Co., Philadelphia, p. 579, 1948.

(4) Thorne, F. C., "Ejaculata Praecox: Cause and Treatment," *Diseases of the Nervous System*, 4:273–275, 1943.

(5) Semans, J. H., "Premature Ejaculation: A New Approach," *Southern Medical Journal*, 49:353–358, 1956.

(6) Masters, W. H., and V. E. Johnson, "Premature Ejaculation," *in* "Human Sexual Inadequacy," Little, Brown and Co., Boston, pp. 92–115, 1970.

C. Categorization of Data

1. *Category I conditions.* These are conditions under which active ingredients used as male genital desensitizers are generally recognized as safe and effective and are not misbranded. The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the Federal Register.

a. *Category I ingredients.*

Benzocaine, Lidocaine.

(1) *Benzocaine.* The Panel concludes that a 3- to 7.5-percent concentration of benzocaine in a water-soluble base is safe and effective for OTC use as a male genital desensitizer.

Benzocaine (ethyl aminobenzoate) has a long history of use as an anesthetic (Ref. 1). In the Federal Register of December 4, 1979 (44 FR 69768), the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products (hereinafter referred to as the External Analgesic Panel) stated that the use of benzocaine dates to the early 1900's.

Benzocaine occurs as small, white, odorless crystals, or as a white crystalline powder, melting between 88° and 92° C. It is stable in air and exhibits local anesthetic properties when placed on the tongue. One g of benzocaine is soluble in about 2,500 mL of water, 5 mL of alcohol, 2 mL of chloroform, 4 mL of ether, and 30 to 50 mL of expressed (pressed) almond oil or olive oil. It is also soluble in dilute mineral acids (Ref. 2). Benzocaine may be prepared by reducing aminobenzoic acid and esterifying the latter with ethyl alcohol in the presence of sulfuric acid (Ref. 2).

Some local anesthetics are poorly soluble in water and consequently are too slowly absorbed to be toxic. Benzocaine falls into this category (Refs. 3 and 4).

Benzocaine is a base because of the amino group on the benzoic acid nucleus. It is lipid soluble (fat soluble) and poorly ionized. Benzocaine readily penetrates the lipid barriers of the cell membranes, causing the onset of analgesia to occur within minutes (Ref. 5).

Benzocaine acts, as do other topical anesthetics, on the axonal membrane of nerve cells to interrupt conduction of nerve impluses to central receptors in the brain. Like other local anesthetics, it stabilizes the membrane and prevents passage of sodium ions into the axonal cytoplasm, thereby preventing depolarization. Its anesthetic activity is decreased or lost when benzocaine is formulated in an acid medium and salts are formed (Refs. 3, 6, and 7). The salts are then ionized and do not readily penetrate the lipid barriers of cell membranes.

The buffering mechnisms of mucous membranes act to break down the benzocaine salts and release benzocaine in its basic form. For this reason, the salts are effective on mucous membranes, but not on intact skin (Ref. 8).

In the Federal Register of December 4, 1979 (44 FR 69768), the External Analgesic Panel concluded that benzocaine and other topical analgesics should be formulated in water-soluble bases. The External Analgesic Panel based this conclusion on a study by Campbell and Adriani (Ref. (9) which showed that topical anesthetics are not released as rapidly from oleaginous (oily) or petrolatum bases as they are from water-soluble bases. The Miscellaneous External Panel agrees with the External Analgesic Panel and recommends that benzocaine for use as a male genital desensitizer be formulated in a water-soluble base.

(i) *Safety.* Benzocaine has a relatively low water solubility, with little or no absorption occurring when it is applied to either intact skin or mucous membranes (Ref. 10). Blood levels of benzocaine are undetactable following such application. This is in contract to the water-soluble amide topical anesthetics. The convulsions and cardiac depression resulting from high plasma levels of the amide anesthetics do not occur with benzocaine; reports of such reactions with the use of benzocaine are nonexistent (Ref. 10).

Studies using guinea pigs to determine the systemic toxicity of a topically applied mixture containing 7.5 percent benzocaine failed to produce any gross macroscopic or microscopic alterations in visceral organs. The 7.5-percent benzocaine mixture was also found to be nontoxic, nonsensitizing, and nonirritating to the eyes, skin, and oral mucosa. Further studies on rabbits have shown no change in cellular morphology (structure) of the circulating blood (Ref. 5).

The Panel is aware of conflicting reports in the literature regarding the sensitizing potential of benzocaine. Fisher (Ref. 11) states. "This topical anesthetic is still widely used even though it is a common and potent sensitizer, which can produce allergic dermatitis from infancy to old age. In my opinion, its use should be prohibited * * *". In Fisher's view, there is also a strong possibility of cross-sensitization with other aminobenzoic acid esters, such as procaine, tetracaine, butacaine, and other durgs in this series. About 25 percent of benzocaine-sensitive individuals cross-react with paraphenylenediamine (the most popular hair dye), with the sulfonamides, and with sunscreening agents based on aminobenzoic esters (Ref. 11).

In the North American Contact Dermatitis Group study (Ref. 12), the incidence of benzocaine sensitivity was shown to be 5 percent in patients with a history of chronic skin disorders. There is a lower incidence of allergic sensitizatikon (2 percent) to benzocaine in pharmaceutical industry employees who work with this ingredient (Ref. 12).

In the general population, a study was done by Prystowsky (Ref. 13) in San Francisco on 1,158 volunteers who were free of dermatitis. Benzocaine sensitivity was found in 0.17 percent of these normal volunteers (Ref. 13).

Adriani, affirming the safety of benzocaine, stated his view in a presentation to the Panel (Ref. 14) that reported adverse reactions to benzocaine have not been considered in relation to the total number of repeated applications of the drug and with subjects who are not "high risk."

Another supporter of the relative safety of benzocaine is Mathieu (Ref. 15). After reviewing the literature on cross-sensitivity, he found instances of cross-sensitivity among all the local anesthetics to be rare, regardless of the mode of administration.

It has been found that contact dermatitis occurs more frequently on the skin than on the mucous membranes. Possibly this is because the keratin layer of the skin may contain proteins that more readily combine with simple chemicals to form allergens (Ref. 16). The oral mucosa dilutes benzocaine with saliva, and the vaginal and penile mucous membranes also secrete enough fluid to decrease the concentration of benzocaine.

Methemoglobinemia (a condition where the blood contains ferric ions and is unable to combine reversibly with molecular oxygen) and its attendant cyanosis (a blue skin coloration due to excessive concentration of reduced hemoglobin in the blood) have been reported after the use of benzocaine in persons with deficiency of a particular enzyme normally present in red blood cells (Ref. 17). Although this reaction is rare, it does occur and has been confirmed in laboratory animals by the topical application of relatively high doses of benzocaine to the mucous membranes (Ref. 5). It has also occurred in children who have had the drug applied rectally (Ref. 7). However, Adriani and Zepernick (Ref. 18) reported that "of the entire group at Charity Hospital in the past twenty years on whom benzocaine ointment was used for lubrication in phyaryngeal and tracheal areas, only one patient developed methoemoglobinemia. This was promptly reversed by the intravenous administration of methylene blue."

The Panel, therefore, concludes that the use of benzocaine on a small area of mucous membrane, such as the glans penis, for genital desensitization is safe. To protect individuals who may be sensitive to benzocaine, the Panel recommends the following warning: "Use this product with caution if you or your partner are sensitive to topical anesthetics, sunscreens, sulfa drugs, or hair dyes."

(ii) *Effectiveness.* Dalili and Adriani (Ref. 16) devised a method for testing the sensation of itch on the unbroken skin by means of a Grass S–44 model electrical stimulator using low-energy, high-frequency currents. A subminimal stimulus to a cutaneous pain fiber induces a sensation of itch, while currents of greater intensity produce pain. Dalili and Adriani (Ref. 16) found that benzocaine was effective as an antipruritic (anti-itch) in human volunteers when applied to the intact skin in concentrations over 10 percent. However, in concentrations below 5 percent, benzocaine was ineffective as an intipruritic in the majority of instances. The salts of benzocaine were ineffective as antipruritics on the intact skin, regardless of the concentration, as were the salts of other local anesthetics tested, such as tetracaine, lidocaine, pramoxine, and butacaine.

On the ultraviolet-burned intact skin of human volunteers, the base form of benzocaine was an effective topical analgesic in concentrations ranging from 10 to 20 perent. Concentrations below 10 percent were partially effective in relieving an itching, burning, and prickling sensation. On the ultraviolet-burned intact skin, all salts including the salts of benzocaine, tetracaine, lidocaine, dibucaine, and procaine were ineffective.

The onset of analgesia in intact skin occurred in 10 to 15 minutes following the application of a 20-percent benzocaine preparation, with the duration of the blockade of sensation apparently limited only by the duration of contact of the benzocaine preparation with the skin (Ref. 16). Within 30 seconds after the benzocaine preparation is wiped off, the ability to perceive the electrical stimulus and the sensation of burning in the ultraviolet-burned subjects returned. The studies of Dalili and Adriani (Ref. 16) show that an effective blockade lasted even after 4 hours, as long as the preparation remained in contact with the skin and was not rubbed off.

Benzocaine has been shown to be an excellent topical anesthetic for endoscopy (Ref. 18) and burns of all degrees (Ref. 19).

Damrau (Ref. 20) conducted a study on 13 men, with an average age of 31.2 years (range 22 to 39 years), who ejaculated prior to, or upon, insertion of the penis into the vagina. The subjects had experienced this condition for an average of 2.7 years (range 0.5 to 5 years). During the average treatment period of 2 months, a 3-percent benzocaine cream was applied to the head and shaft of the penis prior to intercourse. This resulted in correction of or premature ejaculation in all 13 cases. The average time interval between insertion of the penis into the vagina and orgasm was lengthened to 1.6 minutes (range 0.5 to 5 minutes). The use of a 3-percent benzocaine preparation had no reported effect on vaginal sensation in the female partners.

Another study by Damrau (Ref. 20), using benzocaine, was conducted on nine volunteers, with an average age 32.6 years (range 18 to 42 years) who did not claim to have a premature ejaculation problem. The procedure was to massage a small amount of the cream (2 g by weight) over the glans penis, wait 5 minutes, wipe off any excess, and proceed with intercourse. The observation period was for 3 days in five cases and for 30 days in four cases. This study compared the results of the anesthesia produced with a 3-percent benzocaine cream to that of a 5-percent benzocaine cream. The average duration of topical anesthesia on the mucous membrane with the 3-percent cream was 19.4 minutes. The 5-percent cream anesthesized for 20.2 minutes. The average delay of orgasm with the 3-percent cream was 2.8 minutes as compared to 2.9 minutes with the 5-percent strength. There were no adverse effects.

Vajay (Ref. 21) conducted a study on 120 men with premature ejaculation problems during intercourse. He compared the effectiveness of a 7.5-percent benzocaine ointment to a placebo. Results of this study showed that 108 of the men (90 percent) benefited by maintaining an average of at least 2 minutes control over their ejaculatory reflex when using the 7.5-percent benzocaine ointment. Of the 120 subjects, 86 men or 71.7 percent benefited substantially (3 minutes or more). Only 8 of the 120 men benefited from a placebo. Seventy-two and one-half percent of the female partners achieved climax when the benzocaine ointment was used, as compared to only 2.5 percent when the placebo was used.

Thirty-two of the 120 female partners voluntarily reported that the clitoris was not anesthetized when the male partner used a 7.5-percent benzocaine ointment, nor were any other adverse vaginal effects reported.

The long OTC marketing history of benzocaine for other desensitizing uses and its effective use in clinical studies to temporarily delay premature ejaculation provide the basis for the Panel's conclusion that benzocaine when properly formulated in a water-soluble base is safe and effective as a male genital desensitizer.

In addition the Panel believes that patients should be directed to wash off any of the remaining benzocaine preparation after intercourse to minimize the chance of an allergic reaction occurring.

(iii) *Dosage.* Topical dose is a preparation of 3 to 7.5 percent benzocaine in a water-soluble base.

(iv) *Directions.* "Apply a small amount to head and shaft of penis before intercourse. Wash off after intercourse."

(v) *Warning.* "Use this product with caution if you or your partner are sensitive to topical anesthetics, sunscreens, sulfa drugs, or hair dyes."

(vi) *Labeling.* The Panel recommends the Category I labeling for male genital desensitizing active ingredients. (See part VI. paragraph C.1.b. below—*Category I labeling.*)

References

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(2) *Lidocaine.* The Panel concludes that lidocaine is safe and effective for OTC use as a male genital desensitizer when used within the dosage limits stated below.

Lidocaine is a widely used local anesthetic of the amide group. In the **Federal Register** of December 4, 1979 (44 FR 69768), the External Analgesic Panel reached the conclusion that lidocaine is safe and effective on the skin and mucous membranes when properly formulated in a concentration of 0.5 to 4 percent. The maximum recommended dose for adults is 200 mg and 500 mg for local infiltration or nerve block, not to be repeated in less than 2 hours (Refs. 1 and 2). Rapid injection of 50 to 100 mg of lidocaine or an infusion of 1 to 4 mg per minute is used to control ventricular arrhythmias; the therapeutic blood levels range from 2 to 5 micrograms per milliliter (μg/mL).

(i) *Safety.* Adverse effects to lidocaine can occur from toxicity or from allergy.

The major effect of lidocaine toxicity, as with all nitrogenous local anesthetics, is stimulation of the central nervous system, producing restlessness, tremor, and convulsions. However, depression of the central nervous system may occur in some patients, causing drowsiness, coma, and respiratory arrest. High doses may depress myocardial contractility.

Sensitivity to lidocaine is rare, although anaphylactic (hypersensitive) reactions have been reported (Ref. 3). A

patient who is allergic to an ester-type local anesthetic such as procaine may be able to tolerate an amide such as lidocaine. Allergic contact dermatitis is more frequent with benzocaine and procaine than with lidocaine (Ref. 4).

Lidocaine is not irritating on local application to the skin or mucous membrane (Refs. 5 and 6). An aerosol spay, delivering a dose of 95 mg lidocaine, was applied to one side of the penis of each of 90 men (80 were 17 to 25 years of age and 10 were 25 to 45 years of age). The spray was left on for 2 days. No skin reactions were visible except on one man's penis which had immediate irritation and erythema interpreted as an allergic reaction. This person was a diabetic with chronic candidal balanitis (a yeast infection) who had previously reacted to other topical medications (Ref. 6). A smaller dose of the same spray was applied to the vulva and inserted into the vagina of each of 10 women without any reactions (Ref. 6).

Absorption of topical anesthetics from mucous membranes is rapid and significant (Ref. 3). Thomas (Ref. 7) measured plasma lidocaine concentrations following topical aerosol application to the perineum or vagina of women in labor. Fifteen women received 400 mg (40 sprays) each of lidocaine. The highest venous plasma concentration, obtained by frequent blood sampling within 2 to 4 hours after spraying, was 1.22 μg/mL; this was the only value above 1μg/mL and most were considerably lower. Seven women received lidocaine aerosol spray to the vagina and perineum before episiotomy repair; two received 400 mg, and five received 1 g. the highest blood level noted in 75 minutes of blood sampling was 0.65 μg/mL even though the lidocaine was applied to or near cut and broken skin or mucous membranes. In determining the toxic blood level of lidocaine, studies quoted by Mazze and Dunbar (Ref. 8) showed that, at rapid rates of infusion, signs of toxicity occur when plazma lidocaine concentrations exceed 4.4 to 5.3 μg/mL. At slower infusion rates, the toxic level was 10μg/mL.

A male genital desensitizer containing lidocaine in either a pump or aerosol vehicle is marketed in a metered spray which limits the maximum amount of lidocaine dispensed per metered dose to 11.7 mg (Ref. 5). The product label recommends application of 2 or more sprays, not to exceed 10, to the external surfaces of the penis. The minimal effective dose was shown to be 30 mg or approximately 3 sprays. The maximum recommended dose of 10 sprays (117 mg) would be well below the dose applied to the parturient women described in the study above. The Panel believes a metered dose would be safe for OTC use provided that the maximum dose recommended not be more than 120 mg.

An unmetered aerosol preparation containing 9.6 percent lidocaine in a ½ ounce container is also marketed (Ref. 5). If the entire container is used at once, a dose of 0.096×15 g, equal to 1.44 g, would be applied. No safety studies using an application of this amount of lidocaine to the penis were submitted to the Panel, and the Panel considers this product to be unsafe because the dose is not controlled.

(ii) *Effectiveness.* Studies supporting the effectiveness of lidocaine were done on a marketed product containing 9.6 percent lidocaine in a metered aerosol vehicle (Refs. 8 through 11).

In one study (Ref. 8), 21 men (18 to 36 years of age) were asked to masterbate, and the time from erection to ejaculation was noted. Seven were given 10 spray doses of lidocaine aerosol (total amount of lidocaine equal to 117 mg), 7 were given 10 sprays of a deodorant, and 7 received no spray. The next day 2 dropped out of the study, and the remaining 19 volunteers from the day before received 10 sprays of the lidocaine product, and the masturbation time required to achieve ejaculation was remeasured. Masturbation time for the control group ranged from less than 1 minute to less than 5 minutes, while masturbation time for those receiving the lidocaine spray was greater than 5 minutes, with four volunteers being unable to ejaculate after 15 minutes. Of the four volunteers unable to ejaculate, only one of them was previously unable to ejaculate without the spray. The first seven men returned in 3 weeks for masturbation time testing without spray. This group served as a control. According to the researcher conducting the study, the lidocaine spray significantly prolonged the time from erection to ejaculation.

In another study (Ref. 9), the response of the penile skin to touch, pressure, pain, temperature, position, vibration, and tactile stimulation was studied—first without spray, then with a vaginal deodorant spray, and then with 10 sprays of the lidocaine product. In each of the five subjects, no difference was noted between sensitivity without spray and sensitivity following deodorant spray, but the lidocaine spray was effective in reducing the sensitivity of the penis.

A third study (Ref. 10) measured the effect of 9.6 percent lidocaine on 10 men using a metered aerosol, varying from 2 to 10 sprays (the dosage recommended in the labeling of the product), on the length of time required to achieve ejaculation by masturbation. Each spray contained 11.7 mg. After four sprays or fewer, 50 percent showed prolongation of masturbation time before ejaculation, while doses of six or more sprays were effective in 100 percent of the subjects.

In a final study conducted by Linken (Ref. 11), 10 normal volunteers were measured for length of masturbatory time, from time of erection to time of ejaculation (a technique discribed by Linken in previous lidocaine study). Each volunteer used 2, 3, 4, 6, 8, or 10 sprays of a proprietary lidocaine with 3 minutes between each period of masturbation. Each volunteer was given a different dosage schedule, i.e., some volunteers started with 10 sprays, next 4 sprays, etc. The dosage schedule for each volunteer was chosen at random. Two re-evaluations were done during the study on each volunteer with different dosage schedules. At the conclusion of the study each volunteer was asked to give a subjective feeling on the alteration of sensuality.

Before the study was initiated, masturbatory times were measured with each volunteer. Masturbatory times ranged from 0.50 minute to 4.20 minutes (an average of 2.28 minutes). With use of product, 2 sprays produced an increase in masturbatory time in 6 cases, a decrease in 4 cases, and on the reevaluation, 2 volunteers showed an increase giving an overall 30 percent increase above the norm. With the 3-spray dosage schedule, 70 percent showed above average masturbatory times, with the 4-spray dosage schedule, 50 percent were above the average, and with the 6-, 8-, and 10-spray dosage schedule, 100 percent were above the average. (Two cases failed to complete the total experiments.)

Results of the subjectives questioning at the conclusion of the study revealed that all the volunteers noted different feelings, i.e. stinging, coolness, and/or an indescribable alteration of penile feeling.

The Panel concludes that these studies (Refs. 8 through 11) show lidocaine spray to be an effective male genital desensitizer. The Panel notes that three of the studies deal with ejaculation resulting from masturbation, and two studies deals with penile sensitivity. It considers the results of these studies predictive of effectiveness of lidocaine in retarding the onset of ejaculation in sexual intercourse.

(iii) *Dosage.* A metered spray with approximately 10 mg per spray in a

container of not more than 120 mg capacity.

(iv) *Directions.* "Apply 3 or more sprays, not to exceed 10, to head and shaft of penis before intercourse. Wash off after intercourse."

(v) *Labeling.* The Panel recommends the Category I labeling for male genital desensitizing active ingredients. (See part VI. paragraph C.1.b. below—*Category I labeling.)*

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b. *Category I labeling.* The Panel recommends the following Category I labeling for male genital desensitizing drug products to be generally recognized as safe and effective and not misbranded.

(1) *Indications.* The indications should be limited to one or more of the following phrases:

(i) "For temporary male genital desensitization helping to slow the onset of ejaculation."

(ii) "Aids in temporarily retarding the onset of ejaculation."

(iii) "Aids in temporarily slowing the onset of ejaculation."

(iv) "Aids in temporarily prolonging time until ejaculation."

(v) "For reducing oversensitivity in the male in advance of intercourse."

(vi) "As an aid in the prevention of premature ejaculation."

2. *Warnings.* (i) "Premature ejaculation may be due to a condition requiring medical supervision. If this product, used as directed, does not provide relief, discontinue use and consult a doctor."

(ii) "Avoid contact with the eyes."

(iii) "If skin to which you apply this product becomes irritated, discontinue use and consult a doctor."

(iv) "Keep this and all drugs out of the reach of children."

(v) "The effect of this product on sperm and fertility has not been determined."

2. *Category II conditions.* These are conditions under which active ingredients used as male genital desensitizers are not generally recognized as safe and effective or are misbranded. The Panel recommends that the Category II conditions be eliminated from OTC male genital desensitizing drug products effective 6 months after the date of publication of the final monograph in the **Federal Register.**

a. *Category II ingredients.* (See part VI. paragraph A.3.c. above—*Other ingredients.*)

b. *Category II labeling.* The Panel has placed in Category II the following claims:

(1) "Aids in temporarily retarding rapidity of ejaculation" and "Aids in temporarily slowing the speed of ejaculation." These claims are considered misleading because male genital desensitizer drug products have not been demonstrated to affect the rate of the normal sexual reflex mechanism.

(2) "To strengthen sexual confidence."

(3) "Original and unchallenged throughout the world for quality, effectiveness, and satisfaction."

3. *Category III conditions.* Those conditions for which available data are insufficient to permit final classification at the time.

a. *Category III ingredients.* None.

b. *Category III labeling.* None.

4. *Combination policy.* No male genital desensitizing drug product combinations were submitted to the Panel for review. The Panel is not aware of any data on such combinations, and therefore any such combinations are placed in Category II.

V. Statement on OTC Astringent Drug Products

A. Submission of Data and Information

In an attempt to make this review as extensive as possible and to aid manufacturers and other interested persons, the agency compiled a list of ingredients recognized, either through historical use or use in marketed products, as astringents, astringent (styptic pencil), and wet dressings active ingredients. Thirty-one ingredients were identified as follows: acetone, alcohol 14 percent, aluminum acetate, aluminum chlorhydroxy complex, aluminum sulfate, ammonium alum, benzalkonium chloride, benzethonium chloride, boric acid, calcium acetate, camphor, cresol, cupric sulfate, ferric subsulfate, isopropyl alcohol, menthol, oxyquinoline sulfate, phenol, polyoxyethylene monolaurate, potassium alum, potassium ferrocyanide, silver nitrate, sodium diacetate, starch, talc, tannic acid, tannic acid glycerite, zinc chloride, zinc phenolsulfonate, zinc stearate, and zinc sulfate. Notices were published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) requesting the submission of data and information on these ingredients or any other ingredients used in OTC astringent drug products.

Pursuant to the above notices, the following submissions were received:

Firms	Marketed products
Commerce Drug Co., Inc., Farmingdale, NY 11735.	Tanac.
Cooper Laboratories, Inc., Cedar Knolls, NJ 07927	Bur-Veen.
Cox Drugs, Asheville, NC 28803	Formula U.
The E. E. Dickinson Co., Essex, CT 06426.	Witch Hazel.
Dome Division, Miles Laboratories, Inc., West Haven, CT 06516.	Domeboro Effervescent Tablets, Domeboro Powder Packets.
Foxpharmacal, Inc., Ft. Lauderdale, FL 33310.	Secret Mirache.
R. L. Gaddy Co., Tallahassee, FL 32302.	Ez-It Medicated Foot Powder
Humphreys Pharmacal, Inc., Rutherford, NJ 07070.	Witch Hazel.
Marion Laboratories, Inc., Kansas City, MO 64137.	Bluboro Powder.
Requa Manufacturing Co., Inc., Greenwich, CT 06830.	Aluminum Sulfate.
Sea Breeze Laboratories, Inc., Pittsburgh, PA 15244.	Sea Breeze.
The Woltra Company, Inc., New York, NY 10011.	Mammoth Styptic Pencil, Styptic Pencil.

B. Ingredients Reviewed by the Panel

1. *Labeled ingredients contained in marketed products submitted to the Panel.*

Alcohol
Alum
Aluminum acetate
Aluminum sulfate
Aromatics

Benzalkonium chloride
Benzocaine
Benzoic acid
Borax
Boric acid
para-tertiary-Butyl-*meta*-cresol
Calcium acetate
Camphor
Carbolic acid
Colloidal oatmeal
Eugenol
Gum camphor
Honey
Menthol
Modified Burow's solution
Oil of cloves
Oil of eucalyptus
Oil of peppermint
Oil of sage
Oil of wintergreen
Powdered alum
Starch
Talc
Tannic acid
Thymol
Witch hazel
Zinc oxide
Zinc stearate

2. *Other ingredients.* The following list contains ingredients that appeared in the call-for-data notice published in the **Federal Register** of August 27, 1975 (40 FR 38179) and were not contained in marketed products submitted to the Panel.

Acetone
Alcohol 14 percent
Aluminum chlorhydroxy complex
Ammonium alum
Benzethonium chloride
Cresol
Cupric sulfate
Ferric subsulfate
Isopropyl alcohol
Oxyquinoline sulfate
Phenol
Polyoxyethylene monolaurate
Potassium ferrocyanide
Silver nitrate
Sodium diacetate
Tannic acid glycerite
Zinc chloride
Zinc phenolsulfonate
Zinc sulfate

C. Classification of Ingredients

1. *Active ingredients.*

Aluminum acetate (modified Burow's solution)
Aluminum sulfate
Witch hazel

2. *Tannic acid.* The Panel decided not to review tannic acid as an astringent, but will discuss this ingredient for use in the treatment of fever blisters. (See part III above—STATEMENT ON OTC DRUG PRODUCTS FOR THE TREATMENT OF FEVER BLISTERS.) This decision was based on the fact that the only submission on tannic acid contained data and information for use in treating fever blisters (OTC Volume 160012). The Panel concluded that it is dangerous to use tannic acid as an astringent over large areas of the body because it precipitates protein which forms a protective coating over mucous membranes and abraded tissue and because the area under the coating is conducive for bacterial growth.

3. *Other ingredients.* The Panel was not able to locate nor is it aware of data demonstrating the safety and effectiveness of the following ingredients when used as OTC astringent active ingredients. The Panel, therefore, classifies these ingredients as Category II for this use, and they will not be discussed further in this document.

Acetone
Alcohol
Alcohol 14 percent
Alum (powdered alum)
Aluminum chlorhydroxy complex
Ammonium alum
Aromatics
Benzalkonium chloride
Benzethonium chloride
Benzocaine
Benzoic acid
Borax
Boric acid
para-tertiary-Butyl-*meta*-cresol
Calcium acetate
Camphor (gum camphor)
Collodial oatmeal
Cresol
Cupric sulfate
Eugenol
Ferric subsulfate
Honey
Isopropyl alcohol
Menthol
Oil of cloves
Oil of eucalyptus
Oil of peppermint
Oil of wintergreen
Oxyquinoline sulfate
Phenol (carbolic acid)
Polyoxyethylene monolaurate
Potassium alum
Potassium ferrocyanide
Silver nitrate
Sodium diacetate
Starch
Talc
Tannic acid glycerite
Thymol
Zinc chloride
Zinc oxide
Zinc phenolsulfonate
Zinc stearate
Zinc sulfate

D. General Discussion

The Panel has thoroughly reviewed the literature and data submissions, and has considered all pertinent information submitted through December 15, 1980 in arriving at its conclusions and recommendations.

The Panel has determined that some of the ingredients contained in products with "astringent" claims submitted to this Panel (Ref. 1), or labeling claims related to astringent use, have previously been reviewed by other OTC advisory review panels.

In the **Federal Register** of December 4, 1979 (44 FR 69768), FDA published a proposed monograph (advance notice of proposed rulemaking) on OTC external analgesic drug products. The OTC drug products subject to this rulemaking include products used as topical analgesics, anesthetics, antipruritics, or counterirritants. The Miscellaneous external Panel believes that the use of astringents may also be useful to relieve the discomfort and itching that may be due to skin irritation. Furthermore, the Panel notes that none of the astringent ingredients listed above are included in the external analgesic rulemaking. However, the Panel recommends that the use of these ingredients as "astringents" be referred to that rulemaking because of the similarity of labeling claims.

Note.—In order to assure that these ingredients have been referred to the most appropriate rulemaking, FDA is seeking public comment from any interested person. Written comments should be submitted in the manner described at the end of this document.

The Panel also recommended that FDA review the Category I labeling recommended in this document and the Category I labeling already developed for astringents in other rulemakings.

Note.—Elsewhere in this issue of the **Federal Register**, the Panel's recommendations on OTC astringent drug products are included in the rulemaking for skin protectant drug products. The Panel presents a discussion of aluminum acetate, aluminum sulfate, and witch hazel and also presents the following general comments on astringents.

The skin which covers the body is often subjected to injuries. Astringents are locally applied protein precipitants which have such a low cell penetrability that the action is essentially limited to the cell surface and the interstitial spaces. The permeability of the cell membrane is reduced, but the cells remain viable. The astringent action is accompanied by contraction and wrinkling of the tissue and by blanching. The cement substance of the capillary endothelium is hardened, thus pathological transcapillary movement of plasma protein is inhibited and local edema, inflammation, and exudation are thereby reduced. Mucus and other secretions therefore may be reduced; thus the affected area becomes drier (Ref. 2).

Astringents are employed therapeutically to arrest hemorrhage by coagulating blood and to check diarrhea,

reduce inflammation of mucous membranes, promote healing, toughen the skin, or decrease sweating. The mechanism of action by which astringents are thought to decrease sweating is to coagulate protein in the sweat ducts and also by causing a peritubular irritation that results in duct closure. Styptics are substances not especially related to the clotting mechanism but are capable of promoting clotting by precipitating proteins.

There are several varied definitions for astringents. Webster (Ref. 3) defines astringent as a medicine for checking the discharge of mucous or serum by causing shrinkage of tissue and also as a liquid cosmetic for cleansing the skin and contracting the pores. Dorland (Ref. 4) defines astringent as causing contracting, usually locally, after topical application. Based on standard texts, and wishing to standardize the definition, the panel has adopted the definition of an astringent as a substance which checks oozing, discharge, or bleeding when applied to the skin or mucous membrane and works by coagulating protein.

The principal astringents are (1) the salts of aluminum, zinc, manganese, iron, and bismuth; (2) certain other salts that contain these metals such as permanganates; and (3) tannins, or related polyphenolic compounds. Acids, alcohols, phenols, and other substances that precipitate proteins may be astringent in the appropriate amount or concentration; however, such substances generally are not employed for their astringent effects because they readily penetrate cells and promote tissue damage. Strongly hypertonic solutions dry the affected tissues and are thus often but wrongly called astringents, unless protein precipitation also occurs (Ref. 2).

References

(1) OTC Volumes 160022, 160038, 160039, 160069, 160070, 160093, 160140, 160219, 160230, 160233, 160354, 160396, 160409, 160413, 160428, 160429, 160433, and 160435.

(2) Harvey, S. C., "Topical Drugs," *in* "Remington's Pharmaceutical Sciences," 15th Ed., edited by J. Hoover, Mack Publishing Co., Easton, PA, pp. 716–717, 1975.

(3) "Webster's Third New International Dictionary," edited by P. B. Gove, G. and C. Merriam Co., Springfield, MA, 1971, s.v. "astringent."

(4) "Dorland's Illustrated Medical Dictionary," 25th Ed., W. B. Saunders, Philadelphia, 1965, s.v. "astringent."

E. Categorization of Data

1. *Category I conditions.* The following are Category I conditions under which OTC astringent drug products are generally recognized as safe and effective and not misbranded.

Category I active ingredients.
Aluminum acetate
Witch hazel

(1) *Aluminum acetate.* The Panel concludes that aluminum acetate is safe and effective for OTC use as an astringent active ingredient in OTC topical drug products when used within the concentration specified below.

Aluminum acetate solution is classified as an astringent for topical use on the skin and mucous membranes (Ref. 1). It has been used by dilution with 10 to 40 parts of water as a wet dressing. The solution may be stabilized by the addition of not more than 0.6 percent of boric acid, and it must be dispensed only as a clear solution (Ref. 2).

Aluminum acetate solution has been referred to for years as Burow's solution, named from a similar mixture often prescribed by Dr. August Burow. In preparing aluminum acetate solution, various methods can be employed to produce aluminum acetate. Aluminum acetate solution can be prepared by adding 545 milliliters (mL) aluminum subacetate solution to 15 mL glacial acetic acid and adding sufficient water to make 1,000 mL (Ref. 1). Aluminum subacetate solution is prepared by mixing 145 grams (g) of aluminum sulfate with 160 mL acetic acid and 70 g of precipitated calcium carbonate and sufficient water to make 1,000 mL. Previously aluminum acetate had been prepared by dissolving 150 g of lead acetate and 87 g of aluminum sulfate in water. However, this method of preparation has been abandoned. In order for the finished product to meet the compendial standards for strength, quality, and purity, each 100 mL should yield 4.8 to 5.8 g of aluminum acetate (Ref. 2).

(i) *Safety.* Concentrated solutions of aluminum salts have produced gingival necrosis, hemorrhagic gastroenteritis, clonic contractions, and evidence of nephritis. The acute oral LD_{50} of aluminum sulfate, a precursor to aluminum acetate, is 6.1 grams/kilogram (g/kg). Burow's solution is reported to be moderately irritating if mistakenly ingested (Refs. 3 and 4).

The degree of absorption of ingested aluminum and its related compounds is minimal (Ref. 5). The toxicity of aluminum is now considered to be low. Adverse effects appear due to inhalations of finely divided powders of aluminum oxide and metallic aluminum.

Driesbach (Ref. 6) states that no fatalities from aluminum salts have been reported in recent years. Gosselin et al. (Ref. 3) state that Burow's solution is slightly toxic with a probable lethal dose for humans of 5 to 15 g/kg. It is moderately irritating if ingested. Lansdown (Ref. 7) has shown some effect of aluminum compounds applied topically to the mouse, rabbit, and pig skin. Epidermal changes consisting of hyperplasia, microabscess formation, dermal inflammatory cell infiltration, and occasional ulceration were evident in all three species treated with aluminum chloride (10 percent), aluminum nitrate (10 percent), aluminum sulfate, aluminum hydroxide, or aluminum chlorhydrate.

(ii) *Effectiveness.* Many historical references are made to the effectiveness and use of aluminum acetate as an astringent wet dressing, compress, or soak for minor skin irritations due to allergies, insect bites, athlete's foot, poison ivy, swelling associated with minor bruises, and ulcerations of the skin. The studies reviewed in the literature and submissions may be classified as limited uncontrolled studies and testimonials supporting the use of aluminum acetate in diseases of the legs, eczema, varicose ulcers, acute cutaneous inflammation, various dermatoses, and other conditions. Aluminum acetate soaks are used for relief of acute irritation while treating plantar lesions of the foot (Ref. 8) (as a soak the patient begins soaking the treated foot (feet) three times a day) (Ref. 9). The solution can also be used as a wet dressing in the treatment of athlete's foot (Ref. 10). Moist compresses of Burow's solution are used to hasten healing of plantar perforation ulcers (Ref. 11).

Leyden (Ref. 12) induced a poison ivy dermatitis in six poison ivy sensitive volunteers. Forty-eight hours later a cell-mediated immune reaction was seen consisting of blisters which represented dermal cell necrosis. The blisters were treated with aluminum acetate 1:40 (2.5 percent), aluminum acetate 1:20 (5 percent), tap water, or saline compresses. Leyden found no significant difference in aluminum acetate 1:40 compared to tap water compresses, but did find aluminum acetate 1:20 compresses superior to both the tap water compresses and saline compresses.

Based on the current literature and wide clinical usage, the Panel concludes that aluminum acetate solution 1:20 to 1:40 is safe and effective for topical use as an astringent.

(iii) *Dosage.* Topical dosage is a solution containing 2.5 to 5 percent aluminum acetate.

(iv) *Indications.* "For use as a wet dressing, compress, or soak for relief of inflammatory conditions and minor skin

irritations due to allergies, insect bites, athlete's foot, poison ivy, or swelling associated with minor bruises and ulcerations of the skin."

(v) *Warnings.* (*a*) "If condition worsens or symptoms persist for more than 7 days, discontinue use of the product and consult a doctor."

(*b*) "Do not cover wet dressings or compresses with plastic to prevent evaporation."

(*c*) "Keep away from eyes."

(*d*) "For external use only."

(*e*) "Store in a cool dry place."

(vi) *Directions.* (*a*) Depending on the formulation and concentration of the marketed product, the manufacturer must provide adequate directions so that the resulting solution to be used by the consumer contains 2.5 to 5 percent aluminum acetate.

(*b*) *For products containing aluminum acetate for use as a soak.* "Soak affected area for 15 to 30 minutes. Repeat 3 times a day" (Ref. 9).

(*c*) *For products containing aluminum acetate for use as a compress or wet dressing.* "Saturate a clean, soft, white cloth (such as a diaper or torn sheet) in the solution, gently squeeze, and apply loosely to the affected area. Saturate the cloth in the solution every 15 to 30 minutes and apply to the affected area. Repeat as often as necessary. Discard remaining solution after use" (Refs. 13, 14, and 15).

References

(1) Harvey, S. C., "Topical Drugs," *in* "Remington's Pharmaceutical Sciences," 15th Ed., edited by J. Hoover, Mack Publishing Co., Easton, PA, p. 717, 1975.

(2) "The United States Pharmacopeia," 19th Revision, Mack Publishing Co., Easton, PA, p. 20, 1975.

(3) Gosselin, R. E., et al., "Clinical Toxicology of Commerical Products," 4th Ed., The Williams and Wilkins Co., Baltimore, p. 89, 1976.

(4) Hertzler, A. E., "Dangers In The Use Of Aluminum Solution As A Wet Dressing," *Amercian Journal of Surgery*, 2:573–574, 1927.

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(9) Shapiro, L. J., "Oblique Displacement Osteotomy for Correction of Hallux Adducto Valgus," *Current Podiatry*, 29:13–15, 1980.

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(11) Anastasio, A. S., "Role of the Podiatrist in the Management of Diabetic Foot Problems," *Current Podiatry*, 25:7–9, 1976.

(12) Presentation by J. Leyden to the Advisory Review Panel on OTC Miscellaneous External Drug Products contained in the Transcripts of the Proceedings of its 42d meeting, pp. 7–18, November 7, 1980.

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(14) Combes, F. C., "The Wet Dressing. Its Use in Acute Cutaneous Inflammation," *Industrial Medicine and Surgery*, 30:29–34, 1961.

(15) Parker, G. F., and P. C. Logan, "Poison Ivy (Rhus) Dermatitis," *American Family Physician*, 6:62–6, 1972.

(2) *Witch hazel.* The Panel concludes that witch hazel (witch hazel water or hamamelis water) is safe and effective for OTC use as an astringent active ingredient in OTC topical drug products when used within the concentration specified below.

Witch hazel is a clear, colorless liquid having a characteristic odor and taste and is neutral or slightly acid to litmus paper (Ref. 1). It is prepared by macerating recently cut and partially dried dormant twigs of *Hamamelis virginiana* for about 24 hours in about twice their weight of water and then distilling until 850 mL of distillate is obtained from each 100 g. To each 850 mL distillate, 150 mL alcohol is added. Witch hazel contains 14 to 15 percent alcohol. It contains only a trace of volatile oils (0.01 to 0.02 percent) (Ref. 2). The tannin of witch hazel bark on distillation remains in the residue and is absent from the distilled extract (Refs. 2 and 4 through 12). Witch hazel has not been recognized in an official compendium since 1960 (Refs. 1 and 3).

(i) *Safety.* Aside from the slight stinging sensation, which has been attributed to the alcohol content (Ref. 9), no other reports of adverse effects to witch hazel have been found in the available madical literature. However, because witch hazel contains minute amounts of volatile oils, an allergic contact dermatitis is possible and cannot be discounted, although the occurrence is rare (Refs. 2 and 12).

The Panel concludes that witch hazel can be used safely OTC, based on its use since the days of the early Colonists who learned of the drug from the American Indians (Ref. 3).

(ii) *Effectiveness.* Literature reports have attributed the astringent action of witch hazel to its tannin content (Refs. 4, 8, 11, 13, and 14). This tannin is hamamelitannin (Ref. 15), a catechol tannin (Ref. 3). One major manufacturer of witch hazel (which makes its product from a distillate of a combination of the witch hazel bark and leaf) states that the tannin concentration of hamamelitannin falls between 2.5 and 4.2 milligrams/liter (mg/L) (Ref. 16) which is considered to be a range of concentrations effective for use as an OTC astringent drug product. It may also be probable, but is not documented, that the astringent effect is due to the alcohol present in witch hazel. The same manufacturer maintains that even though alcohol is an astringent by itself, and enhances the action of the witch hazel distillate, its purpose for being in the product is only as a preservative (Ref. 16). Assumptions that the effectiveness of witch hazel is due to the small amount (0.01 to 0.02 percent) of volatile oils present have not been scientifically validated (Ref. 2).

Studies to show that witch hazel is an effective astringent have been done. One study shows that witch hazel shortened the bleeding time and accelerated the blood clotting in rabbits (Ref. 2), which may be related to the astringency effect of witch hazel. Another study was performed using the plasma recovered from six human blood samples. Duplicate prothrombin (clotting) times were done using the undiluted plasma (0.1 mL plus 0.1 mL normal saline) and 0.1 mL of three test samples—witch hazel containing 14 percent ethyl alcohol, 14 percent ethyl alcohol alone, and undiluted witch hazel. The study showed that the witch hazel alone was superior to the witch hazel containing 14 percent ethyl alcohol, and that both were superior to the 14 percent ethyl alcohol alone, in accelerating the clotting time of the human plasma (Ref. 17).

The popularity of witch hazel and its use by consumers and the medical profession may be attributed, as mentioned above, to the trace amount of volatile oils which gives the product a characteristically pleasant odor (Ref. 18). One major manufacturer maintains that its popularity is due to the astringent action provided by the significant amounts of natural hamamelitannin found in the witch hazel distillate. Hamamelitannin is one of a broad class of tannins. Tannins are classified as astringents due to their action when applied to living tissue. They precipitate proteins making that area resistant to the action of proteolytic enzymes. For example, when tannins (either purified or a derivative) are applied to abraded tissue, the proteins of the exposed tissues precipitate, forming a mildly antiseptic, protective

coat allowing new tissue to grow underneath. According to data submitted by one manufacturer, witch hazel is effective in treating bruises, contusions, and sprains; for protecting slight cuts and scrapes; for relieving muscular pains; and for treating the pain and swelling of nonpoisonous insect bites (Ref. 19). Another manufacturer states that witch hazel has been used in the household for years as a local astringent for the treatment of bruises, skin irritations, sunburn, insect bites and external hemorrhoids (Ref. 16). The Panel concludes that witch hazel is safe and effective as an OTC astringent drug product for external application.

(iii) *Dosage.* Topical dosage is witch hazel prepared according to National Formulary XI.

(iv) *Indications.* (*a*) "For use as an astringent for the treatment of bruises, contusions, and sprains."

(*b*) "For protecting slight cuts and scrapes."

(*c*) "For relieving muscular pains."

(*d*) "For treating the pain and swelling of insect bites."

(*e*) "For use as an astringent for the treatment of skin irritation, sunburn, and external hemorrhoids."

(v) *Warnings.* "For external use only."

(vi) *Directions.* "Apply as often as necessary."

References

(1) "The National Formulary," 11th Ed., Mack Publishing Co., Easton, PA, p. 158, 1960.

(2) Neugebauer, H., "The Effect of the Distillates of *Hamamelis Virginiana* and of *Corylus Avellana*," *Die Pharmazie*, 3:313–314, 1948.

(3) Claus, E. P., and V. E. Tyler, "Tannins," *in* "Pharmacognosy," 5th Ed., Lea and Febiger, Philadelphia, pp. 156–163, 1965.

(4) "The Dispensatory of the United States of America," 22d Ed., edited by H. C. Wood, et al., J. B. Lippincott Co., Philadelphia, p. 174, 1937.

(5) "The Dispensatory of the United States of America," 25th Ed., edited by A. Osol and G. E. Farrar, Jr., J. B. Lippincott Co., Philadelphia, p. 633, 1955.

(6) "The United States Dispensatory and Physicians' Pharmacology," 26th Ed., edited by A. Osol, R. Pratt, and M. D. Altshule, J. B. Lippincott Co., Philadelphia, p. 559, 1967.

(7) "The United States Dispensatory," 27th Ed., edited by A. Osol and R. Pratt, J. B. Lippincott Co., Philadelphia, p. 576, 1973.

(8) "Martindale. The Extra Pharmacopoeia," 26th Ed., edited by N. W. Blacow, The Pharmaceutical Press, London, p. 1417, 1972.

(9) Harry, R. G., "Harry's Cosmeticology," 6th Ed., Chemical Publishing Co., Inc., New York, pp. 97–99, 1973.

(10) Yosida, Y., "Pharmacognostic Study of the Leaves of Hamamelis Species II," *Journal of the Pharmaceutical Society of Japan*, 59:656–659, 1939.

(11) Trease, G. E., and W. C. Evans, "Pharmacognosy," 10th Ed., The Williams and Wilkins Co., Baltimore, p. 429, 1972.

(12) Guenther, E., "The Essential Oils," Volume II, D. Van Nostrand Co., Inc., New York, p. 255, 1949.

(13) Longo, R., and G. Mazzoldi, "The Determination of Tannins in the Drug and Extracts of *Hamamelis Virginiana*," *Bollettino Chimico Farmaceutico*, 105:241–244, 1966.

(14) DiPalma, J. R., editor "Drill's Pharmacology in Medicine," 4th Ed., McGraw-Hill Book Co., New York, p. 1035, 1971.

(15) Windholz, M., editor, "The Merck Index," 9th Ed., Merck and Co., Inc., Rahway, NJ, pp. 560, 600, and 1172–1173, 1976.

(16) OTC Volume 160428.

(17) OTC Volume 160433.

(18) Nesselrod, J. P., "Clinical Proctology," W. B. Saunders Co., Philadelphia, pp. 164–169, 1957.

(19) OTC Volume 160354.

2. *Category II conditions.* The following are Category II conditions under which OTC astringent drug products are not generally recognized as safe and effective or are misbranded.

a. *Category II ingredients.* (See part IV. paragraph C.3 above—*Other ingredients.*)

b. *Category II labeling.* The Panel has placed in Category II the following labeling claims because no data were submitted to establish safety and effectiveness of these claims:

(1) "For anthrax."

(2) "Lymphangitis."

3. *Category III conditions.* The following are Category III conditions for which available data are insufficient to permit the final classification of OTC astringent drug products at this time.

Category III active ingredient—Aluminum sulfate. The Panel concludes that aluminum sulfate is safe, but there are insufficient data to establish its effectiveness for use as a styptic pencil.

(1) *Safety.* Aluminum sulfate is generally recognized as safe and is utilized in food processing, brining pickles, baking powder, and clarifying fats and oils. It has been used as an ingredient in deodorant preparations. However, it has been shown to be deleterious to clothing.

The LD_{50} of aluminum sulfate has been determined to be 6.1 g/kg in mice by oral administration. Aluminum sulfate can cause a mild yet persistent irritation to the eyes, but it does not irritate the skin. When 200 human volunteers were patch tested, no visual irritation was observed on the arms or legs. By moistening a styptic pencil, containing approximately 57 percent aluminum sulfate and applying it to a cut, approximately 0.1 to 0.2 mL will be applied. This application will result in a local coagulation of capillary bleeding.

In 75 years of marketing styptic pencils there have been reported instances of human toxicity (Ref. 1). However, application of the pencil on a cut may result in some stinging.

The Panel concludes that aluminum sulfate is safe for use as a styptic pencil.

(2) *Effectiveness.* Aluminum sulfate, when applied to minor cuts, acts as an astringent and a protein precipitant. The substance has little, if any, cell permeability and exerts its effect on the cell surface (Ref. 2). This effect has been elucidated over many years of use (Ref. 3).

Aluminum sulfate has been used widely for many years although modern day clinical trials have not been conducted with this ingredient.

The Panel concludes there are insufficient data to establish the effectiveness of aluminum sulfate as a styptic.

(3) *Indication.* "For use in stopping bleeding caused by minor surface cuts, particularly those caused during shaving."

(4) *Warnings.* (i) "For external use only."

(ii) "Do not use in or around eyes."

(5) *Directions.* "Moisten and apply. Dry after use."

References

(1) OTC Volume 160409.

(2) OTC Volume 160411.

(3) Harvey, S. C., "Topical Drugs," *in* "Remington's Pharmaceutical Sciences," 16th Ed., edited by A. Osol, Mack Publishing Co., Easton, PA, p. 721, 1980.

2. *Category III labeling.* None.

F. Combination Policy

The Panel is not aware of products combining OTC ingredients used as astringents for topical use. The Panel is aware of products which combine various OTC ingredients with an astringent. Any such combination of ingredients reviewed in this document with ingredients from other therapeutic categories should meet the regulation outlined in § 330.10(a)(4)(iv) which states:

> An OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredient does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population.

Regarding combinations of ingredients for topical astringent use with

ingredients from other therapeutic categories, the Panel also concurs with the FDA guidelines for OTC combination products (Ref. 1) which state that Category I active ingredients from different therapeutic categories may be combined to treat different symptoms concurrently only if each ingredient is present within its established safe and effective dosage range and the combination meets the OTC combination policy in all other aspects.

Reference

(1) Food and Drug Administration, "General Guidelines for OTC Drug Combination Products, September 1978," Docket No. 78D–0322, Dockets Management Branch.

VI. Statement on OTC Insect Bite Neutralizer Drug Products

A. Submission of Data and Information

In an attempt to make this review as extensive as possible and to aid manufacturers and other interested persons, the agency compiled a list of ingredients recognized, either through historical use or use in marketed products, as insect bite active ingredients. Nineteen ingredients were identified as follows: Alcohol, ammonium hydroxide, aqua ammonia, bicarbonate of soda, calamine, camphor, ethoxylated alkyl alcohol, ferric chloride, fluid extract ergot, menthol, obtundia surgical dressing, oil of turpentine, peppermint oil, phenol, pyrilamine maleate, sodium borate, triethanolamine, zinc oxide, and zirconium oxide. Notices were published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) requesting the submission of data and information on these ingredients or any other ingredients used on OTC insect bite drug products.

Pursuant to the above notices, the following submissions were received:

Firms	Products
Marion Health and Safety, Inc., Rockford, IL 61101.	Sting-Kill Swabs.
Tender Corp., Littleton, NH 03561	After Bite.

B. Ingredients Reviewed by the Panel

1. *Labeled ingredients contained in marketed products submitted to the Panel.*

Benzalkonium chloride
Triethanolamine
Ammonium hydroxide

2. *Other ingredients.* The following list contains ingredients in OTC insect bite drug products, which appeared in the call-for-data notice published in the **Federal Register** of August 27, 1975, for which no marketed products were submitted to the Panel.

Alcohol
Aqua ammonia
Bicarbonate of soda
Calamine
Camphor
Ethoxylated alkyl alcohol
Ferric chloride
Fluid extract ergot
Menthol
Obtundia surgical dressing
Oil of turpentine
Peppermint oil
Phenol
Pyrilamine maleate
Sodium borate
Zinc oxide
Zirconium oxide

C. Classification of Ingredients

In this document, the Panel has reviewed only those ingredients with a claim for treating insect bites by neutralization or inactivation of insect venom.

1. *Active ingredients.*

Ammonium hydroxide,
Triethanolamine.

2. *Other ingredients.* The Panel was not able to locate nor is it aware of data demonstrating the safety and effectiveness of the following ingredients when used as OTC insect bite neutralizer active ingredients. The Panel, therefore, classifies these ingredients as Category II for this use, and they will not be discussed further in this document.

Alcohol
Aqua ammonia
Benzalkonium chloride
Bicarbonate of soda
Calamine
Camphor
Ethoxylated alkyl alcohol
Ferric chloride
Fluid extract ergot
Menthol
Obtundia surgical dressing
Oil of turpentine
Peppermint oil
Phenol
Pyrilamine maleate
Sodium borate
Zinc Oxide
Zirconium oxide

D. General Discussion

The Panel has reviewed the literature and data submissions, and has considered all pertinent information submitted through December 15, 1980 in arriving at its conclusions and recommendations.

Insect bites can be fatal to individuals who are hypersensitive to the antigenic substances in insect venom which precipitate anaphylactic shock. Immediate consideration should be given towards obtaining fast, appropriate emergency treatment. Because of the potential danger of cross sensitization to other antigenic substances, appropriate caution should be given to sensitive individuals. A program of desensitization should be implemented if at all possible.

For the majority of insect bites, the reactions are confined to varying degrees of itching and pain at the site of the bite. Uncontrolled itching and pain often lead to scratching that can produce nodules and possibly secondary infections. The use of OTC products for relief of localized pain and itching can be helpful. Additional benefit may be achieved at times with the use of effective antibacterial agents and mild astringents. Ingredients and claims for the relief of minor skin irritation, itching, and rashes due to insect bites have previously been addressed by another OTC Advisory Review Panel. (See the report on OTC External Analgesic Drug Products published in the **Federal Register** of December 4, 1979; 44 FR 69768.) Treatment of infectious diseases caused by insect bites is not within the realm of this Panel's deliberation.

E. Categorization of Data

1. *Category I conditions.* None.

2. *Category II conditions.* None.

3. *Category III conditions.* These are conditions for which available data are insufficient to permit final classification at this time.

a. *Category III ingredients.*

Ammonium hydroxide,
Triethanolamine.

(1) *Ammonium hydroxide.* The Panel concludes that ammonium hydroxide is safe but that there are insufficient data to establish its effectiveness as an insect bite neutralizer.

Ammonia is a colorless, transparent gas having a density approximately 0.6 that of air, an exceedingly pungent odor, and an acrid taste. Ammonia is very soluble in water. A portion of the dissolved ammonia gas reacts chemically with water to form ammonium hydroxide. Aqueous solutions of ammonia exhibit alkaline reaction, and have other properties similar to those of solutions of alkali hydroxides. These properties have been attributed to the ammonium hydroxide formed. Although there is little ammonium hydroxide formed, ammonia water is often referred to and labeled as solution of ammonium hydroxide (Ref. 1).

The ammonium ion is of particular interest because it is toxic in high concentrations and because it serves a

major role in the maintenance of the acid-base balance of the body (Ref. 2).

(i) *Safety.* Ammonia is a naturally occurring product found abundantly in body tissues. Ammonia is absorbed by inhalation, ingestion, and probably percutaneously at concentrations high enough to cause skin injury. Data are not available on absorption of low concentrations through the skin. Once absorbed, ammonia is converted to the ammonium ion as the hydroxide and as salts, especially as carbonates. The ammonium salts are rapidly converted to urea, thus maintaining an isotonic system. Ammonia is also formed and consumed endogenously by the metabolism and synthesis of amino acids. Exception is primarily by way of the kidneys, but a not insignificant amount is passed through the sweat glands (Ref. 3).

Patients with severe hepatic disease or with portacaval shunts often develop derangements of the central nervous system, wich are manifested by disturbance of consciousness, tremor, hyperreflexia, and electroencephalogram abnormalities. Because this syndrome is most often associated with elevated concentrations of ammonia in blood, and because it can be provoked by feeding of protein as well as by ingestion of ammonium salts, it is thought to represent ammonia toxicity to the brain (Ref. 2).

The occurrence of high concentrations of ammonia in the blood (hyperammonemia) in children and infants has been associated with defects of enzymes of the urea cycle. Hyperammonemia due to defects of ornithine transcarbamylase or carbamylphosphate synthetase may be related to cyclic vomiting and to at least one form of migraine. The mechanisms by which ammonia induces changes in the central nervous system is not clear (Ref. 2).

Ammonia gas when inhaled in dilute form can stimulate the medullary respiratory and vasomotor centers reflexly through irritation of the sensory endings of the trigeminal nerve (Ref. 2).

The strong, pungent, penetrating odor of low levels of ammonia at about 35 milligrams per cubic meter (mg/m^3) becomes increasingly irritating as concentrations exceed 70 mg/m^3 (Ref. 3). High concentrations of ammonia vapor are injurious to the lungs, and death may result from pulmonary edema. Long exposure to low concentrations of ammonia may lead to chronic pulmonary irritation. The maximal concentration of ammonia vapor that can be tolerated without harmful effect is probably less than 250 parts per million (ppm). High concentrations of neutral ammonium salts are irritating to the gastric mucosa and may produce nausea and vomiting (Ref. 2).

Ammonia preparations used externally have been discussed in some current sources of chemical and pharmaceutical information (Refs. 4 and 5).

(2) *Effectiveness.* The local reaction that follows insect bites may vary among individuals. Mild local reaction may consist of itching, swelling, and irritation. Solutions of ammonium hydroxide are local irritants. When applied to the skin in low concentrations, they have a rebefacient action, and in high concentrations they are vesicant. Few authoritative publications provide information regarding optimum concentrations of ammonia in counterirritant products.

The venom of stinging insects (bees, wasps, hornets, and ants) and the substances released by biting insects (mosquitos, flies, fleas, bedbugs, ticks, and chiggers) are varied in chemical nature. These substances range from simple amines, such as histamine and 5-hydroxytrytamine, to more complex peptides, kinins, and enzymes, such as hyaluronidase and phospholipase, being both acidic and basic in nature. While some of the substances may be primarily acidic in nature, such as the formic acid injected from the bite of some ants, it is erroneous to expect that solely neutralizing the acids will lead to complete and effective relief of all insect stings or bites (Ref. 6). Therefore, the use of remedies which are alkaline and solely directed to neutralizing acids of stinging insect venoms or insect bites are not generally acceptable treatment at this time.

(3) *Evaluation.* The submitted data (Ref. 7) do not establish the effectiveness of ammonium hydroxide in neutralizing insect bites or stings. The Panel recommends Category III for effectiveness of ammonium hydroxide either alone or in combination for the neutralization of inset stings and bites.

References

(1) Osol, A., "Remington's Pharmaceutical Sciences," 16th Ed., Mack Publishing Co., Easton, PA, p. 350, 1980.

(2) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 6th Ed., Macmillan Publishing Co., Inc., New York, pp. 869–870, 1975.

(3) Wands, R. C., "Alkaline Materials," *in* "Patty's Industrial Hygiene and Toxicology," 3d Ed., Vol. 2B., edited by G. D. Clayton and F. E. Clayton, A Wiley—Interscience Publication, New York, pp. 3045–3052, 1978.

(4) Todd, R. G., "Martindale, The Extra Pharmacopeia," 27th Ed., The Pharmaceutical Press, London, pp. 44–45, 1977.

(5) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 69 1976.

(6) Sadik, F., "Insect Sting and Bite Products," *in* "Handbook of Nonprescription Drugs," 6th Ed., American Pharmaceutical Association, Washington, pp. 326–327, 1979.

(7) OTC Volumes 160119 and 160434.

(2) *Triethanolamine.* The Panel concludes that triethanolamine is safe but that there are insufficient data to establish its effectiveness as an insect bite neutralizer.

Triethanolamine is an organic base related to ammonia in which the three hydrogen atoms in the ammonia structure have been replaced by the ethanol group. An important physical property of triethanolamine is its complete solubility in water and many organic solvents. It is one of the most hygroscopic organic solvents available, and its high boiling point makes it less volatile when used alone or in combination. It has a low vapor pressure and is compatible with many materials. It is used as a mild alkaline hygroscopic agent, acid gas absorbent, penetrant solvent, dispersing agent, and as an intermediate in the preparation of emulsifying agents and other derivatives (Ref. 1).

(i) *Safety.* Evidence has been previously presented to the Panel that indicates that triethanolamine is relatively safe when ingested or administered orally to experimental animals. Its oral LD_{50} in the rat and guinea pig is in the 8-milligram-per-kilogram (mg/kg) range. Several ounces can be tolerated by humans according to Gosselin et al. (Ref. 2). The principal effect of triethanolamine has been limited to the gastrointestinal tract or to systemic alkalosis as a result of its alkalinity. While it can be absorbed when applied to the skin, little evidence exists to indicate that it is toxic to the skin in concentrations of 2.5 percent found in lotions, creams, or solutions, or in concentrations of 30 percent found in swabs. Because of its alkalinity, it may be irritating to the skin if applied in large concentrations for long periods of time.

(ii) *Effectiveness.* The use of triethanolamine in insect remedies may be related partly to its physical-chemical properties. It is alkaline in solution, with a pH between 10 and 11, and has been used as a binding agent, emulsifier, and solvent. However, it is emphasized that the rationale of using triethanolamine to neutralize acids from insect bites or stings is based on the erroneous assumption that acids are the sole causative agents in insect bites or stings.

In the data submitted (Refs. 1 and 3), triethanolamine is in combination with benzalkonium chloride. Triethanolamine

is purported to be a strong alkalizing agent, neutralizing the antigens in the insect venom. The benzalkonium chloride is purported to be present as an antiseptic for the sting site. (The combination will not be discussed further as this report deals solely with the neutralization of insect bites.) The same double-blind clinical study is provided in both submissions, which cover the same product. Bee stings were simulated in 26 previously determined nonallergenic subjects by injecting 0.02 mL of a reconstituted lyophilized (freeze-dried) bee venom into the arms of each subject. When pain was sensed, a pair of swabs, one saturated with the test product and one saturated with a saline placebo and given in a double-blind fashion, was spread gently over the lesions, one on each arm. The time for reduction of pain or its elimination was recorded. While some limitations exist in the quality of data generated to make definite statements regarding the time it took to achieve pain reduction or pain elimination, reevaluation of the data by an agency statistician indicated that the test product gave a faster response than did the placebo. Specifically, the data support the claim that a large proportion, 13 of 26 (50 percent), of subjects experienced pain reduction or elimination within 120 seconds with the test product as compared to the number of subjects who experienced pain reduction or relief (6 of 26 or 23 percent) when given the placebo. The degree of erythema and edema (swelling) was not affected by either treatment.

(iii) *Evaluation.* Because no similar study nor demonstration of efficacy has been shown for triethanolamine as a single active ingredient in neutralizing insect bites, it is not possible to assess its contribution to the effectiveness of the product. Therefore, the Panel recommends Category III for effectiveness of triethanolamine, either alone or in combination, for the neutralization of insect stings or bites. The clinical study using artificially induced bee stings outlined above, while not in the report, could serve as a model by which single ingredients can be tested for effectiveness in the relief or elimination of pain or itch from insect bites or stings.

References

(1) OTC Volume 160159.

(2) Gosslin, R. E., al., "Clinical Toxicology of Commercial Products," 4th Ed., The Williams and Wilkins Co., Baltimore, p. 73, 1976.

(3) OTC Volume 160074.

b. *Category III labeling.* "For the temporary relief of stings caused by wasps, hornets, bees, mosquitos, spiders, fleas, chiggers, ticks, and ants."

List of Subjects in 21 CFR Part 348

OTC drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C 321(p), 352, 355, 371)), and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)), and under 21 CFR 5.11 as revised (see 47 FR 16010; April 14, 1982), the agency advises in this advance notice of proposed rulemaking that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations would be amended in Part 348 (as set forth in the advance notice of proposed rulemaking for external analgesic drug products that was published in the **Federal Register** of December 4, 1979 (44 FR 69768)) as follows:

PART 348—EXTERNAL ANALGESIC PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. In Subpart A, § 348.3 would be amended by adding new paragraphs (h) and (i), to read as follows:

§ 348.3 Definitions.

* * * * * *

(h) *Astringent drug product.* A drug product which checks oozing, discharge, or bleeding when applied to skin or mucous membrane and works by coagulating protein.

(i) *Male genital desensitizing drug product.* A drug product applied to the penis to aid in temporarily slowing the onset of ejaculation.

2. In Subpart B, § 348.10 would be amended by adding new paragraphs (c) and (d), to read as follows:

§ 348.10 External analgesic active ingredients.

* * * * *

(c) *External analgesic active ingredients that precipitate protein (astringents).*

(1) Aluminum acetate, 2.5 to 5 percent.

(2) Witch hazel, NF XI.

(d) *External analgesic active ingredients that depress cutaneous sensory receptors (male genital desensitizers).*

(1) Benzocaine, 3 to 7.5 percent in a water-soluble base.

(2) Lidocaine in a metered spray with approximately 10 milligrams per spray in a container of not more than 120 milligrams capacity.

3. In Subpart D, § 348.50 would be amended by adding new paragraphs (a)(3) and (4), (b)(4), (5), and (6), (c)(7), (8), and (9), and by revising paragraph (d) to read as follows:

§ 348.50 Labeling of external analgesic drug products.

(a) *Statement of identity.* * * *

* * * * *

(3) *For products containing any external analgesic ingredient identified in § 348.10(c).* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "astringent."

(4) *For products containing any external analgesic ingredient identified in § 348.10(d).* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "male genital desensitizer."

* * * * *

(b) *Indications.* * * *

* * * * *

(4) *For products containing aluminum acetate identified in § 348.10(c)(1).* "For use as a wet dressing, compress, or soak for relief of inflammatory conditions and minor skin irritations due to allergies, insect bites, athlete's foot, poison ivy, or swelling associated with minor bruises and ulcerations of the skin."

(5) *For products containing witch hazel identified in § 348.10(c)(2).* (i) "For ues as an astringent for the treatment of bruises, contusions, and sprains."

(ii) "For protecting slight cuts and scrapes."

(iii) "For relieving muscular pains."

(iv) "For treating the pain and swelling of insect bites."

(v) "For use as an astringent for the treatment of skin irritation, sunburn, and external hemorrhoids."

(6) *For products containing any ingredient identified in § 348.10(d).* (i) "For temporary male genital desensitization helping to slow the onset of ejaculation."

(ii) "Aids in temporarily retarding the onset of ejaculation."

(iii) "Aids in temporarily slowing the onset of ejaculation."

(iv) "Aids in temporarily prolonging time until ejaculation."

(v) "For reducing oversensitivity in the male in advance of intercourse."

(vi) "As an aid in the prevention of premature ejaculation."

* * * * *

(c) *Warnings.* * * *

* * * * *

(7) *For products containing aluminum acetate identified in § 348.10(c)(1).* (i) "If condition worsens or symptoms persist for more than 7 days, discontinue use of the product and consult a doctor."

(ii) "Do not cover wet dressing or compress with plastic to prevent evaporation."

(iii) "Keep away from eyes."

(iv) "For external use only."

(v) "Store in a cool dry place."

(8) *For products containing witch hazel identified in § 348.10(c)(2).* "For external use only."

(9) *For products containing any ingredient identified in § 348.10(d).* The labeling of the product contains the following warnings under the heading, "Warnings":

(i) "Premature ejaculation may be due to a condition requiring medical supervision. If this product, used as directed, does not provide relief, discontinue use and consult a doctor."

(ii) "Avoid contact with the eyes."

(iii) "If skin to which you apply this product becomes irritated, discontinue use and consult a doctor."

(iv) "Keep this and all drugs out of the reach of children."

(v) "The effect of this product on sperm and fertility has not been determined."

(vi) *For products containing benzocaine identified in § 348.10(d)(2).* "Use this product with caution if you or your partner are sensitive to topical anesthetics, sunscreens, sulfa drugs, or hair dyes."

(d) *Directions—(1) for products containing any ingredient identified in § 348.10(a) or (b).* The labeling of the product for adults and children 2 years of age and older contains the following statement under the heading "Directions": "Apply to affected area not more than 3 to 4 times daily." For children under 2 years of age there is no recommended dosage except under the advice and supervision of a physician.

(2) *For products containing any ingredient identified in § 348.10(c).* The labeling of the product contains the following information under the heading "Directions":

(i) *For products containing aluminum acetate identified in § 348.10(c)(1). (a)* Depending on the formulation and concentration of the marketed product, the manufacturer must provide adequate directions so that the resulting solution to be used by the consumer contains 2.5 to 5 percent aluminum acetate.

(b) For products containing aluminum acetate for use as a soak. "Soak affected area for 15 to 30 minutes. Repeat 3 times a day. Discard remaining solution after use."

(c) For products containing aluminum acetate for use as a compress or set dressing. "Saturate a clean, soft, white cloth (such as a diaper or torn sheet) in the solution, gently squeeze, and apply loosely to the affected area. Saturate the cloth in the solution every 15 to 30 minutes and apply to the affected area. Repeat as often as necessary. Discard remaining solution after use."

(ii) *For products containing witch hazel identified in § 348.10(c)(2).* "Apply as often as necessary."

(3) *For products containing any ingredient identified in § 348.10(d).* The labeling of the product contains the following information under the heading "Directions," followed by "or as directed by a doctor":

(i) *For products containing benzocaine identified in § 348.10(d)(1).* "Apply a small amount to head and shaft of penis before intercourse. Wash off after intercourse."

(ii) *For products containing lidocaine identified in § 348.10(d)(2).* "Apply 3 or more sprays, not to exceed 10, to head and shaft of penis before intercourse. Wash off after intercourse."

Interested persons may, on or before December 6, 1982, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments on this advance notice of proposed rulemaking. Three copies of any comments are to be submitted, except that individuals, may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments replying to comments may also be submitted on or before January 5, 1983. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Mark Novitch,

Acting Commissioner of Food and Drugs.

Dated: August 27, 1982.

Richard S. Schweiker,

Secretary of Health and Human Services.

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federal register

Tuesday
September 7, 1982

Part VI

Department of Health and Human Services

Food and Drug Administration

Skin Protectant Drug Products for Over-the-Counter Human Use; Establishment of a Monograph; and Reopening of Administrative Record

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 347

[Docket No. 78N-0021]

Skin Protectant Drug Products for Over-the-Counter Human Use; Establishment of a Monograph; and Reopening of Administrative Record

AGENCY: Food and Drug Administration.

ACTION: Advance notice of proposed rulemaking and reopening of administrative record.

SUMMARY: The Food and Drug Administration (FDA) is issuing an advance notice of proposed rulemaking that would establish conditions under which over-the-counter (OTC) skin protectant drug products used (1) for the treatment of diaper rash; (2) for the prevention of poison ivy, oak, and sumac; (3) for the treatment of fever blisters; (4) as astringents; and (5) as insect bite neutralizers are generally recognized as safe and effective and not misbranded. This notice relates to the development of a monograph for skin protectant drug products in general, which is part of the ongoing review of OTC drug products conducted by FDA. This notice also reopens the administrative record for OTC skin protectant drug products to allow for consideration of recommendations on external analgesic drug products for the five drug categories listed above that have been received from the Advisory Review Panel on OTC Miscellaneous External Drug Products.

DATES: Written comments by December 6, 1982 and reply comments by January 5, 1983.

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

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In accordance with Part 330 (21 CFR Part 330), FDA received on December 14 and 15, 1980 statements from the Advisory Review Panel on OTC Miscellaneous External Drug Products relating to OTC drug products intended for use (1) in the treatment of diaper rash; (2) for the prevention of poison ivy, oak, and sumac; (3) for the treatment of fever blisters; (4) as astringents; and (5) as insect bite neutralizers. FDA regulations (21 CFR 330.10(a)(6)) provide that the agency issue in the **Federal Register** a proposed rule containing (1) the monograph recommended by the Panel, which establishes conditions under which these OTC drug products are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph because the Panel determined that they would result in the drugs' not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph because the Panel determined that the available data are insufficient to classify these conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel.

Because some ingredients in the five drug categories listed above are marketed in OTC drug products as skin protectants, FDA has determined that the Miscellaneous External Panel's recommendations on OTC drug products for these uses should be included as part of the proposed rulemaking for skin protectant drug products. Development of this rulemaking has been ongoing for some time.

In the **Federal Register** of August 4, 1978 (43 FR 34628), FDA issued an advance notice of proposed rulemaking to establish a monograph for OTC skin protectant drug products. FDA advises that it is reopening the administrative record for OTC skin protectant drug products only as it pertains to drug products for the five drug categories listed above in order to allow for the consideration of the Miscellaneous External Panel's recommndations on these products. Comments received on this advance notice of proposed rulemaking will be addressed in a future issue of the **Federal Register**. Also, the proceedings to develop monographs for drug products for the treatment of diaper rash; for the prevention of poison ivy, oak, and sumac; for the treatment of fever blisters; for astringents; and for insect bite neutralizers will be merged with the general proceeding to establish a monograph for OTC skin protectant drug products.

The Panel did not recommend any Category I conditions for skin protectant ingredients contained in drug products for the treatment of diaper rash; for the prevention of poison ivy, oak, and sumac; for the treatment of fever blisters; and as insect bite neutralizers. Therefore, no new sections to Part 347 (as set forth in the advance notice of proposed rulemaking for skin protectant drug products that was published in the **Federal Register** of August 4, 1978 (43 FR 34628)) are included in this advance notice of proposed rulemaking for these drug categories. The Panel did recommend Category I conditions for astringent drug products. Therefore, for this drug category, amendments to Part 347 are included in this advance notice of proposed rulemaking (§§ 347.3(a), 347.12, and 347.52).

The unaltered statements of the Panel relating to OTC skin protectant ingredients contained in drug products for the treatment of diaper rash; for the prevention of poison ivy, oak, and sumac; for the treatment of fever blisters; as astringents; and as insect bite neutralizers is issued to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The statements have been prepared independently of FDA, and the agency has not yet fully evaluated the Panel's recommendations. The Panel's findings appear in this document to obtain public comment before the agency reaches any decision on the Panel's statements. This document represents the best scientific judgment of the Panel members, but does not necessarily reflect the agency's position on any particular matter contained in it.

After reviewing all comments submitted in response to this document, FDA will issue in the **Federal Register** a tentative final monograph for OTC skin protectant drug products, to include the five drug categories listed above. Under the OTC drug review procedures, the agency's position and proposal are first stated in the tentative final monograph, which has the status of a proposed rule. Final agency action occurs in the final monograph, which has the status of a final rule.

The Agency's position on OTC skin protectant drug products will be stated when the tentative final monograph is published in the **Federal Register** as a notice of proposed rulemaking. In that notice of proposed rulemaking, the agency also will announce its initial determination whether the proposed rule is a major rule under Executive Order 12291 and will consider the requirements of the Regulatory Flexibility Act (5 U.S.C. 601-612). The present notice is referred to as an advance notice of proposed rulemaking to reflect its actual status and to clarify that the requirements of the Executive Order and the Regulatory Flexibility Act will be considered in the amended notice of proposed rulemaking. At that time FDA also will consider whether the proposed rule has a significant impact on the human environment under 21 CFR Part 25 (proposed in the **Federal**

Register of December 11, 1979; 44 FR 71742).

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC skin protectant drug products used for the treatment of diaper rash; for the prevention of poison ivy, oak, and sumac; for the treatment of fever blisters; as astringents; and as insect bite neutralizers. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on skin protectant drug products relating to the five drug categories listed above should be accompanied by appropriate documentation. Comments will not be accepted at this time on any portion of the OTC skin protectant rulemaking other than that relating to drug products for the five listed drug categories.

In accordance with § 330.10(a)(2), the Panel and FDA have held as confidential all information concerning OTC drug products for the treatment of diaper rash; for the prevention of poison ivy, oak, and sumac; for the treatment of fever blisters; as astringents; and as insect bite neutralizers submitted for consideration by the Panel. All the submitted information will be put on public display in the Dockets Management Branch, Food and Drug Administration, after October 7, 1982, except to the extent that the person submitting it demonstrates that it falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Requests for confidentiality should be submitted to William E. Gilbertson, Bureaus of Drugs and Biologics (HFD-510) address above).

FDA published in the **Federal Register** of September 29, 1981 (46 FR 47730) a final rule revising the OTC procedural regulations to conform to the decision in *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). The Court in *Cutler* held that the OTC drug review regulations (21 CFR 330.10) were unlawful to the extent that they authorized the marketing of Category III drugs after a final monograph had been established. Accordingly, this provision is now deleted from the regulations. The regulations now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph.

Although it was not required to do so under *Cutler*, FDA will no longer use the terms "Category I," "Category II," and "Category III" at the final monograph stage in favor of the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III because that was the framework in which the Panel conducted its evaluation of the data.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the **Federal Register.** In some advance notices of proposed rulemaking previously published in the OTC drug review, the agency suggested an earlier effective date. However as explained in the tentative final monograph for OTC topical antimicrobial drug products (published in the **Federal Register** of July 9, 1982; 47 FR 29986), the agency has concluded that, generally, it is more reasonable to have a final monograph be effective 12 months after the date of its publication in the **Federal Register.** This period of time should enable manufacturers to reformulate, relabel, or take other steps to comply with a new monograph with a minimum disruption of the marketplace thereby reducing economic loss and ensuring that consumers have continued access to safe and effective drug products.

On or after the effective date of the monograph, no OTC drug products that are subject to the monograph and that contain nonmonograph conditions, i.e., conditions which would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce. Further, any OTC drug products subject to this monograph which are repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

A proposed review of the safety, effectiveness, and labeling of all OTC drugs by independent advisory review panels was announced in the **Federal Register** of January 5, 1972 (37 FR 85). The final regulations providing for this OTC drug review under § 330.10 were published and made effective in the **Federal Register** of May 11, 1972 (37 FR 9464). In accordance with these regulations, a request for data and information on all active ingredients used in OTC miscellaneous external drug products was issued in the **Federal Register** of November 16, 1973 (38 FR 31697). (In making their categorizations with respect to "active" and "inactive" ingredients, the advisory review panels relied on their expertise and understanding of these terms. FDA has defined "active ingredient" in its current good manufacturing practice regulations (§ 210.3(b)(7), (21 CFR 210.3(b)(7))), as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect." An "inactive ingredient" is defined in § 210.3(b)(8) as "any component other than an "active ingredient.") In the **Federal Register** of August 27, 1975 (40 FR 38179) a notice supplemented the original notice with a detailed, but not necessarily all inclusive, list of ingredients in miscellaneous external drug products to be considered in the OTC drug review. The list, which included "baby cream (diaper rash, rash, prickly heat);" "poision ivy and oak remedies;" "cold sore, fever blister;" "astringents (styptic pencil)," "astringents," and "wet dressing;" and "insect bites" active ingredients, was provided to give guidance on the kinds of active ingredients for which data should be submitted. The notices of November 16, 1973 and August 27, 1975 informed OTC drug product manufacturers of their opportunity to submit data to the review at those times and of the applicability of the monographs from the OTC drug review to all OTC products.

Under § 330.10(a)(1) and (5), the Commissioner of Food and Drugs appointed the following Panel to review the information submitted and to prepare a report on the safety, effectiveness, and labeling of the active ingredients in these OTC miscellaneous external drug products:

William E. Lotterhos, M.D., Chairman

Rose Dagirmanjian, Ph. D.

Vincent J. Derbes, M.D. (resigned July 1976)

George C. Cypress, M.D. (resigned November 1978)
Yelva L. Lynfield, M.D. (appointed October 1977)
Harry E. Morton, Sc. D.
Marianne N. O'Donoghue, M.D.
Chester L. Rossi, D.P.M.
J. Robert Hewson, M.D. (appointed September 1978)

Representatives of consumer and industry interests served as nonvoting members of the Panel. Marvin M. Lipman, M.D., of Consumers Union served as the consumer liaison. Gavin Hildick-Smith, M.D., served as industry liaison from January until August 1975, followed by Bruce Semple, M.D., until February 1978. Both were nominated by the Proprietary Association. Saul A. Bell, Pharm. D., nominated by the Cosmetic, Toiletry, and Fragrance Association, also served as an industry liaison since June 1975.

Two nonvoting consultants, Albert A. Belmonte, Ph. D., and Jon J. Tanja, R.Ph., M.S., have provided assistance to the Panel since February 1977.

The following FDA employees assisted the Panel: John M. Davitt served as Executive Secretary until August 1977, followed by Arthur Auer until September 1978, followed by John T. McElroy, J.D. Thomas D. DeCillis, R.Ph., served as Panel Administrator until April 1976, followed by Michael D. Kennedy until January 1978, followed by John T. McElroy, J.D. Joseph Hussion, R.Ph., served as Drug Information Analyst until April 1976, followed by Victor H. Lindmark, Pharm. D., until March 1978, followed by Thomas J. McGinnis, R.Ph.

The Advisory Review Panel on OTC Miscellaneous External Drug Products was charged with the review of many categories of drugs. Due to the large number of ingredients and varied labeling claims, the Panel decided to review and publish its findings separately for several drug categories and individual drug products. The Panel presents in this document its conclusions and recommendations on OTC drug products containing skin protectant ingredients for the treatment of diaper rash; for the prevention of poison ivy, oak, and sumac; for the treatment of fever blisters; as astringents; and as insect bite neutralizers. The Panel's findings on other categories of miscellaneous external drug products are being published periodically in the **Federal Register.**

The Panel was first convened on January 13, 1975 in an organizational meeting. Working meetings at which OTC drug products for the treatment of diaper rash were discussed were held on November 12 and 13, 1976; June 5 and 6, 1977; October 5 and 6, November 7 and 8, and December 14, 1980. Working meetings at which OTC drug products for the prevention of poison ivy, oak, and sumac were discussed were held on April 2 and 3, May 16 and 17, October 8 and 9, and November 12 and 13, 1976; January 14 and 15, April 3 and 4, June 5 and 6, August 5 and 6, and September 30 and October 1, 1977; October 5 and 6, November 7 and 8, and December 14 and 15, 1980. Working meetings at which OTC drug products for the treatment of fever blisters were discussed were held on October 5 and 6, November 7 and 8, and December 14, 1980. Working meetings at which OTC astringent drug products were discussed were held on September 28 and 29, and November 9 and 10, 1975; May 16 and 17, June 11 and 12, and October 8 and 9, 1976; February 27 and 28 and December 11 and 12, 1977; June 11 and 12, August 11 and 12, and October 29 and 30, 1978; May 18 and 19, and September 28 and 29, 1979; August 3 and 4, October 5 and 6, November 7 and 8, and December 14 and 15, 1980. Working meetings at which OTC insect bite neutralizer drug products were discussed were held on October 8 and 9, and November 12 and 13, 1976; April 3 and 4, and June 5 and 6, 1977; October 5 and 6, November 7 and 8, and December 14 and 15, 1980.

The minutes of the Panel meetings are on public display in the Dockets Management Branch (HFA–305), Food and Drug Administration (address above).

No individuals requested to appear before the Panel to discuss skin protectant ingredients contained in drug products used for the treatment of diaper rash; for the prevention of poison ivy, oak, and sumac; for the treatment of fever blisters; or as insect bite neutralizers, nor was any individual requested to appear by the Panel.

The following individuals were given an opportunity to appear before the Panel, either at their own request or at the request of the Panel to express their views on astringent drug products:

Steven Carson, Ph. D.
Edward Jackowitz
James Leyden, M.D.
Kenneth Klippel
Robert Scheuplein, Ph. D.

No person who so requested was denied an opportunity to appear before the Panel to discuss astringent drug products.

The Panel has reviewed the literature and data submissions, and has considered all pertinent information submitted through December 14 and 15, 1980 in arriving at its conclusions and recommendations.

In accordance with the OTC drug review regulations in § 330.10, the Panel reviewed the OTC drug products discussed in this document with respect to the following three categories:

Category I. Conditions under which OTC drug products are generally recognized as safe and effective and are not misbranded.

Category II. Conditions under which OTC drug products are not generally recognized as safe and effective or are misbranded.

Category III. Conditions for which the available data are insufficient to permit final classification at this time.

Referenced OTC Volumes

The "OTC Volumes" cited in this document include submissions made by interested persons in response to the call-for-data notices published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179). All of the information included in these volumes, except for those deletions which are made in accordance with confidentiality provisions set forth in § 330.10(a)(2), will be put on public display after October 7, 1982, in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

I. Statement on OTC Drug Products for the Treatment of Diaper Rash

A. Submission of Data and Information

In an attempt to make this review as extensive as possible and to aid manufacturers and other interested persons, the agency compiled a list of ingredients recognized, either through historical use or use in marketed products, as baby cream (diaper rash, rash, prickly heat) active ingredients. Fifty ingredients were identified as follows: alkyldimethyl benzylammonium chloride, allantoin (5-ureidohydantoin), aluminum acetate, aluminum hydroxide, amylum, balsam peru, benzethonium chloride, benzocaine, bicarbonate of soda, bismuth subnitrate, boric acid, calamine, calcium carbonate, camphor, casein, cod liver oil, cysteine hydrochloride, dibucaine, diperodon hydrochloride, glycerin, hexachlorophene, 8-hydroxyquinoline, iron oxide, lanolin, menthol, methapyrilene, methionine, methylbenzethonium chloride, oil of eucalyptus, oil of lavender, oil of peppermint, oil of white thyme, panthenol, *para*-chloromercuriphenol, petrolatum, phenol, pramoxine

hydrochloride, salicylic acid, silicone, sorbitan, monostearate, talc, tetracaine, vitamin A, vitamin A palmitate, vitamin D, vitamin D_2, vitamin E, white petrolatum, zinc oxide, and zinc stearate. Notices were published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) requesting the submission of data and information on these ingredients or any other ingredients used in OTC drug products for the treatment of diaper rash.

1. *Submissions.* Pursuant to the above notices, the following submissions were received:

Firms	Marketed products
Block Drug Co., Inc., Jersey City, NJ 07302.	Tashan Super Skin Cream.
Bristol-Myers Col., New York, NY 10022.	Ammens Powder.
Chesebrough-Pond's, Inc., Trumbull, CT 06611.	Vaseline Pure Petroleum Jelly.
Cooper Laboratories, Inc., Cedar Knolls, NJ 07927.	Aveeno Colloidal Oatmeal.
Corona Manufacturing Co., Atlanta, GA 30301.	Corona Ointment.
Macsil, Inc., Philadelphia, PA 19125.	Balmex Ointment.
Miles Laboratories, Inc., Elkhart, IN 46514.	Acid Mantle Creme, Acid Mantle Lotion.
DPennwalt Corp., Rochester, NY 14603.	Caldesene Powder, Caldesene Ointment, Proposed Product Containing Calcium Undecylenate and Hydrocortisone Acetate.
Pfizer Pharmaceuticals, New York, NY 10017.	Desitin Ointment.
Resinol Chemical Col., Baltimore, MD 21201.	Resinol Ointment, Resinol Greaseless Cream.
Sterling Drug, Inc., New York, NY 10016.	Diaparene Ointment, Diaparene Peri Anal, Diaparene Baby Lotion, Diaparene Medicated Baby Powder, Diaparene Diaper Rinse Solution, Diaparene Diaper Rinse (Tablets), Diaparene Diaper Rinse (Granules).
Stiefel Laboratories, Inc., Oak Hill, NY 12460.	Zeasorb Super Absorbent Medicated Powder.
Syntex Laboratories, Inc., Palo Alto, CA 94304.	Methakote Diaper Rash Cream.
The Upjohn Co., Kalamazoo, MI 49001.	Clocream Skin Cream.
USV Pharmaceutical Corp., Tuckahoe, NY 10707.	Panthoderm Cream, Panthoderm Lotion.
Whitehall Laboratories, Inc., New York, NY 10017.	Sperti Healing Ointment.
Warren-Teed Pharmaceuticals, Inc., Columbus, OH 43215.	Taloin Diaper Rash Ointment.

2. *Related submissions.* The Panel received data on the role of corn starch as a nutrient for *Candida albicans* from the Department of Dermatology, University of Pennsylvania. Data on the safety of 100 percent corn starch as a dusting powder and an evaluation of the effectiveness of methylbenzethonium chloride in diaper rash remedies were received from Glenbrook Laboratories (a Division of Sterling Drug, Inc.).

3. *Ingredients.* The following list contains ingredients in marketed products submitted to the Panel or ingredients that appeared in the call-for-data notice pulished in the **Federal Register** of August 27, 1975 (40 FR 38179):

Alkyldimethyl benzylammonium chloride
Allantoin (5-ureidohydantoin)
Aluminum acetate
Aluminum hydroxide
Aluminum dihydroxy allantoinate
Amylum
Aromatic oils
Balsam peru
Balsam peru oil
Beeswax
Benzethonium chloride
Benzocaine
Bicarbonate of soda
Bismuth subcarbonate
Bismuth subnitrate
Boric acid
Calamine (prepared calamine)
Calcium carbonate
Calcium undecylenate
Camphor
Casein
Cellulose
Chloroxylenol (*p*-chloro-*m*-xylenol)
Cod liver oil
Corn starch
Cysteine hydrochloride
Dexpanthenol (*D*-panthenol)
Dibucaine
Diperodon hydrochloride
Eucalyptol
Glycerin
Hexachlorophene
Hydrocortisone acetate
8-Hydroxyquinoline
Iron oxide
Lanolin
Live yeast cell derivative
Magnesium carbonate
Menthol
Methapyrilene
Methionine
DL-Methionine
Methylbenzethonium chloride
Microporous cellulose
Mineral oil
Oil of cade
Oil of eucalptus
Oil of lavender
Oil of peppermint
Oil of white thyme
Panthenol
Para-chloromercuriphenol
Petrolatum
Phenol
Phenylmercuric nitrate
Pramoxine hydrochloride
Protein hydrolysate (composed of *L*-leucine, *L*-isoleucine, *L*-methionine, *L*-phenylalanine, and *L*-tyrosine)
Resorcinol (resorcin)
Salicylic acid
Shark liver oil
Silicone
Sorbitan monostearate
Starch
Talc
Tetracaine
Vitamin A
Vitamin A palmitate
Vitamin D
Vitamin D_2
Vitamin E (*DL-alpha*-tocopheryl acetate)
White petrolatum
Zinc oxide
Zinc stearate

B. General Discussion

The Panel has determined that many of the ingredients contained in products with "diaper rash" claims submitted to this Panel (Ref. 1), or labeling claims related to diaper rash (skin irritation), have previously been reviewed by other OTC advisory review panels. In this statement, the Panel presents some general comments on OTC drug products for the treatment of diaper rash.

In the **Federal Register** of August 4, 1978 (43 FR 34628), FDA published a proposed monograph (advance notice of proposed rulemaking) on OTC skin protectant drug products used as absorbents, adsorbents, astringents, demulcents, emollients, lubricants, and wound-healing aids. The Miscellaneous External Panel believes that the use of these products to provide mechanical or physical protection may prevent further skin irritation associated with diaper rash. Furthermore, the Panel notes that the ingredients allantoin (5-ureidohydantoin), aluminum hydroxide, bicarbonate of soda, bismuth subnitrate, boric acid, calamine (prepared calamine), corn starch, glycerin, live yeast cell derivative, petrolatum, shark liver oil, white petrolatum, and zinc oxide are included in the skin protectant rulemaking and, therefore, recommends that the use of these ingredients for "diaper rash" be referred to that rulemaking.

The Panel recommends that the other ingredients listed above be referred to the rulemaking(s) that FDA considers most appropriate.

Note.—In order to assure that these ingredients are referred to the most appropriate rulemakings, FDA is seeking public comment from any interested person. Written comments should be submitted in the manner described at the end of this document.

The Panel also recommends that FDA develop labeling for diaper rash drug products by reviewing the Category I labeling already developed in other rulemakings for possible modification to include "diaper rash."

Note.—Elsewhere in this issue of the **Federal Register**, the Panel's statement on OTC drug products for the treatment of diaper rash is included in the rulemakings for topical antifungal drug products, topical antimicrobial drug products, and external analgesic drug products.

The Panel further notes that hexachlorophene is included in the above list of ingredients. However, the use of hexachlorophene as a component

of OTC drug products is restricted by 21 CFR 250.250(d). Hexachlorophene is limited to situations where an alternative preservative has not yet been shown to be as effective or where adequate integrity and stability data for the reformulated product are not yet available. Use of hexachlorophene as a preservative at a level higher than 0.1 percent is regarded as a new drug use requiring an approved new drug application.

The Panel did not review any individual ingredients. Instead, the Panel presents the following general comments on the use of OTC diaper rash drug products.

Diaper rash is a common skin problem of infancy, caused by contact with urine and feces, worsened by occlusion with plastic pants, and often secondarily infected with *Candida albicans*. It has an excellent prognosis for permanent cure after an infant is toilet trained. Incontinent adults may get similar irritant contact dermatitis.

The skin under the diaper is macerated by prolonged wetness. Disposable diapers with a plastic backing, or plastic pants used over regular diapers, keep heat as well as moisture in, causing miliaria (prickly heat) as well as more maceration than occurs with the use of regular diapers alone. Bacteria proliferate in this warm, moist environment, thriving on nutrients in feces and metobolizing urine to produce ammonia, an irritant. *Candida Albicans*, often present in feces, also proliferates to produce a characteristic bright red, sharply marginated rash with satellite pustules and erosions. Other exacerbating factors are diarrhea, heat, mechanical irritation (chafing) from rough cloth or tight or stiff plastic, and chemical irritation from detergent and bleach in diapers or from soap used to cleanse the baby.

Ordinary mild diaper rash, characterized by erythema of the buttocks, perineum, and lower abdomen, responds to very frequent diaper changes, cleansing with water, and removal of plastic occlusion (switching to cloth diapers, often two at the same time). Most treatments help by protecting the skin, acting as a physical barrier to irritants, and absorbing or adsorbing moisture. Examples are talc and zinc oxide ointment and paste.

The Panel wishes to point out that physicians treat severe diaper rash with topical antifungal and anticandidal drugs such as iodochlorhydroxyquin, nystatin, amphotericin B, miconazole nitrate, and clotrimazole, often in combination with a topical steroid (Refs. 2 and 3). Potent fluorinated steroids, such as 0.1 percent triamcinolone cream, should not be used on diaper rash because when applied under occlusive dressing these steroids can produce local thinning of the skin, with striae and easy bruising, but 0.5 to 1 percent hydrocortisone cream is recommended.

References

(1) OTC Volumes 160021, 160025, 160027, 160028, 160038, 160040, 160041, 160042, 160053, 160067, 160069, 160070, 160077, 160088, 160091, 160104, 160204, 160236, 160242 through 160247, 160271, 160272, 160277, 160357, 160362, and 160427.

(2) Weston, W. L., "Practical Pediatric Dermatology," Little, Brown and Co., Boston, pp. 51–53, 1979.

(3) Weinberg, S., and R. Hoekelman, "Pediatric Dermatology for the Primary Care Practitioner," McGraw Hill, New York, p. 121, 1979.

II. Statement on OTC Drug Products for the Prevention of Poison Ivy, Oak, and Sumac

A. Submission of Data and Information

In an attempt to make this review as extensive as possible and to aid manufacturers and other interested persons, the agency compiled a list of ingredients recognized, either through historical use or use in marketed products, as active ingredients in poison ivy and oak remedies. Forty-six ingredients were identified as follows: Alcohol, allantoin (5-ureidohydantoin), beechwood creosote, benzethonium chloride, benzocaine, benzyl alcohol, bicarbonate of soda, bichloride of mercury, bithionol, calamine, camphor, cetyldimethylbenzylammonium chloride, chloral hydrate, chloroform, chlorpheniramine maleate, dimethyl polysiloxane, diperodon hydrochloride, diphenhydramine hydrochloride, endothermic hectorite, ferric chloride, glycerin, hexachlorophene, hydrogen peroxide, hydrous zirconia, iron oxide, isopropyl alcohol, lanolin, lead acetate, lidocaine, menthol, merbromin, oil of eucalyptus, oil of turpentine, panthenol, parethoxycaine, phenol, phenyltoloxamine dihydrogen citrate, polyvinyl pyrrolidone, pyrilamine maleate, salicylic acid, tannic acid, tincture of impatiens bi-flora, triethanolamine, zinc acetate, zirconium oxide, and zyloxin. Notices were published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) requesting the submission of data and information on these ingredients or any other ingredients used in OTC poison ivy and oak remedy drug products.

Pursuant to the above notices, the following submissions were received:

Firms	Products
Marion Health and Safety, Inc., Rockford, IL 61101.	Poison Ivy Wash, Ferric Chloride, and Zircreme.
Unimed, Inc., Somerville, NJ 08876.	Residerm.

B. Classification of Ingredients

In this document, the Panel has reviewed only those ingredients with a claim for preventing poison ivy, oak, or sumac.

1. *Active ingredients.* Buffered mixture of cation and anion exchange resins.

2. *Other ingredient.* The Panel was not able to locate nor is it aware of data demonstrating the safety and effectiveness of ferric chloride when used as an OTC poison ivy, oak, and sumac prevention active ingredient. The Panel, therefore, classifies ferric chloride as Category II for this use, and it will be briefly discussd later in this document. (See part II. paragraph C. below—*General Discussion.)*

3. *Ingredients deferred to other rulemakings.* The Panel has determined that some of the ingredients that appeared in the **Federal Register** of August 27, 1975 (40 FR 38179) are contained in products usually associated with the symptomatic treatment of poison ivy, oak, and sumac. These types of products have been previously reviewed by the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products as skin protectant drug products (for symptoms of oozing or weeping due to contact dermatitis, poison oak, or poison ivy) in the **Federal Register** of August 4, 1978 (43 FR 34628).

Note.—Elsewhere in this issue of the **Federal Register**, the Panel's statement on OTC drug products for the prevention of poison ivy, oak, and sumac is included in the rulemaking for external analgesic drug products.

The Panel did not receive any data on the following ingredients used for the prevention of poison ivy, poison oak, and poison sumac. These ingredients should be considered in other appropriate rulemakings for their use in treating poison ivy, poison oak, poison sumac, and their related symptoms.

Alcohol
Allantoin
Benzethonium chloride
Benzocaine
Benzyl alcohol
Bithionol
Calamine
Camphor
Cetalkonium chloride
(cetyldimethylbenzylammonium chloride)
Chloral hydrate

Chlopheniramine maleate
Creosote (beechwood creosote)
Diperodon hydrochloride
Diphenhydramine hydrochloride
Endothermic hectorite
Eucalyptus oil (oil of eucalyptus)
Glycerin
Hydrogen peroxide
Iron oxide
Isopropyl alcohol
Lanolin
Lead acetate
Lidocaine
Menthol
Merbromin
Mercuric chloride (bichloride of mercury)
Oil of turpentine
Panthenol
Parethoxycaine hydrochloride (parethoxycaine)
Phenol
Phenyltoloxamine citrate (phenyltoloxamine dihydrogen citrate)
Polyvinylpyrrolidone (polyvinyl pyrrolidone)
Pyrilamine maleate
Salicylic acid
Simethicone (dimethyl polysiloxane)
Sodium bicarbonate (bicarbonate of soda)
Tannic acid
Tincture of impatiens bi-flora
Trolamine (triethanolamine)
Zinc acetate
Zirconium oxide (hydrous zirconia)
Zyloxin

4. *Ingredients subject to existing regulation.* The Panel notes that hexachlorophene and chloroform are restricted as components of OTC drug products under 21 CFR 250.250(d) and 21 CFR 310.513.

C. General Discussion

The Panel received three submissions for products claiming to prevent poison ivy, oak, or sumac by complexing with the plant antigen before it enters the skin (Refs. 1, 2, and 3). Two submissions contained no substantial data to establish the safety and effectiveness of the active ingredient (ferric chloride) contained in the product (Refs. 2 and 3). The Panel has therefore placed this ingredient in Category II. (See paragraph B.2. above—Other ingredients.) The third submission (Ref. 1) contained data on the use of a buffered mixture of cation and anion exchange resins in the prevention and treatment of poison ivy. The Panel addresses these data below. (See part II. paragraph D.3.a. below—*Category III ingredient—Buffered mixture of cation and anion exchange resins.)*

The Panel wishes to emphasize that claims for the relief of minor skin irritations, itching, and rashes due to poison ivy, oak, and sumac have been previously addressed by another OTC Advisory Review Panel. (See the report on OTC External Analgesic Drug Products published in the **Federal Register** of December 4, 1979 (44 FR 69768).) Therefore, this document only discusses the use of OTC drug products for the prevention of poison ivy, oak, and sumac. The Panel recommends that the agency defer to other appropriate rulemakings those ingredients and labeling claims submitted for treatment of the symptoms of poison ivy, oak, and sumac.

References

(1) OTC Volume 160103.
(2) OTC Volume 160132.
(3) OTC Volume 160152.

D. Categorization of Data

1. *Category I conditions.* None.

2. *Category II conditions.* (See part II, paragraph B.2. above—*Other ingredient.*)

3. *Category III conditions.* These are conditions for which available data are insufficient to permit final classification at this time.

a. *Category III ingredient—Buffered mixture of cation and anion exchange resins.* The Panel concludes that there are insufficient data to establish the effectiveness of a buffered mixture of cation and anion exchange resins for the prevention of poison ivy, oak, and sumac.

This mixture is a resin bed that contains both acidic groups and basic groups, mixed intimately in definite ratios, and possesses the ability to remove cations and anions simultaneously from solution.

(i) *Safety.* Skin irritation studies submitted show insignificant degrees of irritation during the first 2 weeks of observation. During the fourth week of observation severe lesions with cellulitis were seen in the rabbit skin and the technician applying the test material. It was the conclusion of the investigators that the test material was safe for topical application if it were used for a period not exceeding 14 to 21 days (Ref. 1).

(ii) *Effectiveness.* The mechanism of action of the buffered mixture of anion and cation exchange resins is claimed to be that these ingredients react chemically with the plant irritants that cause poison ivy, oak, and sumac to inactivate them. The inactivated irritants can then be readily removed from the skin by washing. However, Fisher (Ref. 2) states that no topical measure is effective in preventing poison ivy dermatitis.

The data submitted included an unblinded, poison ivy efficacy study using 20 subjects to determine efficacy of the mixture and an unblinded, uncontrolled clinical study. The uncontrolled clinical study consisted of 32 case reports submitted by 13 different physicians who claimed effective results from the product.

Twenty male subjects, who were sensitive to poison ivy, were chosen for the unblinded study to evaluate the efficacy of a buffered mixture of cation and anion exhange resin in the treatment of poison ivy. Ten subjects followed a therapeutic course, and ten of the subjects followed a prophylactic course. For purposes of this document only, the portion of the study dealing with dermatitis prevention properties of the active ingredient is relevant. In this portion, the placebo showed almost the same degree of efficacy as the mixture of resins (Ref. 1).

(iii) *Evaluation.* The Panel concludes that there are insufficient data to show the effectiveness of a buffered mixture of anion and cation exchange resins when used in the prevention of poison ivy dermatitis.

References

(1) OTC Volume 160103.
(2) Fisher, A. A., "Contact Dermatitis," 2d Ed., Lea and Febiger, Philadelphia, pp. 260–265, 1973.

b. *Category III labeling.* None.

III. Statement on OTC Drug Products for the Treatment of Fever Blisters

A. Submission of Data and Information

In an attempt to make this review as extensive as possible and to aid manufacturers and other interested persons, the agency compiled a list of ingredients recognized, either through historical use or use in marketed products, as "cold sore, fever blister" active ingredients. Eighteen ingredients were identified as follows: alcohol, allantoin (5-ureidohydantoin), ammonia, ammonium carbonate, benzalkonium chloride, benzocaine, camphor, lanolin, lanolin alcohol, menthol, mineral oil, paraffin, peppermint oil, petrolatum, phenol, sorbitan sesquioleate, soya sterol, and tannic acid. Notices were published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) requesting the submission of data and information on these ingredients or any other ingredients used in OTC "cold sore, fever blister" drug products.

1. *Submissions.* Pursuant to the above notices, the following submissions were received:

Firms	Marketed products
Blistex, Inc., Oak Brook, IL 60521	Blistex Ointment, Blistik Medicated Lip Balm.
Campbell Laboratories, Inc., Farmingdale, NY 10022.	Herpecin-L.
Commerce Drug Co., Inc., Farmingdale, NY 11735.	Bio-Stik, Tanac Stik, Tanac.

Firms	Marketed products
International Pharaceutical Corp., Kansas City, MO 64114.	Gly-Oxide.
Oral Prophylactic Association, Inc., Duluth, MN 5512.	Mouth Komfort.
Sterling Drug, Inc., New York, NY 10016.	Campho-Phenique.

2. *Ingredients.* The following list contains labeled ingredients contained in marketed products submitted to the Panel or ingredients that appeared in the call-for-data notice published in the **Federal Register** of August 27, 1975 (40 FR 38179):

Alcohol
Allantoin (5-ureidohydantoin)
Ammonia
Ammonium carbonate
Amyl Dimethyl-*p*-aminobenzoate
Amyl *para*-dimethylaminobenzoate
Anhydrous glycerol
Aromatic oily solution
Beeswax
Benzalkonium chloride
Benzocaine
BHA
Bismuth sodium tartrate
Calcium silicate
Camphor
Candlelillia wax
Carbamide peroxide
Carnauba wax
Castor oil
Cetyl alcohol
Escalol 506
Glycerol
Homosalate
Lanolin
Lanolin alcohol
Menthol
Mineral oil
Octyldodecanol
Ozokerite
Paraffin
Pectin
Peppermint oil
Petrolatum
Pheno
Propyl *p*-benzoate
Pyridoxine hydrochloride
Sorbitan sesquioleate
Soya sterol
Sesame oil
Spermaceti
Talcum powder
Tannic acid
Thymol
Titanium dioxide
Wheat germ glycerides
White petrolatum

B. General Discussion

The Panel has determined that many of the ingredients contained in products with "cold sore, fever blister" claims submitted to this Panel (Ref. 1), or labeling claims related to fever blisters (irritation and discomfort), have previously been reviewed by other OTC advisory review panels. In this statement, the Panel presents some general comments on OTC drug products for the treatment of fever blisters.

In the **Federal Register** of August 4, 1978 (43 FR 34628), FDA published a proposed monograph (advance notice of proposed rulemaking) on OTC drug products. The OTC drug products subject to this rulemaking include products used as absorbents, adsorbents, astringents, demulcents, emollients, lubricants, and wound-healing aids. The Miscellaneous External Panel believes that the use of these products may also be useful for the treatment of fever blisters. Furthermore, the Panel notes that the ingredients allantoin, glycerin, petrolatum, tannic acid, and white petrolatum are included in the skin protectant rulemaking and, therefore, recommends that the use of these ingredients for "fever blisters" be referred to that rulemaking.

The Panel recommends that the other ingredients listed above be referred to the rulemaking(s) that FDA considers most appropriate. (Note: In order to assure that these ingredients are referred to the most appropriate rulemaking(s), FDA is seeking public comment from any interested person. Written comments should be submitted in the manner described at the end of this document.) The Panel also recommends that FDA develop labeling for cold sore and fever blister drug products by reviewing the Category I labeling already developed in other rulemakings for possible modification to include "cold sore" and "fever blister" claims.

Note.—Elsewhere in this issue of the **Federal Register**, the Panel's statement on OTC drug products for the treatment of fever blisters is included in the rulemaking for external analgesic drug products.

The OTC remedies for treating fever blisters consist of internally taken (oral) and externally applied (topical) medications. Only those which are externally administered to the lips are considered in this document. Preparations to be taken internally have been considered by the Advisory Review Panel on OTC Miscellaneous Internal Drug Products and its recommendations were published in the **Federal Register** of January 5, 1982 (47 FR 502).

The Panel did not review any individual ingredients. Instead, the Panel presents the following general comments on the use of OTC externally applied cold sore and fever blister drug products.

"Fever blisters" and "cold sores" are common names for herpes simplex, an acute infestious disease caused by the filterable (capable of passing through filters) virus *Herpes simplex*, type 1. Herpes simplex viruses are deoxyribonucleic acid (DNA) viruses, sensitive to ethyl ether and of two antigenic types. The type 1 virus is usually, but not exclusively, associated with nongenital lesions. The usual site of the lesion is at the junction of the mucous membrane and skin on the lips or nose. Hence, the term *herpes labialis* is frequently used. Occasionally, the lesions may occur in the skin in various areas of the body. The virus is spread from person to person by the oral or respiratory route. One the other hand, the type 2 virus is usually, but not exclusively (a small percentage of fever blisters are caused by this type), associated with genital lesions and is spread from person to person by sexual contact. Hence, the term *herpes genitalis* is frequently used for this type of infection, which, at the present time, is perhaps the third most common sexually transmitted disease.

A description of the development of a herpes simplex lesion provides the explanation why there are no adequate OTC measures currently available for specifically preventing or curing the infection. The assemblying of the virus capsid within the nucleus of an infected cell is the beginning of virus production. The envelope is assembled around the capsid when it passes through the membrane of the nucleus into the cytoplasm of the host cell. Later the virus is released from the host's cell. Thus it is believed that any locally applied drug is likely to be without direct action upon the intracellular virus and is not beneficial prophylactically or therapeutically.

The course of events during herpetic infections in man is well understood and occurs in a predictable order. The majority of adults have humoral immunity (antibodies) to the herpes simplex type 1 virus so the majority of infants are born with passive immunity comparable to the degree of active immunity of the mother. The inherited passive immunity of the infant disappears during the first few months of life and by about 5 years of age the child begins to develop active immunity by exposure to the virus. The first infection in the nonimmune individual due to exposure to the virus is designated primary herpes. It may be so mild as to be unnoticed, a subclinical infection, or it may be severe; the symptoms in the latter case may range from a severe localized infection to a generalized infection that occasionally is fatal.

Usually the primary herpetic infection in the nonimmune person manifests itself by vesicles (blisters) on the mucous membranes in the mouth. The gums and tonsils may be involved as well as the regional lymph nodes. There may be a constitutional reaction and higher fever. The virus may gain entrance to the blood stream that may result in a generalized vesicular eruption on the skin (a herpeticum eczema). The eyes may become involved, which results in a keratoconjunctivitis, and the central nervous system may become involved, giving rise to meningoencephalitis. Severe primary herpetic infections require laboratory procedures for specific diagnosis in order to differentiate them from infections with other viruses which may produce similar symptoms. Fortunately, the primary herpetic infection usually is self-limited. It persists longer than the recurrent infections, possibly 2 weeks, the period during which the body develops antibodies to combat the infection. The virus is not eliminated from the body with recovery from the primary infection. Once infected, an individual probably harbors the virus for the remainder of his or her lifetime. (Ref. 2).

During the intervals between the primary infection and the first recurrent infection, and between subsequent recurrent infections, the herpes virus is thought to remain dormant in the neurons of the sensory ganglia serving the region of the primary infection (a latent infection). The current thinking is that the incomplete virus may be integrated into the host cell chromosomes. In any event, the humoral and cellular immunities of the host keep the infection under control until some event occurs to reduce the immunity (resistance) of the host. Such events as fever, chilling, sunburn, windburn, menstruation, upset stomach or gastrointestinal disturbance, emotional stress, or excitement may reduce the immune state suficiently for the virus to become activated and again cause an infection, designated recurrent herpes (Ref. 2).

Recurrent herpes usually begins with a sensation of mild burning or itching and a feeling of firmness in the local area. Shortly thereafter, papules appear followed by vesicles. The sensation of firmness and the appearance of papules are due to the intra- and inter-cellular edema (accumulation of fluid). If erythema (redness) occurs in the area, it is due to the dilation of the blood capillaries. The vesicles may coalesce to form groups of thin-walled vesicles which may rupture. The vesicle fluid contains the complete virus and it is infectious. The stratum mucosum (prickle-cells) of the skin is involved and when the vesicles rupture and the overlying layers of the skin slough off, scabs form and healing takes place without scarring. If large denuded areas appear before scab formation occurs, bleeding may occur. If the scabs are large, cracking or separation may occur due to the movement of the lips. Necrosis does not occur. Occasionally, secondary bacterial infection may take place. Healing usually takes place in about 7 to 10 days. If healing does not take place within this time period, the consumer may have made a misdiagnosis of a fever blister and actually had something worse. Hence, the Panel recommends that labeling for fever blister drug products contain the warning "If the fever blister does not improve in one week, consult a doctor." Recurrent infections usually occur in the same general area. The only preventive measure is to avoid, where possible, the conditions that bring about activation of the virus, if such events are known and can be controlled (Ref. 2).

The Panel concludes that primary infections with herpes virus type 1 may be so mild as to go unnoticed or sufficiently serious as to require the attention of a physician. The recurrent herpetic infections are more annoying or embarrassing than they are serious. While these, too, may be sufficiently serious to justify the services of a physician, the recurrent local infections usually can be self-diagnosed and OTC preparations used for palliative or symptomatic treatment.

The Panel discussed a newly developed technique for evaluating herpes treatment (Ref. 3). This technique used a guinea pig model in which the immune system was stimulated by drying the herpes lesion. The quicker the drying of the herpes cell, the faster it can be controlled from spreading to surrounding epithelial cells. Once the spread of herpes is slowed, the antigen-antibody reaction starts to inactivate the herpes virus.

Astringents such as tannic acid have been used in products for the relief of fever blisters (Ref. 4). The Miscellaneous External Panel notes that the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products, in the **Federal Register** of August 4, 1978 (43 FR 34628), noted that tannic acid has little action on intact skin. When applied to abraded tissue, it precipitates a protein-tannate film that serves as a mechanical cover which may encourage bacterial growth under the protein-tannate crust (43 FR 34644). However, the Panel concludes that tannic acid in low concentrations applied to a small area such as a fever blister would be safe (Ref. 5), but the data submitted (Ref. 4) on the use of this ingredient in treating fever blisters are insufficient to establish effectiveness. Nevertheless, the Panel recommends that human studies be conducted because the use of astringents may be a rational treatment in shortening the healing time of fever blisters.

Only one human study (Ref. 6) was submitted to the Panel. The study employed carbamide peroxide 10 percent in anyhdrous glycerin and a control of anhydrous glycerin. According to the researchers, the medication provided highly dependable relief of pain (the chief complaint from subjects) and surprisingly frequent reduction in healing time.

There is no prophylactic OTC therapy of proven value. Vaccines are being evaluated and may be useful in the future. The repeated use of small pox inoculations has never been reliably shown to inhibit recurrent herpes simplex (Ref. 7).

Although most viral infections cannot be cured by OTC drugs, fever blisters should not be neglected. Local anesthetics can relieve pain, antibiotics can control secondary bacterial infections when they occur, and ointments (protectants) can soften crusts. Steroid hormone ointments are not recommended against infections and may spread the virus (Ref. 8). Drying agents such as alcohols, astringents, or skin protectant agents may be useful (Ref. 7).

References

(1) OTC Volumes 160008, 160012, 160013, 160048, 160096, 160136, 160177, 160197, 160213, 160218, and 160231.

(2) Dorsett, P. H., "Burrows Textbook of Microbiology," 21st Ed., W. B. Saunders Co., Philadelphia, pp. 972–989, 1979.

(3) Transcript of Proceedings of the Advisory Review Panel on OTC Miscellaneous External Drug Products, October 6, 1980, pp. 28–33.

(4) OTC Volume 160012.

(5) Transcript of Proceedings of the Advisory Review Panel on OTC Miscellaneous External Drug Products, November 8, 1980, p. 24.

(6) OTC Volume 160177.

(7) Arndt, K. A., "Manual of Dermatologic Therapeutics With Essentials of Diagnosis," 2d Ed., Little, Brown and Co., Boston, pp. 103–110, 1978.

(8) "Canker Sores and Fever Blisters," National Institute of Dental Research, DHEW Publication No. (NIH) 79–247.

IV. Statement on OTC Astringent Drug Products

A. Submission of Data and Information

In an attempt to make this review as extensive as possible and to aid manufacturers and other interested persons, the agency compiled a list of ingredients recognized, either through historical use or use in marketed products, as astringents, astringent (styptic pencil), and wet dressings active ingredients. Thirty-one ingredients were indentified as follows: acetone, alcohol 14 percent, aluminum acetate, aluminum chlorhydroxy complex, aluminum sulfate, ammonium alum, benzalkonium chloride, benzethonium chloride, boric acid, calcium acetate, camphor, cresol, cupric sulfate, ferric subsulfate, isopropyl alcohol, menthol, oxyquinoline sulfate, phenol, polyoxyethylene monolaurate, potassium alum, potassium ferrocyanide, silver nitrate, sodium diacetate, starch, talc, tannic acid, tannic acid glycerite, zinc chloride, zinc phenolsulfonate, zinc stearate, and zinc sulfate. Notices were published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) requesting the submission of data and information on these ingredients or any other ingredients used in OTC astringent drug products.

Pursuant to the above notices, the following submissions were received:

Firms	Marketed products
Commerce Drug Co., Inc., Farmingdale, NY 11735..	Tanac.
Cooper Laboratories, Inc., Cedar Knolls, NJ 07927..	Bur-Veen.
Cox Drugs, Asheville, NC 28803.....	Formula U.
The E. E. Dickinson Co., Essex, CT 06426..	Witch Hazel.
Dome Division, Miles Laboratories, Inc., West Haven, CT 06516..	Domeboro Effervescent Tablets, Domeboro Powder Packets.
Foxpharmacal, Inc., Ft. Lauderdale, FL 33310..	Secret Mirache.
R. L. Gaddy Co., Tallahassee, FL 32302..	Ez-It Medicated Foot Powder.
Humphreys Pharmacal, Inc., Rutherford, NJ 07070..	Witch Hazel.
Marion Laboratories, Inc., Kansas City, MO 64137..	Bluboro Powder.
Requa Manufacturing Co., Inc., Greenwich, CT 06830..	Aluminum Sulfate.
Sea Breeze Laboratories, Inc., Pittsburg, PA 15244..	Sea Breeze.
The Woltra Company, Inc., New York, NY 10011..	Mammoth Styptic Pencil, Styptic Pencil.

B. Ingredients Reviewed by the Panel

1. *Labeled ingredients contained in marketed products submitted to the Panel*

Alcohol
Alum
Aluminum acetate
Aluminum sulfate
Aromatics
Benzalkonium chloride
Benzocaine
Benzoic acid
Borax
Boric acid
para-tertiary-Butyl-*meta*-cresol
Calcium acetate
Camphor
Carbolic acid
Colloidal oatmeal
Eugenol
Gum camphor
Honey
Menthol
Modified Burow's solution
Oil of cloves
Oil of eucalyptus
Oil of peppermint
Oil of sage
Oil of wintergreen
Powdered alum
Starch
Talc
Tannic acid
Thymol
Witch hazel
Zinc oxide
Zinc stearate

2. *Other ingredients.* The following list contains ingredients that appeared in the call-for-data notice published in the **Federal Register** of August 27, 1975 (40 FR 38179) and were not contained in marketed products submitted to the Panel.

Acetone
Alcohol 14 percent
Aluminum chlorhydroxy complex
Ammonium alum
Benzethonium chloride
Cresol
Cupric sulfate
Ferric subsulfate
Isopropyl alcohol
Oxyquinoline sulfate
Phenol
Polyoxyethylene monolaurate
Potassium ferrocyanide
Silver nitrate
Sodium diacetate
Tannic acid glycerite
Zinc chloride
Zinc phenolsulfonate
Zinc sulfate

C. Classification of Ingredients

1. *Active ingredients.*

Alumium acetate (modified Burow's solution)
Aluminum sulfate
Witch hazel

2. *Tannic acid.* The Panel decided not to review tannic acid as an astringent, but will discuss this ingredient for use in the treatment of fever blisters. (See part III, above—STATEMENT ON OTC DRUG PRODUCTS FOR THE TREATMENT OF FEVER BLISTERS.) This decision was based on the fact that the only submission on tannic acid contained data and information for use in treating fever blisters (OTC Volume 160012). The Panel concluded that it is dangerous to use tannic acid as an astringent over large areas of the body because it precipitates protein which forms a protective coating over mucous membranes and abraded tissue and because the area under the coating is conducive for bacterial growth.

3. *Other ingredients.* The Panel was not able to locate nor is it aware of data demonstrating the safety and effectiveness of the following ingredients when used as OTC astringent active ingredients. The Panel, therefore, classifies these ingredients as Category II for this use, and they will not be discussed further in this document.

Acetone
Alcohol
Alcohol 14 percent
Alum (powdered alum)
Aluminum chlorhydroxy complex
Ammonium alum
Aromatics
Benzalkonium chloride
Benzethonium chloride
Benzocaine
Benzoic acid
Borax
Boric acid
para-tertiary-Butyl-*meta*-cresol
Calcium acetate
Camphor (gum camphor)
Collodial oatmeal
Cresol
Cupric sulfate
Eugenol
Ferric Subsulfate
Honey
Isopropyl Alcohol
Menthol
Oil of cloves
Oil of eucalyptus
Oil of peppermint
Oil of sage
Oil of wintergreen
Oxyquinoline sulfate
Phenol (carbolic acid)
Polyoxyethylene monolaurate
Potassium alum
Potassium ferrocyanide
Silver nitrate
Sodium diacetate
Starch
Talc
Tannic acid glycerite
Thymol
Zinc chloride
Zinc oxide
Zinc phenolsulfonate
Zinc stearate
Zinc sulfate

D. General Discussion

The Panel has determined that some of the ingredients contained in products with "astringent" claims submitted to this Panel (Ref. 1), or labeling claims related to astringent use, have previously been reviewed by other OTC advisory review panels.

In the **Federal Register** of August 4, 1978 (43 FR 34628), FDA published an advance notice of proposed rulemaking on OTC skin protectant drug products. The OTC drug products subject to this rulemaking include products used as absorbents, adsorbents, astringents, demulcents, emollients, lubricants, and wound-healing aids. The Miscellaneous External Panel believes that the astringents discussed in this statement may also be useful to provide mechanical or physical protection that may prevent further skin irritation. Therefore, the Panel recommends that the astringent ingredients listed above be referred to the skin protectant rulemaking. (Note: In order to assure that these ingredients have been referred to the most appropriate rulemaking, FDA is seeking public comment from any interested person. Written comments should be submitted in the manner described at the end of this document.) The Panel also recommends that FDA review the Category I labeling recommended in this document and the Category I labeling already developed for astringents in other rulemakings. (Note: Elsewhere in this issue of the **Federal Register**, the Panel's recommendations on OTC astringent drug products are included in the rulemaking for external analgesic drug products. The Panel presents a discussion of aluminum acetate, aluminum sulfate, and witch hazel and also presents the following general comments on astringents.

The skin which covers the body is often subjected to injuries. Astringents are locally applied protein precipitants which have such a low cell penetrability that the action is essentially limited to the cell surface and the interstitial spaces. The permeability of the cell membrane is reduced, but the cells remain viable. The astringent action is accompanied by contraction and wrinkling of the tissue and by blanching. The cement substance of the capillary endothelium is hardened, thus pathological transcapillary movement of plasma protein is inhibited and local edema, inflammation, and exudation are thereby reduced. Mucus and other secretions therefore may be reduced; thus the affected area becomes drier (Ref. 2).

Astringents are employed therapeutically to arrest hemmorrhage by coagulating blood and to check diarrhea, reduce inflammation of mucous membranes, promote healing, toughen the skin, or decrease sweating. The mechanism of action by which astringents are thought to decrease sweating is to coagulate protein in the sweat ducts and also by causing a peritubular irritation that results in duct closure. Styptics are substances not especially related to the clotting mechanism but are capable of promoting clotting by precipitating proteins.

There are several varied definitions for astringents. Webster (Ref. 3) defines astringent as a medicine for checking the discharge of mucus or serum by causing shrinkage of tissue and also as a liquid cosmetic for cleansing the skin and contracting trhe pores. Dorland (Ref. 4) defines astringent as causing contracting, usually locally, after topical application. Based on standard tests, and wishing to standardize the definition, the panel has adopted the definition of an astringent as a substance which checks oozing, discharge, or bleeding when applied to the skin or mucous membrane and works by coagulating protein.

The principal astringents are (1) the salts of aluminum, zinc, manganese, iron, and bismuth; (2) certain other salts that contain these metals such as permanganates; and (3) tannins, or related polyphenolic compounds. Acids, alcohols, phenols, and other substances that precipitate proteins may be astringent in the appropriate amount or concentration; however, such substances generally are not employed for their astringent effects because they readily penetrate cells and promote tissue damage. Strongly hypertonic solutions dry the affected tissues and are thus often but wrongly called astringents, unless protein precipitation also occurs (Ref. 2).

References

(1) OTC Volumes 160022, 160038, 160039, 160069, 160070, 160093, 160140, 160219, 160230, 160233, 160354, 160396, 160409, 160413, 160428, 160429, 160433, and 160435.

(2) Harvey, S. C., "Topical Drugs," *in* "Remington's Pharmaceutical Sciences," 15th Ed., edited by J. Hoover, Mack Publishing Co., Easton, PA, pp. 716–717, 1975.

(3) "Webster's Third New International Dictionary," edited by P. B. Gove, G. and C. Merriam Co., Springfield, MA, 1971, s.v. "astringent."

(4) "Dorland's Illustrated Medical Dictionary," 25th Ed., W. B. Saunders, Philadelphia, 1965, s.v. "astringent."

E. Categorization of Data

1. *Category I conditions.* The following are Category I conditions under which OTC astringent drug products are generally recognized as safe and effective and not misbranded.

Category I active ingredients.

Aluminum acetate, Witch hazel.

(1) *Aluminum acetate.* The Panel concludes that aluminum acetate is safe and effective for OTC use as an astringent active ingredient in OTC topical drug products when used within the concentration specified below.

Aluminum acetate solution is classified as an astringent for topical use on the skin and mucous membranes (Ref. 1). It has been used by dilution with 10 to 40 parts of water as a wet dressing. The solution may be stabilized by the addition of not more than 0.6 percent of boric acid, and it must be dispensed only as a clear solution (Ref. 2).

Aluminum acetate solution has been referred to for years as Burow's solution, named from a similar mixture often prescribed by Dr. August Burow. In preparing aluminum acetate solution, various methods can be employed to produce aluminum acetate. Aluminum acetate solution can be prepared by adding 545 milliliters (mL) aluminum subacetate solution to 15 mL glacial acetic acid and adding sufficient water to make 1,000 mL (Ref. 1). Aluminum subacetate solution is prepared by mixing 145 grams (g) of aluminum sulfate with 160 mL acetic acid and 70 g of precipitated calcium carbonate and sufficient water to make 1,000 mL. Previously aluminum acetate had been prepared by dissolving 150 g of lead acetate and 87 g of aluminum sulfate in water. However, this method of preparation has been abandoned. In order for the finished product to meet the compendial standards for strength, quality, and purity, each 100 mL should yield 4.8 to 5.8 g of aluminum acetate (Ref. 2).

(i) *Safety.* Concentrated solutions of aluminum salts have produced gingival necrosis, hemorrhagic gastroenteritis, clonic contractions, and evidence of nephritis. The acute oral LD_{50} of aluminum sulfate, a precursor to aluminum acetate, is 6.1 grams/kilogram (g/kg). Burow's solution is reported to be moderately irritating if mistakenly ingested (Refs. 3 and 4).

The degree of absorption of ingested aluminum and its related compounds is minimal (Ref. 5). The toxicity of aluminum is now considered to be low. Adverse effects appear due to inhalations of finely divided powders of aluminum oxide and metallic aluminum.

Driesbach (Ref. 6) states that no fatalities from aluminum salts have been reported in recent years. Gosselin et al. (Ref. 3) state the Burow's solution is slightly toxic with a probable lethal dose for humans of 5 to 15 g/kg. It is moderately irritating if ingested. Lansdown (Ref. 7) has shown some effect of aluminum compounds applied topically to the mouse, rabit, and pig skin. Epidermal changes consisting of

hyperplasia, microabscess formation, dermal inflammatory cell infiltration, and occasional ulceration were evident in all three species treated with aluminum chloride (10 percent), aluminum nitrate (10 percent), aluminum sulfate, aluminum hydroxide, or aluminum chlorhydrate.

(ii) *Effectiveness.* Many historical references are made to the effectiveness and use of aluminum acetate as an astringent wet dressing, compress, or soak for minor skin irritations due to allergies, insect bites, athlete's foot, poison ivy, swelling associated with minor bruises, and ulcerations of the skin. The studies reviewed in the literature and submissions may be classified as limited uncontrolled studies and testimonials supporting the use of aluminum acetate in diseases of the legs, eczema, varicose ulcers, acute cutaneous inflammation, various dermatoses, and other conditions. Aluminum acetate soaks are used for relief of acute irritation while treating plantar lesions of the foot (Ref. 8) (as a soak the patient begins soaking the treated foot (feet) three times a day) (Ref. 9). The solution can also be used as a wet dressing in the treatment of athlete's foot (Ref. 10). Moist compresses of Burow's solution are used to hasten healing of plantar perforation ulcers (Ref. 11).

Leyden (Ref. 12) induced a poison ivy dermatitis in six poison ivy sensitive volunteers. Forty-eight hours later a cell-mediated immune reaction was seen consisting of blisters which represented dermal cell necrosis. The blisters were treated with aluminum acetate 1:40 (2.5 percent), aluminum acetate 1:20 (5 percent), tap water, or saline compresses. Leyden found no significant difference in aluminum acetate 1:40 compared to tap water compresses, but did find aluminum acetate 1:20 compresses superior to both the tap water compresses and saline compresses.

Based on the current literature and wide clinical usage, the Panel concludes that aluminum acetate solution 1:20 to 1:40 is safe and effective for topical use as an astringent.

(iii) *Dosage.* Topical dosage is a solution containing 2.5 to 5 percent aluminum acetate.

(iv) *Indications.* "For use as a wet dressing, compress, or soak for relief of inflammatory conditions and minor skin irritations due to allergies, insect bites, athlete's foot, poison ivy, or swelling associated with minor bruises and ulcerations of the skin."

(v) *Warnings.* (*a*) "If condition worsens or symptoms persist for more than 7 days, discontinue use of the product and consult a doctor."

(*b*) "Do not cover wet dressings or compresses with plastic to prevent evaporation."

(*c*) "Keep away from eyes."

(*d*) "For external use only."

(*e*) "Store in a cool dry place."

(vi) *Directions.* (a) Depending on the formulation and concentration of the marketed product, the manufacturer must provide adequate directions so that the resulting solution to be used by the consumer contains 2.5 to 5 percent aluminum acetate.

(b) *For products containing aluminum acetate for use as a soak.* "Soak affected area for 15 to 30 minutes. Repeat 3 times a day" (Ref. 9).

(c) *For products containing aluminum acetate for use as a compress or wet dressing.* "Saturate a clean, soft, white cloth (such as a diaper or torn sheet) in the solution, gently squeeze, and apply loosely to the affected area. Saturate the cloth in the solution every 15 to 30 minutes and apply to the affected area. Repeat as often as necessary. Discard remaining solution after use" (Ref. 13, 14, and 15).

References

(1) Harvey, S. C., "Topical Drugs," *in* "Remington's Pharmaceutical Sciences," 15th Ed., edited by J. Hoover, Mack Publishing Co., Easton, PA, p. 717, 1975.

(2) "The United States Pharmacopeia," 19th Revision, Mack Publishing Co., Easton, PA, p. 20, 1975.

(3) Gosselin, R. E., et al., "Clinical Toxicology of Commercial Products," 4th Ed., The Williams and Wilkins Co., Baltimore, p. 89, 1976.

(4) Hertzler, A. E., "Dangers In The Use of Aluminum Solution As A Wet Dressing," *American Journal of Surgery*, 2:573–574, 1927.

(5) Casarett, L. J., and J. Doull, editors, "Toxicology. The Basic Science of Poisons," Macmillan Publishing Co., Inc., New York, p. 463, 1975.

(6) Driesbach, R. H., "Irritants and Rubefacients," *in* "Handbook of Poisoning: Diagnosis and Treatment," Lange Medical Publications, Los Altos, CA, p. 406, 1977.

(7) Lansdown, A. B. G., "Production of Epidermal Damage in Mammalian Skins by Some Simple Aluminum Compounds," *British Journal of Dermatology*, 89:67–76, 1973.

(8) Khoure, R. R., et al., "Verrucous Carcinoma of the Foot," *Journal of the American Podiatry Association*, 69:327–328, 1980.

(9) Shapiro, L. J., "Oblique Displacement Osteotomy for Correction of Hallux Adducto Valgus," *Current Podiatry*, 29:13–15, 1980.

(10) Barkes, K., et al., "Investigation of Clotrimagle Usage in Tinea Pedis Without Nail Involvement," *Journal of the American Podiatry Association*, 69:297–298, 1980.

(11) Anastasio, A. S., "Role of the Podiatrist in the Management of Diabetic Foot Problems," *Current Podiatry*, 25:7–9, 1976.

(12) Presentation by J. Leyden to the Advisory Review Panel on OTC Miscellaneous External Drug Products contained in the Transcripts of the Proceedings of its 42d meeting, pp. 7–18, November 7, 1980.

(13) Boedeker, E. C., and J. H. Dauber, editors, "General Care of the Patient. Topical Therapy of the Skin," *in* "Manual of Medical Therapeutics," 21st Ed., Little, Brown and Co., Boston, pp. 21–22. 1964.

(14) Combes, F. C., "The Wet Dressing, Its Use in Acute Cutaneous Inflammation," *Industrial Medicine and Surgery*, 30:29–34, 1961.

(15) Parker, G. F., and P. C. Logan, "Poison Ivy (Rhus) Dermatitis," *American Family Physician*, 6:62–66, 1972.

(2) *Witch hazel.* The Panel concludes that witch hazel (witch hazel water or hamamelis water) is safe and effective for OTC use as an astringent active ingredient on OTC topical drug products when used within the concentration specified below.

Witch hazel is a clear, colorless liquid having a characteristic odor and taste and is neutral or slightly acid to litmus paper (Ref. 1). It is prepared by macerating recently cut and partially dried dormant twigs of *Hamamelis virginiana* for about 24 hours in about twice their weight of water and then distilling until 850 mL of distillate is obtained from each 100 g. To each 850 mL distillate, 150 mL alcohol is added. Witch hazel contains 14 to 15 percent alcohol. It contains only a trace of volatile oils (0.01 to 0.02 percent) (Ref. 2). The tannin of witch hazel bark on distillation remains in the residue and is absent from the distilled extract (Refs. 2 and 4 through 12). Witch hazel has not been recognized in an official compendia since 1960 (Refs. 1 and 3).

(i) *Safety.* Aside from the slight stinging sensation, which has been attributed to the alcohol content (Ref. 9), no other reports of adverse effects to witch hazel have been found in the available medical literature. However, because witch hazel contains minute amounts of volatile oils, an allergic contact dermatitis is possible and cannot be discounted, although the occurance is rare (Refs. 2 and 12).

The Panel concludes that witch hazel can be used safely OTC, based on its use since the days of the early Colonists who learned of the drug from the American Indians (Ref. 3).

(ii) *Effectiveness.* Literature reports have attributed the astringent action of witch hazel to its tannin content (Refs. 4, 8, 11, 13, and 14). This tannin is hamamelitannin (Ref. 15), a catechol tannin (Ref. 3). One major manufacturer of witch hazel (which makes its product from a distillate of a combination of the

witch hazel bark and leaf) states that the tannin concentration of hamamelitannin falls between 2.5 and 4.2 milligrams/liter (mg/L) (Ref. 16), which is considered to be a range of concentrations effective for use as an OTC astringent drug product. It may also be probable, but is not documented, that the astringent effect is due to the alcohol present in witch hazel. The same manufacturer maintains that even though alcohol is an astringent by itself, and enhances the action of the witch hazel distillate, its purpose for being in the product is only as a preservative (Ref. 16). Assumptions that the effectiveness of witch hazel is due to the small amount (0.01 to 0.02 percent) of volatile oils present have not been scientifically validated (Ref. 2).

Studies to show that witch hazel is an effective astringent have been done. One study shows that witch hazel shortened the bleeding time and accelerated the blood clotting in rabbits (Ref. 2), which may be related to the astringency effects of witch hazel. Another study was performed using the plasma recovered from six human blood samples. Duplicate prothrombin (clotting) times were done using the undiluted plasma (0.1. mL plus 0.1 mL normal saline) and 0.1 mL of three test samples—witch hazel containing 14 percent ethyl alcohol, 14 percent ethyl alcohol alone, and undiluted witch hazel. The study showed that the witch hazel alone was superior to the witch hazel containing 14 percent ethyl alcohol, and that both were superior to the 14 percent ethyl alcohol alone, in accelerating the clotting time of the human plasma (Ref. 17).

The popularity of witch hazel and its use by consumers and the medical profession may be attributed, as mentioned above, to the trace amount of volatile oils which gives the product a characteristically pleasant odor (Ref. 18). One major manufacturer maintains that its popularity is due to the astringent action provided by the significant amounts of natural hamamelitannin found in the witch hazel distillate. Hamamelitannin is one of a broad class of tannins. Tannins are classified as astringents due to their action when applied to living tissue. They precipitate proteins making that area resistant to the action of proteolytic enzymes. For example, when tannins (either purified or a derivative) are applied to abraded tissue, the proteins of the exposed tissues precipitate, forming a mildly antiseptic, protective coat allowing new tissues to grow underneath. According to data submitted by one manufacturer, witch hazel is effective in treating bruises, contusions, and sprains; for protecting slight cuts and scrapes; for relieving muscular pains; and for treating the pain and swelling of nonpoisonous insect bites (Ref. 19). Another manufacturer states that witch hazel has been used in the household for years as a local astringent for the treatment of bruises, skin irritations, sunburn, insect bites, and external hemorrhoids (Ref. 16). The Panel concludes that witch hazel is safe and effective as an OTC astringent drug product for external application.

(iii) *Dosage.* Topical dosage is witch hazel prepared according to National Formulary XI.

(iv) *Indications.* (*a*) "For use as an astringent for the treatment of bruises, contusions, and sprains."

(*b*) "For protecting slight cuts and scrapes."

(*c*) "For relieving muscular pains."

(*d*) "For treating the pain and swelling of insect bites."

(*e*) "For use as an astringent for the treatment of skin irritation, sunburn, and external hemorrhoids."

(v) *Warnings.* "For external use only."

(vi) *Directions.* "Apply as often as necessary."

References

(1) "The National Formulary," 11th Ed., Mack Publishing Co., Easton, PA, p. 158, 1960.

(2) Neugebauer, H., "The Effect of the Distillates of *Hamamelis Virginiana* and of *Corylus Avellana*," *Die Pharmazie*, 3:3132–314, 1948.

(3) Claus, E. P., and V. E. Tyler, "Tannins," *in* "Pharmacognosy," 5th ed., Lea and Febiger, Philadelphia, pp. 156–163, 1965.

(4) "The Dispensatory of the United States of America," 22d Ed., edited by H. C. Wood, et al., J. B. Lippincott Co., Philadelphia, p. 174, 1937.

(5) "The Dispensatory of the United States of America," 25th Ed., edited by A. Osol and G. E. Farrar, Jr., J. B. Lippincott Co., Philadelphia, p. 633, 1955.

(6) The United States Dispensatory and Physicians' Pharmacology," 26th Ed., edited by A. Osol, R. Pratt, and M. D. Altshule, J. B. Lippincott Co., Philadelphia, p. 559, 1967.

(7) "The United States Dispensatory," 27th Ed., edited by A. Osol, R. Pratt, and J. B. Lippincott Co., Philadelphia, p. 576, 1973.

(8) "Martindale. The Extra Pharmaceutical Press, London, England, p. 1417, 1972.

(9) Harry, R. G., "Harry's Cosmeticology," 6th Ed., Chemical Publishing Co., Inc., New York, pp. 97–99, 1973.

(10) Yosida, Y., "Pharmacognostic Study of the Leaves of Hamamelis Species II," *Journal of the Pharmaceutical Society of Japan*, 59:656–659, 1939.

(11) Trease, G. E., and W. C. Evans, "Pharmacognosy," 10th Ed., The Williams and Wilkins Co., Baltimore, p. 429, 1972.

(12) Guenther, E., "The Essential Oils," volume II, D. Van Nostrand Co., Inc., New York, p. 255, 1949.

(13) Longo, R., and G. Mazzoldi, "The Determination of Tannins in the Drug and Extracts of *Hamamelis Virginiana*," *Bollettino Chimico Farmaceutico*, 105:241–244, 1966.

(14) DiPalma, J. R., editor, "Drill's Pharmacology in Medicine," 4th Ed., McGraw-Hill Book Co., New York, p. 1035, 1971.

(15) Windholz, M., editor, "The Merck Index," 9th Ed., Merck and Co., Inc., Rahway, NJ, pp. 560, 600, and 1172–1173, 1976.

(16) OTC Volume 160428.

(17) OTC Volume 160433.

(18) Nesselrod, J. P., "Clinical Proctology," W. B. Saunders Co., Philadelphia, pp. 164–169, 1957.

(19) OTC Volume 160354.

2. *Category II conditions.* The following are Category II conditions under which OTC astringent drug products are not generally recognized as safe and effective or are misbranded.

a. *Category II ingredients.* (See part IV, paragraph C.3 above—*Other ingredients.*)

b. *Category II labeling.* The Panel has placed in Category II the following labeling claims because no data were submitted to establish safety and effectiveness of these claims:

(1) "For anthrax."

(2) "Lymphangitis."

3. *Category III conditions.* The following are Category III conditions for which available data are insufficient to permit the final classification of OTC astringent drug products at this time.

a. *Category III active ingredient—Aluminum sulfate.* The Panel concludes that aluminum sulfate is safe, but there are insufficient data to establish its effectiveness for use as a styptic pencil.

(1) *Safety.* Aluminum sulfate is generally recognized as safe and is utilized in food processing, brining pickles, baking powder, and clarifying fats and oils. It has been used as an ingredient in deodorant preparations. However, it has been shown to be deleterious to clothing.

The LD_{50} of aluminum sulfate has been determined to be 6.1 g/kg in mice by oral administration. Aluminum sulfate can cause a mild yet persistent irritation to the eyes, but it does not irritate the skin. When 200 human volunteers were patch tested, no visual irritation was observed on the arms or legs. By moistening a styptic pencil, containing approximately 57 percent aluminum sulfate and applying it to a cut, approximately 0.1 to 0.2 mL will be applied. This application will result in a local coagulation of capillary bleeding.

In 75 years of marketing styptic pencils there have been no reported instances of human toxicity (Ref. 1). However, application of the pencil on a cut may result in some stinging.

The Panel concludes that aluminum sulfate is safe for use as a styptic pencil.

(2) *Effectiveness.* Aluminum sulfate, when applied to minor cuts, acts as an astringent and a protein precipitant. The substance has little, if any, cell permeability and exerts its effect on the cell surface (Ref. 2). This effect has been elucidated over many years of use (Ref. 3).

Aluminum sulfate has been used widely for many years although modern day clinical trials have not been conducted with this ingredient.

The Panel concludes there are insufficient data to establish the effectiveness of aluminum sulfate as a styptic.

(3) *Indication.* "For use in stopping bleeding caused by minor surface cuts, particularly those caused during shaving."

(4) *Warnings.* (*i*) "For external use only."

(*ii*) "Do not use in or around eyes."

(5) *Directions.* "Moisten and apply. Dry after use."

References

(1) OTC Volume 160409.

(2) OTC Volume 160411.

(3) Harvey, S. C., "Topical Drugs," *in* "Remington's Pharmaceutical Sciences," 16th Ed., edited by A. Osol, Mack Publishing Co., Easton, PA, p. 721, 1980.

b. *Category III labeling.* None.

F. Combination Policy

The Panel is not aware of products combining OTC ingredients used as astringents for topical sue. The Panel is aware of products which combine various OTC ingredients with an astringent. Any such combination of ingredients reviewed in this document with ingredients from other therapeutic categories should meet the regulation outlined in § 330.10(a)(4)(iv) which states:

An OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredient does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population.

Regarding combinations of ingredients for topical astringent use with ingredients from other therapeutic categories, the Panel also concurs with the FDA guidelines for OTC combination products (Ref. 1) which state that Category I active ingredients from different therapeutic categories may be combined to treat different symptoms concurrently only if each ingredient is present within its established safe and effective dosage range and the combination meets the OTC combination policy in all other respects.

Reference

(1) Food and Drug Administration, "General Guidelines for OTC Drug Combination Products, September 1978," Docket No. 78D-0322, Dockets Management Branch.

V. Statement on OTC Insect Bite Neutralizer Drug Products

A. Submission Data and Information.

In an attempt to make this review as extensive as possible and to aid manufacturers and other interested persons, the agency compiled a list of ingredients recognized, either through historical use or use in marketed products, as insect bite active ingredients. Nineteen ingredients were identified as follows: alcohol, ammonium hydroxide, aqua ammonia, bicarbonate of soda, calamine, camphor, ethoxylated alkyl alcohol, ferric chloride, fluid extract ergot, menthol, obtundia surgical dressing, oil of turpentine, peppermint oil, phenol, pyrilamine maleate, sodium borate, triethanolamine, zinc oxide, and zirconium oxide. Notices were published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) requesting the submission of data and information on these ingredients or any other ingredients used in OTC insect bite drug products.

Pursuant to the above notices, the following submissions were received:

Firms	Products
Marion Health and Safety, Inc., Rockford, IL 61101.	Sting-Kill Swabs.
Tender Corp., Littleton, NH 03561	After Bite.

B. Ingredients Reviewed by the Panel

1. *Labeled ingredients contained in marketed products submitted to the Panel.*

Benzalkonium chloride
Triethanolamine
Ammonium hydroxide

2. *Other ingredients.* The following list contains ingredients in OTC insect bite drug products, which appeared in the call-for-data notice published in the **Federal Register** of August 27, 1975, for which no marketed products were submitted to the Panel.

Alcohol
Aqua ammonia
Bicarbonate of soda
Calamine
Camphor
Ethoxylated alkyl alcohol
Ferric chloride
Fluid extract ergot
Menthol
Obtundia surgical dressing
Oil of turpentine
Peppermint oil
Phenol
Pyrilamine maleate
Sodium borate
Zinc oxide
Zirconium oxide

C. Classification of Ingredients

In this document, the Panel has reviewed only those ingredients with a claim for treating insect bites by neutralization or inactivation of insect venom.

1. *Active ingredients.*

Ammonium hydroxide
Triethanolamine

2. *Other ingredients.* The Panel was not able to locate nor is it aware of data demonstrating the safety and effectiveness of the following ingredients when used as OTC insect bite neutralizer active ingredients. The Panel, therefore, classifies these ingredients as Category II for this use, and they will not be discussed further in this document.

Alcohol
Aqua ammonia
Benzalkonium chloride
Bicarbonate of soda
Calamine
Camphor
Ethoxylated alkyl alcohol
Ferric chloride
Fluid extract ergot
Methol
Obtundia surgical dressing
Oil of turpentine
Peppermint oil
Phenol
Pyrilamine maleate
Sodium borate
Zinc oxide
Zirconium oxide

D. General Discussion

Insect bites can be fatal to individuals who are hypersensitive to the antigenic substances in insect venom which precipitate anaphylactic shock. Immediate consideration should be given towards obtaining fast, appropriate emergency treatment. Because of the potential danger of cross sensitization to other antigenic substances, appropriate caution should be given to sensitive individuals. A program of desensitization should be implemented if at all possible.

For the majority of insect bites, the reactions are confined to varying degrees of itching and pain at the site of

the bite. Uncontrolled itching and pain often lead to scratching that can produce nodules and possibly secondary infections. The use of OTC products for relief of localized pain and itching can be helpful. Additional benefit may be achieved at times with the use of effective antibacterial agents and mild astringents. Ingredients and claims for the relief of minor skin irritation (which may result from insect bites) have previously been addressed by another OTC Advisory Review Panel. (See the report on OTC Skin Protectant Drug Products published in the **Federal Register** of August 4, 1978; 43 FR 34628.) Treatment of infectious diseases caused by insect bites is not within the realm of this Panel's deliberation.

E. Categorization of Data

1. *Category I conditions.* None.
2. *Category II conditions.* None.
3. *Category III conditions.* These are conditions for which available data are insufficient to permit final classification at this time.

a. *Category III ingredients.*

Ammonium hydroxide
Triethanolamine

(1) *Ammonium hydroxide.* The Panel concludes that ammonium hydroxide is safe but that there are insufficient data to establish its effectiveness as an insect bite neutralizer.

Ammonia is a colorless, transparent gas having a density approximately 0.6 that of air, an exceedingly pungent odor, and an acrid taste. Ammonia is very soluble in water. A portion of the dissolved ammonia gas reacts chemically with water to form ammonium hydroxide. Aqueous solutions of ammonia exhibit alkaline reaction, and have other properties similar to those of solutions of alkali hydroxides. These properties have been attributed to the ammonium hydroxide formed. Although there is little ammonium hydroxide formed, ammonia water is often referred to and labeled as solution of ammonium hydroxide (Ref. 1).

The ammonium ion is of particular interest because it is toxic in high concentrations and because it serves a major role in the maintenance of the acid-base balance of the body (Ref. 2).

(i) *Safety.* Ammonia is a naturally occurring product found abundantly in body tissues. Ammonia is absorbed by inhalation, ingestion, and probably percutaneously at concentrations high enough to cause skin injury. Data are not available on absorption of low concentrations through the skin. Once absorbed, ammonia is converted to the ammonium ion as the hydroxide and as salts, especially as carbonates. The ammonium salts are rapidly converted to urea, thus maintaining an isotonic system. Ammonia is also formed and consumed endogenously by the metabolism and synthesis of amino acids. Excretion is primarily by way of the kidneys, but a not insignificant amount is passed through the sweat glands (Ref. 3).

Patients with severe hepatic disease or with portacaval shunts often develop derangements of the central nervous system, which are manifested by disturbance of consciousness, tremor, hyperreflexia, and electroencephalogram abnormalities. Because this syndrome is most often associated with elevated concentrations of ammonia in blood, and because it can be provoked by feeding of protein as well as by ingestion of ammonium salts, it is thought to represent ammonia toxicity to the brain (Ref. 2).

The occurrence of high concentrations of ammonia in the blood (hyperammonemia) in children and infants has been associated with defects of enzymes of the urea cycle. Hyperammonemia due to defects of ornithine transcarbamylase or carbamylphosphate synthetase may be related to cyclic vomiting and to at least one form of migraine. The mechanisms by which ammonia induces changes in the central nervous system is not clear (Ref. 2).

Ammonia gas when inhaled in dilute form can stimulate the medullary respiratory and vasomotor centers reflexly through irritation of the sensory endings of the trigeminal nerve (Ref. 2).

The strong, pungent, penetrating odor of low levels of ammonia at about 35 milligrams per cubic meter (mg/m^3) becomes increasingly irritating as concentrations exceed 70 mg/m^3 (Ref. 3). High concentrations of ammonia vapor are injurious to the lungs, and death may result from pulmonary edema. Long exposure to low concentrations of ammonia may lead to chronic pulmonary irritation. The maximal concentration of ammonia vapor that can be tolerated without harmful effect is probably less than 250 parts per million (ppm). High concentrations of neutral ammonium salts are irritating to the gastric mucosa and may produce nausea and vomiting (Ref. 2).

Ammonia preparations used externally have been discussed in some current sources of chemical and pharmaceutical information (Refs. 4 and 5).

(2) *Effectiveness.* The local reaction that follows insect bites may vary among individuals. Mild local reaction may consist of itching, swelling, and irritation. Solutions of ammonium hydroxide are local irritants. When applied to the skin in low concentrations, they have a rubefacient action, and in high concentrations they are vesicant. Few authoritative publications provide information regarding optimum concentrations of ammonia in counterirritant products.

The venom of stinging insects (bees, wasps, hornets, and ants) and the substances released by biting insects (mosquitos, flies, fleas, bedbugs, ticks, and chiggers) are varied in chemical nature. These substances range from simple amines, such as histamine and 5-hydroxytrytamine, to more complex peptides, kinins, and enzymes, such as hyaluronidase and phospholipase, being both acidic and basic in nature. While some of the substances may be primarily acidic in nature, such as the formic acid injected from the bite of some ants, it is erroneous to expect that solely neutralizing the acids will lead to complete and effective relief of all insect stings or bites (Ref. 6). Therefore, the use of remedies which are alkaline and solely directed to neutralizing acids of stinging insect venoms or insect bites are not generally acceptable treatment at this time.

(3) *Evaluation.* The submitted data (Ref. 7) do not establish the effectiveness of ammonium hydroxide in neutralizing insect bites or stings. The Panel recommends Category III for effectiveness of ammonium hydroxide either alone or in combination for the neutralization of insect stings and bites.

References

(1) Osol, A., "Remington's Pharmaceutical Sciences," 16th Ed., Mack Publishing Co., Easton, PA., p. 350, 1980.

(2) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 6th Ed., Macmillan Publishing Co., Inc., New York, pp. 869–870, 1975.

(3) Wands, R. C., "Alkaline Materials," *in* "Patty's Industrial Hygiene and Toxicology," 3d Ed., Vol. 2B., edited by G. D. Clayton and F. E. Clayton, A Wiley—Interscience Publication, New York, pp. 3045–3052, 1978.

(4) Todd, R. G., "Martindale, The Extra Pharmacopeia," 27th Ed., The Pharmaceutical Press, London, pp. 44–45, 1977.

(5) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, N.J., p. 69, 1976.

(6) Sadik, F., "Insect Sting and Bite Products," *in* "Handbook of Nonprescription Drugs," 6th Ed., American Pharmaceutical Association, Washington, pp. 326–327, 1979.

(7) OTC Volumes 160119 and 160434.

(2) *Triethanolamine.* The Panel concludes that triethanolamine is safe but that there are insufficient data to establish its effectiveness as an insect bite neutralizer.

Triethanolamine is an organic base related to ammonia in which the three hydrogen atoms in the ammonia structure have been replaced by the ethanol group. An important physical property of triethanolamine is its complete solubility in water and many organic solvents. It is one of the most hygroscopic organic solvents available, and its high boiling point makes it less volatile when used alone or in combination. It has a low vapor pressure and is compatible with many materials. It is used as a mild alkaline hygroscopic agent, acid gas absorbent, penetrant solvent, dispersing agent, and as an intermediate in the preparation of emulsifying agents and other derivatives (Ref. 1).

(i) *Safety.* Evidence has been previously presented to the Panel that indicates that triethanolamine is relatively safe when ingested or administered orally to experimental animals. Its oral LD_{50} in the rat and guinea pig is in the 8-milligram-per-kilogram (mg/kg) range. Several ounces can be tolerated by humans according to Gosselin et al. (Ref. 2). The principal effect of triethanolamine has been limited to the gastrointestinal tract or to systemic alkalosis as a result of its alkalinity. While it can be absorbed when applied to the skin, little evidence exists to indicate that it is toxic to the skin in concentrations of 2.5 percent found in lotions, creams, or solutions, or in concentrations of 30 percent found in swabs. Because of its alkalinity, it may be irritating to the skin if applied in large concentrations for long periods of time.

(ii) *Effectiveness.* The use of triethanolamine in insect remedies may be related partly to its physical-chemical properties. It is alkaline in solution, with a pH between 10 and 11, and has been used as a binding agent, emulsifier, and solvent. However, it is emphasized that the rationale of using triethanolamine to neutralize acids from insect bites or stings is based on the erroneous assumption that acids are the sole causative agents in insect bites or stings.

In the data submitted (Refs. 1 and 3), triethanolamine is in combination with benzalkonium chloride. Triethanolamine is purported to be a strong alkalizing agent, neutralizing the antigens in the insect venom. The benzalkonium chloride is purported to be present as an antiseptic for the sting site. (The combination will not be discussed further as this report deals solely with the neutralization of insect bites.) The same double-blind clinical study is provided in both submissions, which cover the same product. Bee stings were simulated in 26 previously determined nonallergenic subjects by injecting 0.02 ml of a reconstituted lyophilized (freeze-dried) bee venom into the arms of each subject. When pain was sensed, a pair of swabs, one saturated with the test product and one saturated with a saline placebo and given in a double-blind fashion, was spread gently over the lesions, one on each arm.

The time for reduction of pain or its elimination was recorded. While some limitations exist in the quality of data generated to make definite statements regarding the time it took to achieve pain reduction or pain elimination, reevaluation of the data by an agency statistician indicated that the test product gave a faster response than did placebo. Specifically, the data support the claim that a large proportion, 13 of 26 (50 percent), of subjects experienced pain reduction or elimination within 120 seconds with the test product as compared to the number of subjects who experienced pain reduction or relief (6 of 26 or 23 percent) when given the placebo. The degree of erythema and edema (swelling) was not affected by either treatment.

(iii) *Evaluation.* Because no similar study nor demonstration of efficacy has been shown for triethanolamine as a single active ingredient in neutralizing insect bites, it is not possible to assess its contribution to the effectiveness of the product. Therefore, the Panel recommends Category III for effectiveness of triethanolamine, either alone or in combination, for the neutralization of insect stings or bites. The clinical study using artificially induced bee stings outlined above, while not in the report, could serve as a model by which single ingredients can be tested for effectiveness in the relief or elimination of pain or itch from insect bites or stings.

References

(1) OTC Volume 160159.

(2) Gosselin, R. E., et al., "Clinical Toxicology of Commercial Products," 4th Ed., The Williams and Wilkins Co., Baltimore, p. 73, 1976.

(3) OTC Volume 160074.

b. *Category III labeling.* "For the temporary relief of stings caused by wasps, hornets, bees, mosquitos, spiders, fleas, chiggers, ticks, and ants."

List of Subjects in 21 CFR Part 347

OTC drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371)), and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)), and under 21 CFR 5.11 as revised (see 47 FR 16010; April 14, 1982), the agency advises in this advance notice of proposed rulemaking that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations would be amended in Part 347 (as set forth in the advance notice of proposed rulemaking for skin protectant drug products that was published in the **Federal Register** of August 4, 1978 (43 FR 34628)) as follows:

PART 347—SKIN PROTECTANT PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. In Subpart A, § 347.3 would be amended to include the following definition:

§ 347.3 Definitions.

* * * * *

Astringent. A drug product which checks oozing, discharge, or bleeding when applied to skin or mucous membrane and works by coagulating protein.

2. Subpart B would be amended by adding new § 347.12, to read as follows:

§ 347.12 Astringent active ingredients.

The active ingredient of the product consists of the following within the specified concentration:

(a) Aluminum acetate, 2.5 to 5 percent.

(b) Witch hazel, NF XI.

3. Subpart D would be amended by adding new § 347.52, to read as follows:

§ 347.52 Labeling of astringent drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "astringent."

(b) *Indications.* The labeling of the product contains a statement under the heading "Indications" that is limited to the following:

(1) *For products containing aluminum acetate identified in § 347.12(a).* "For use as a wet dressing, compress, or soak for relief of inflammatory conditions and minor skin irritations due to allergies, insect bites, athlete's foot, poison ivy, or swelling associated with minor bruises and ulcerations of the skins."

(2) *For products containing witch hazel identified in § 347.12(b).* (i) "For use as an astringent for the treatment of bruises, contusions, and sprains."

(ii) "For protecting slight cuts and scrapes."

(iii) "For relieving muscular pains."

(iv) "For treating the pain and swelling of insect bites."

(v) "For use as an astringent for the treatment of skin irritation, sunburn, and external hemorrhoids."

(c) *Warnings.* The labeling of the product contains the following warnings under the reading, "Warnings":

(1) *For products containing aluminum acetate identified in § 347.12(a). (i)* "If condition worsens or symptons persist for more than 7 days, discontinue use of the product and consult a doctor."

(ii) "Do not cover wet dressing or compress with plastic to prevent evaporation."

(iii) "Keep away from eyes."

(iv) "For external use only."

(v) "Store in a cool dry place."

(2) *For products containing witch hazel identified in § 347.12(b).* For external use only."

(d) *Directions.* The labeling of the product contains the following information under the heading "Directions":

(1) *For products containing aluminum acetate identified in § 347.12(a).* (i) Depending on the formulation and concentration of the marketed product, the manufacturer must provide adequate directions so that the resulting solution to be used by the consumer contains 2.5 to 5 percent aluminum acetate."

(ii) *For products containing aluminum acetate for use as a soak.* "Soak affected area for 15 to 30 minutes. Repeat 3 times a day. Discard remaining solution after use."

(iii) *For products containing aluminum acetate for use as a compress or wet dressing.* "Saturate a clean, soft, white cloth (such as a diaper or torn sheet) in the solution, gently squeeze, and apply loosely to the affected area. Saturate the cloth in the solution every 15 to 30 minutes and apply to the affected area. Repeat as often as necessary. Discard remaining solution after use.

(2) *For products containing witch hazel identified in § 347.12(b).* "Apply as often as necessary."

Interested persons may, on or before December 6, 1982, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments on this advance notice of proposed rulemaking. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments replying to comments may also be submitted on or before January 5, 1983. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Mark Novitch,

Acting Commissioner of Food and Drug.

Dated: August 27, 1982.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82–24422 Filed 9–3–82; 8:45 am]

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federal register

Tuesday
September 7, 1982

Part VII

Department of the Interior

Office of the Secretary
National Park Service

Department of Agriculture

Office of the Secretary
Forest Service

National Wild and Scenic Rivers System; Final Revised Guidelines for Eligibility, Classification and Management of River Areas

DEPARTMENT OF THE INTERIOR

Office of the Secretary

National Park Service

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Forest Service

National Wild and Scenic Rivers System; Final Revised Guidelines for Eligibility, Classification and Management of River Areas

AGENCY: National Park Service and Office of the Secretary, Interior; Forest Service and Office of the Secretary, USDA.

ACTION: Publication of final revised guidelines.

FOR FURTHER INFORMATION CONTACT:
Bob Brockwehl (NPS), 202/272–3566.
William R. Snyder (USFS), 202/382–8014.

SUPPLEMENTARY INFORMATION:
Guidelines for the study of potential national wild and scenic rivers and management of designated rivers were first issued jointly by the Department of Agriculture and the Department of the Interior in 1970. On January 28, 1981 draft revised guidelines were published in the **Federal Register** for public comment (Vol. 46, No. 18, pp. 9148–9158). The document which follows was prepared after consideration of 50 letters of comment received from other Federal agencies, State governments, private industry, citizens' groups and individuals. Major comments and responses are summarized below. Many of the comments received were not addressed because they related to aspects of the wild and scenic rivers program beyond the scope of these guidelines. (See Preface of the revised guidelines.)

Comments and Responses

Comment: The definition of the term outstandingly remarkable value is too vague and too liberal. Too many rivers will be eligible for designation, unreasonably constraining economic development of natural resources. *Response:* Balancing of the need for protection versus development of each river area will be considered by the Congress in deciding whether or not to designate the river area. A determination that a particular river is eligible for designation does not necessarily imply that designation is the best use of the river in terms of the national interest.

Comment: The guidelines give inadequate emphasis to public involvement in the study process. *Response:* Public involvement is sufficiently addressed in the context of environmental statements or assessments prepared in the study process.

Comment: The guidelines do not make sufficiently clear which of the management principles apply to private lands. *Response:* The guidelines may be unclear to the general reader in this respect. The managment principles are to be implemented throughout each river area to the fullest extent possible under the managing agency's general statutory authorities and other existing Federal, State and local laws, including zoning ordinances where available. Some management principles obviously apply only to Federal lands within the river area. For instance, the Wild and Scenic Rivers Act does not open private lands to public recreation. Management principles may apply to private lands only to the extent required by other laws such as local zoning and air and water pollution regulations.

Comment: Restriction of timber harvest to selective harvest techniques is unnecessarily limiting from both the timber production and the natural resource preservation standpoints. *Response:* The guidelines have been amended in accordance with this comment.

Comment: Specific guidance contained in the 1970 guideline with respect to the granting of rights-of-way for transmission lines is omitted from the revised draft guidelines. *Response:* The subsection on rights-of-way has been amended in accordance with this comment.

Comment: A protected study area extending one half mile from each bank of the river is excessive when the final boundaries of a river area must average no more than one quarter mile from each bank (320 acres per mile). *Response:* The half-mile figure was intended to ensure that all areas likely to be included within the boundaries of a designated river area would be considered in the study process. Setting a study boundary based on the "visual corridor" concept was considered but rejected. The one-quarter-mile figure was finally selected to avoid unnecessary limitations on resource developments. Some developments which may be initiated beyond the one-quarter-mile boundary during the study period might be affected in the future if the area under development is included in the boundaries of the river area designated by Congress.

Comment: Evaluation of the study area in its existing condition for classification purposes does not allow for the fact that a forest area growing in relatively natural condition at the time of the study may be scheduled for clearcutting at some future date. The classification process should allow for authorized and scheduled future uses which could change the condition and, thus, the classification of the river area. *Response:* The guidelines have been amended to permit consideration of alternative classifications for the river area where authorized future uses could alter classification.

The following additional changes were made in response to suggestions from the reviewing public or from reviewers within the responsible agencies.

- Unnecessary definitions were deleted.
- Quotations and paraphrases of the Wild and Scenic River Act (including the whole of Section II—Policy) were eliminated as much as possible. Instead, the guidelines will reference the appropriate sections of the Act where necessary.
- The entire subsection titled "Findings and Recommendations" and portions of the subsection titled "General Management Principles" were deleted and their content was placed in other appropriate sections.

Additional copies of the guidelines, the Wild and Scenic Rivers Act, as amended, and further information on the National Wild and Scenic Rivers System may be obtained from: National Park Service, Rivers and Trails Division (780), 440 G Street, N.W., Washington, D.C. 20243.

Dated: July 12, 1982.

G. Ray Arnett,

Assistant Secretary for Fish and Wildlife and Parks (Interior).

Dated: August 26, 1982.

Douglas W. MacCleery,

Deputy Assistant Secretary for Natural Resources and Environment (Agriculture).

Department of Agriculture

Department of the Interior

National Wild and Scenic Rivers System

Guidelines for Eligibility, Classification and Management of River Areas.

Contents

Preface
The National Wild and Scenic Rivers System
Addition of Rivers to the System
The Guidelines
Revision of the Guidelines

Section I
Definitions

Section II
The River Study

The Study Process
The Study Report
Description of the Study Area
Determination of Eligibility
Classification
Analysis of Alternatives

Section III

Management
General Management Principles

Tables

Table 1

Accelerated Study Schedule

Table 2

Classification Criteria for Wild, Scenic and Recreational River Areas

Appendix

The Wild and Scenic Rivers Act (Pub. L. 90–542 as amended through Pub. L. 96–487)

Preface

The National Wild and Scenic Rivers System

The Wild and Scenic Rivers Act, (Pub. L. 90–542 as amended; 16 U.S.C. 1271–1287) established a method for providing Federal protection for certain of our country's remaining free-flowing rivers, preserving them and their immediate environments for the use and enjoyment of present and future generations. Rivers are included in the system so that they may benefit from the protective management and control of development for which the Act provides.

The preamble of the Act states:

> It is hereby declared to be the policy of the United States that certain selected rivers of the Nation which, with their immediate environments, possess outstandingly remarkable scenic, recreational, geologic, fish and wildlife, historic, cultural, or other similar values, shall be preserved in free-flowing condition, and that they and their immediate environments shall be protected for the benefit and enjoyment of present and future generations. The Congress declares that the established national policy of dam and other construction at appropriate sections of the rivers of the United States needs to be complemented by a policy that would preserve other selected rivers or sections thereof in their free-flowing condition to protect the water quality of such rivers and to fulfill other vital national conservation purposes.

Addition of Rivers to the System

The Wild and Scenic Rivers Act provides two methods for adding a river to the National Wild and Scenic Rivers System. The first method is by an act of Congress. Congress can designate a river directly or it can authorize a river for study as a potential wild, scenic or recreational river. Upon completion of a study conducted by the Department of the Interior or the Department of Agriculture, a study report is prepared and transmitted to the President who, in turn, forwards it with his recommendations to Congress for action.

The second method for inclusion of a river in the national system is through the authority granted to the Secretary of the Interior in section 2(a)(ii) of the Act. Upon application by the Governor or Governors of the State or States involved, the Secretary can designate a river as a component of the national system provided that the river has been designated as a wild, scenic or recreational river by or pursuant to an act of the legislature of the State or States through which if flows to be permanently administered as a wild, scenic, or recreational river by an agency or political subdivision of the State or States concerned.

To be eligible for inclusion in the system through either method, rivers must meet certain criteria set forth in section 2(b) of the Act. Procedures for proposing State-administered rivers for designation have been issued by the Department of the Interior.

The Guidelines

Subsequent to enactment of the Wild and Scenic Rivers Act in October 1968, the Departments of Agriculture and the Interior initiated studies of twenty-seven rivers which the Act authorized for study as potential additions to the National Wild and Scenic Rivers System. As these studies progressed, it became evident that specific requirements of the Act concerning the evaluation, classification and management of these rivers were subject to differing interpretations within and between the two departments.

It was therefore agreed that a uniform evaluation and management approach should be formulated for use by the two departments, and through a cooperative effort, *Guidelines for Evaluating Wild, Scenic and Recreational River Areas Proposed for Inclusion in the National Wild and Scenic Rivers System Under Section 2, Public Law 90–542* was prepared and promulgated in February 1970.

The guidelines not only provide guidance for the congressionally mandated studies under section 5(a) of the Act, but are also useful for evaluations conducted by water resource development agencies under section 5(d) and for States applying for inclusion of State-designated rivers in the national system.

Revision of the Guidelines

While these guidelines were effective throughout a decade, it became clear that revision was necessary to incorporate changes identified through use and to reflect requirements of new laws and regulations. Therefore, on August 2, 1979, the President directed in his Environmental Message that "the Secretary of Agriculture and the Secretary of the Interior shall jointly revise their guidelines for evaluating wild, scenic and recreational rivers to ensure consideration of river ecosystems and to shorten the time currently used to study rivers for designation."

This revision of the guidelines has been prepared in response to the President's 1979 directive and includes:

- Clarification of the fact that free-flowing rivers which contain outstandingly remarkable ecological values are eligible for addition to the national system.
- Clarification of the fact that free-flowing river segments in or near urban areas that possess outstandingly remarkable values are eligible for addition to the national system.
- Elimination of the 25-mile minimum length guideline.
- Revision of the definition of sufficient river flow or volume of water in the river. Sufficient flow was not defined in the Act and the definition in the existing guidelines was unnecessarily limiting.
- Revised water quality guidelines to allow inclusion in the system of rivers where restoration to high water quality is planned.
- A revised section on management of designated river areas.
- A study schedule to accelerate completion of the river studies authorized by Congress.

Section I—Definitions

The following definitions are provided for the purpose of these guidelines only.

Act: The Wild and Scenic Rivers Act.

Carrying capacity: The quantity of recreation use which an area can sustain without adverse impact on the outstandingly remarkable values and free-flowing character of the river area, the quality of recreation experience, and public health and safety.

Classification criteria: Criteria specified in Section 2(b) of the Act for determining the classification (wild, scenic or recreational) of eligible river segments.

Classification: The process of determining which of the classes outlined in section 2(b) of the Act (wild, scenic, or recreational) best fit the river or its various segments.

Component: A river area designated as a unit of the National Wild and Scenic Rivers System.

Designation: Inclusion of a river area in the national system either by act of Congress or by authority of the Secretary of the Interior.

Development: Any manmade structure or modification of the natural or existing river environment.

Eligibility: Qualification of a river for inclusion in the national system through determination that it is free-flowing and with its adjacent land area possesses at least one outstandingly remarkable value.

Flow: The volume of water in a river passing a given point in a given period of time, usually expressed in terms of cubic feet per second or cubic meters per second.

Impoundment: A body of water formed by any manmade structure.

Management plan: The detailed development plan required under section 3(b) of the Act which states the boundaries and classification of the river area and presents a plan for its public use, development and administration.

Primary contact recreation: Activities in which there is prolonged and intimate contact with the water, (e.g., swimming, water skiing, surfing, kayaking, "tubing," and wading or dabbling by children.

River area: For a river study, that portion of a river authorized by Congress for study and its immediate environment comprising an area extending at least one-quarter mile from each bank. For designated rivers, the river and adjacent land within the authorized boundaries.

Secondary contact recreation: Activities in which contact with the water is either incidental or accidental, e.g., boating, fishing and limiting contact with water incident to shoreline activities.

Study agency: The agency within the Department of Agriculture or the Department of the Interior delegated the responsibility for a wild and scenic river study.

Study report: The report on the suitability or nonsuitability of a study river for inclusion in the national system, which section 4(a) requires the Secretary of Agriculture, or the Secretary of the Interior, or both jointly to prepare and submit to the President. The President transmits the report with his recommendation to the Congress.

Study team: A team of professionals from interested local, State and Federal agencies invited by the study agency and participating in the study.

Section II—The River Study

The Study Process

Section 4(a) mandates that all rivers designated as potential additions to the system in section 5(a) be studied as to their suitability for inclusion in the system:

> The Secretary of the Interior or, where national forest lands are involved, the Secretary of Agriculture or, in appropriate cases, the two Secretaries jointly shall study and submit to the President reports on the suitability or nonsuitability for addition to the national wild and scenic rivers system of rivers which are designated herein or hereafter by the Congress as potential additions to such system. The President shall report to the Congress his recommendations and proposals with respect to the designation of each such river or section thereof under this Act.

The purpose of a wild and scenic river study is to provide information upon which the President can base his recommendation and Congress can make a decision. Procedures for developing the necessary information and preparing the study report may vary depending on the agency which conducts the study, but generally will include the steps shown on Table 1, Accelerated Study Schedule.

Wild and scenic river studies will comply with all applicable statutes and executive orders, which may include the following: the National Environmental Policy Act (Pub. L. 91–190), the National Historic Preservation Act (Pub. L. 89–665), the Endangered Species Act (Pub. L. 93–205), the Fish and Wildlife Coordination Act (Pub. L. 85–264), the Water Resources Planning Act (Pub. L. 89–80), the Floodplain and Wetlands Executive Orders (E.O. 11988 and E.O. 11990), the National Forest Management Act of 1976 (Pub. L. 94–588), the Federal Land Policy and Management Act of 1976 (Pub. L. 94–579), the Wild and Scenic Rivers Act, (Pub. L. 90–542, as amended), and any rules and regulations issued pursuant thereto.

The Study Report

Each river study report will be a concise presentation of the information required in sections 4(a) and 5(c) of the Act as augmented by the Council on Environmental Quality regulations implementing the procedural provisions of the National Environmental Policy Act (40 CFR Parts 1500–1508).

Section 4(a):

> Each report, including maps and illustrations, shall show among other things the area included within the report; the characteristics which do or do not make the area a worthy addition to the system; the current status of land ownership and use in the area; the reasonably foreseeable potential uses of the land an water which woud be enhanced, foreclosed or curtailed if the area were included in the national wild and scenic rivers system; the Federal agency (which in the case of a river which is wholly or substantially within a national forest, shall be the Department of Agriculture) by which it is proposed the area, should it be added to the system, be administered; the extent to which it is proposed that such administration, including the costs thereof, be shared by State and local agencies; and the estimated cost to the United States of acquiring necessary lands and interests in land and of administering the area, should it be added to the system.

In addition, section 5(c) requires that

> The study of any of said rivers * * * shall include a determination of the degree to which the State or its political subdivisions might participate in the preservation and administration of the river should it be proposed for inclusion in the national wild and scenic rivers system.

Study reports may be combined with draft and final environmental impact statements (EIS) as permitted by § 1506.4 of the Council on Environmental Quality regulations. Study reports will be reviewed by other Federal agencies, states and the public as requried by section 4(b) of the Wild and Scenic Rivers Act. Each of the following subsections describes the way in which the information is generated, analyzed and presented in the report.

Description of the River Area

Each report will contain a description of the area included in the study. The study area will cover, as a minimum, an area extending the length of the river segment authorized for study and extending in width one-quarter mile from each bank of the river.

Adjacent river areas beyond one quarter mile form each river bank may be studied if their inclusion could facilitate management of the resources of the river area. For example, there may be important historic, archeological or ecological resource areas which may extend beyond the boundaries of the mandated study area, but could be better managed by inclusion in the river area. Also, management of the river area may be facilitated by extension to include established or available access points not included in the study.

For the purposes of study and determining eligibility and classification, the river area may be divided into segments.

The description of the river area will identify the outstandingly remarkable values and the extent of man's activity in the river environment to provide a clear basis for findings of eligibility and classification. While only one

outstandingly remarkable value is necessary for eligibility, the study report should carefully document all values of the river area.

In addition to the information required by Sections 4(a) and 5(c) of the Act, this section of the report will describe any existing zoning ordinances or other provisions of law governing land use in the study area.

If the study report and the environmental impact statement are combined, the same chapter may describe both the river area and the affected environment. For EIS purposes and for general information, a brief description of the regional setting will also be included.

Determination of Eligibility

Each report will contain a determination as to the eligibility of all portions of the authorized study area.

Section 2(b) of the Act states that "a * * * river area eligible to be included in the system is a free-flowing stream and the related adjacent land area that posseses one or more of the values referred to in section 1, subsection (b) of this Act." The terms "river" and "free-flowing" are defined in section 16 of the act.

In reading and applying the criteria for eligibility, the following points are relevant:

- The fact that a river segment may flow between large impoundments will not necessarily preclude its designation. Such segments may qualify if conditions within the segment meet the criteria.
- Rivers or river segments in or near urban areas that possess outstandingly remarkable values may qualify. Only one outstandingly remarkable value is needed for eligibility.
- In addition to the specific values listed in Section 1(b) of the Act, other similar values, such as ecological, if outstandingly remarkable, can justify inclusion of a river in the national system.
- The determination of whether a river ara contains "outstandingly remarkable" values is a professional judgment on the part of the study team. The basis for the judgment will be documented in the study report.
- There are no specific requirements concerning the length or the flow of an eligible river segment. A river segment is of sufficient length if, when managed as a wild, scenic or recreational river area, the outstandingly remarkable values are protected. Flows are sufficient if they sustain or complement the outstandingly remarkable values for which the river would be designated.

Classification

Study reports will indicate the potential classification which best fits each eligible river segment as viewed in its existing condition. Section 2(b) of the Act states that rivers which are found eligible and included in the National Wild and Scenic Rivers Systems shall be classified as one of the following:

(1) Wild river areas—Those rivers or sections of rivers that are free of impoundments and generally inaccesible except by trail, with watersheds or shorelines essentially primitive and waters unpolluted. These represent vestiges of primitive America.

These criteria are interpreted as follows:

a. "Free of impoundments." Wild river areas shall be free of impoundments.

b. "Generally inaccessible except by trail." Wild river areas will not contain roads, railroads, or other provisions for vehicular travel within the river area. The existence of a few inconspicuous roads leading to the boundary of the river area at the time of study will not necessarily bar wild river classification.

c. "Watersheds or shorelines essentially primitive." Wild river areas will show little or no evidence of human activity. Shorelines and watersheds within the river area should be essentially free of structures including such things as buildings, pipelines, powerlines, dams, pumps, generators, diversion works, rip-rap and other modifications of the waterway or adjacent land within the river corridor. The existence of a few inconspicuous structures, particularly those of historic or cultural value, at the time of study need not bar wild classification.

A limited amount of domestic livestock grazing or hay production may be considered "essentially primitive." There should be no row crops or ongoing timber harvest and the river area should show little or no evidence of past logging activities.

d. "Waters unpolluted." The water quality of a wild river will meet or exceed Federal criteria or federally approved State standards for aesthetics, for propagation of fish and wildlife normally adapted to the habitat of the stream, and for primary contact recreation except where exceeded by natural conditions.

(2) Scenic river areas—Those rivers or sections or rivers that are free of impoundments, with shorelines or watersheds still largely primitive and shorelines largely undeveloped, but accessible in places by roads.

These criteria are interpreted as follows:

a. "Free of impoundments." Scenic river areas will be free of impoundments.

b. "Shorelines or watersheds still largely primitive." To qualify for scenic classification, the rivers segment's shorelines and immediate environment should not show substantial evidence of human activity. The portion of the watershed within the boundary of the scenic river may have some discernible existing development. "Largely primitive" means that the shorelines and the immediate river environment still present an overall natural character, but that in places land may be developed for agricultural purposes. Row crops would be considered as meeting the test of "largely primitive," as would timber harvest and other resource use, providing such activity is accomplished without a substantial adverse effect on the natural appearance of the river or its immediate environment.

c. "Shorelines largely undeveloped" means that any structures or concentration of structures must be limited to relatively short reaches of the total area under consideration for designation as a scenic river area.

d. "Accessible in places by road" means that roads may reach the river area and occasionally bridge the river. The presence of short stretches of conspicuous or longer stretches of inconspicuous and well-screened roads or railroads will not necessarily preclude scenic river designation. In addition to the physical and scenic relationship of the free-flowing river area to roads or railroads, consideration should be given to the type of use for which such roads or railroads were constructed and the type of use which would occur within the proposed scenic river area.

(3) Recreational river areas—Those rivers or sections of rivers that are readily accessible by road or railroad, that may have some development along their shorelines, and that may have undergone some impoundment or diversion in the past.

These criteria are interpreted as follows:

a. "Readily accessible by road or railroad." River areas classified as recreational may contain existing parallel roads or railroads in close proximity to one or both banks of the river as well as bridge crossings and roads fording or ending at the river.

b. "Some development along their shorelines." Lands may have been developed for the full range of agricultural and forestry uses, may show evidence of past and ongoing timber

harvest, and may include some residential, commercial or similar development.

c. "Some impoundment or diversion in the past." There may be some existing impoundments, diversions and other modifications of the waterway having an impact on the river area. Existing low dams, diversion works, rip-rap and other minor structures will not bar recreational classification, provided the waterway remains generally natural and riverine in appearance.

The classification criteria are summarized in Table 2, appended to these guidelines.

There are several points which all participants and observers of the study process should bear in mind when reading and applying the classification criteria:

- It is important to understand each criterion, but it is more important to understand their collective intent. Each river segment and its immediate environment should be considered as a unit. The basis for classification is the degree of naturalness, or stated negatively, the degree of evidence of man's activity in the river area. The most natural rivers will be classified wild; those somewhat less natural, scenic, and those least natural, recreational.
- Generally, only conditions within the river area determine classification; however, occasionally conditions outside the river area, such as developments which could impact air and water quality, noise levels or scenic views within the river area, may influence classification.

For the purpose of classification, a river area may be divided into segments. Each segment, considered as a whole, will conform to one of the classifications. In segmenting the river the study team should take into account the management strategies necessary to administer the entire river area and should avoid excessive segmentation.

The Wild and Scenic Rivers Act provides no specific guidance on water quality for scenic and recreational rivers. However, the Clean Water Act has made it a national goal that all waters of the United States be made fishable and swimmable, and provides the legal means for upgrading water quality in any river which would otherwise be suitable for inclusion in the system. Therefore, rivers will not necessarily be excluded from the system because of poor water quality at the time study, provided a water quality improvement plan exists or is being developed in compliance with applicable State and Federal laws.

- Although each classification permits certain existing development, the criteria do not imply that additional inconsistent development is permitted in the future.
- The classification criteria provide uniform guidance for professional judgment, but they are not absolutes. It is not possible to formulate criteria so as to mechanically or automatically classify river areas. Therefore, there may occasionally be exceptions to some of the criteria. For example, if the study team finds that strict application of the statutory classification criteria would not provide the most appropriate classification for a specific river segment, the study report may recommend for congressional consideration an exception to the classification criteria.

Analysis of the Alternatives

To provide for decisionmaking and to satisfy the requirements of the National Environmental Policy Act, study reports will include an analysis of alternatives. The study team will develop an array of alternative plans encompassing all reasonable proposals for use of the river area including uses which may be incompatible with designation of the river area as a component of the national system. Where appropriate, alternative plans for the river area may be based on, but not limited to:

- Alternative managing agencies for the river area;
- Alternative protective measures other than national designation;
- Alternative uses of the area incompatible with designation as a component of the national system; and
- Alternative classifications for the river area. Occasionally there may be authorized but not yet constructed projects, which if constructed would alter the classification of the river area. In such cases, alternatives may be presented to permit consideration of the river area as it would be classified both with and without the authorized project. Authorized projects may include approved land management plans prepared by a Federal land management agency under its statutory authorities.

The study report will present at least one alternative plan calling for national designation through either Congressional or Secretarial designation of all eligible segments of the congressionally authorized study area.

If the study team finds a segment ineligible for designation as a component of the National Wild and Scenic Rivers System, but still worthy of protection, alternatives for State, local or private preservation may be presented, as well as protection under other Federal programs.

If areas adjacent to the study area have been studied and found eligible, the report may present alternatives which incorporate such areas into the river area proposed for designation. Such expansion of the original study area either in length or in width may be desirable to preserve and facilitate management of river ecosystems, historic or archeological areas or other special areas.

Section III—Management

Wild and scenic rivers shall be managed with plans prepared in accordance with the requirements of the Act, other applicable laws, and the following general management principles. Management plans will state: General principles for any land acquisition which may be necessary; the kinds and amounts of public use which the river area can sustain without impact to the values for which it was designated; and specific management measures which will be used to implement the management objectives for each of the various river segments and protect esthetic, scenic, historic, archeologic and scientific features.

If the classification or classifications determined in the management plan differ from those stated in the study report, the management plan will describe the changes in the existing condition of the river area or other considerations which required the change in classification.

General Management Principles

Section 10(a) states,

> Each component of the national wild and scenic rivers system shall be administered in such a manner as to protect and enhance the values which caused it to be included in said system without, insofar as is consistent therewith, limiting other uses that do not substantially interfere with public use and enjoyment of these values. In such administration primary emphasis shall be given to protecting its esthetic, scenic, historic, archeologic, and scientific features. Management plans for any such component may establish varying degrees of intensity for its protection and development on the special attributes of the area.

This section is interpreted as stating a nondegradation and enhancement policy for all designated river areas, regardless of classification. Each component will be managed to protect and enhance the values for which the river was designated, while providing for public

recreation and resource uses which do not adversely impact or degrade those values. Specific management strategies will vary according to classification but will always be designed to protect and enhance the values of the river area. Land uses and developments on private lands within the river area which were in existence when the river was designated may be permitted to continue. New land uses must be evaluated for their compatibility with the purposes of the Act.

The management principles which follow stem from section 10(a). Managing agencies will implement these principles to the fullest extent possible under their general statutory authorities and existing Federal, State and local laws. Because of these limitations, however, implementation of the principles may differ among and within components of the system depending on whether the land areas involved are federally, State, locally or privately owned.

Carrying Capacity. Studies will be made during preparation of the management plan and periodically thereafter to determine the quantity and mixture of recreation and other public use which can be permitted without adverse impact on the resource values of the river area. Management of the river area can then be planned accordingly.

Public Use and Access. Public use will be regulated and distributed where necessary to protect and enhance (by allowing natural recovery where resources have been damaged) the resource values of the river area. Public use may be controlled by limiting access to the river, by issuing permits, or by other means available to the managing agency through its general statutory authorities.

Basic Facilities. The managing agency may provide basic facilities to absorb user impacts on the resource. Wild river areas will contain only the basic minimum facilities in keeping with the "essentially primitive" nature of the area. If facilities such as toilets and refuse containers are necessary, they will generally be located at access points or at a sufficient distance from the river bank to minimize their intrusive impact. In scenic and recreational river areas, simple comfort and convenience facilities such as toilets, shelters, fireplaces, picnic tables and refuse containers are appropriate. These, when placed within the river area, will be judiciously located to protect the values of popular areas from the impacts of public use.

Major Facilities. Major public use facilities such as developed campgrounds, major visitor centers and administrative headquarters will, where feasible, be located outside the river area. If such facilities are necessary to provide for public use and/or to protect the river resource, and location outside the river area is infeasible, such facilities may be located within the river area provided they do not have an adverse effect on the values for which the river area was designated.

Motorized Travel. Motorized travel on land or water is generally permitted in wild, scenic and recreational river areas, but will be restricted or prohibited where necessary to protect the values for which the river area was designated.

Agricultural and Forestry Practices. Agricultural and forestry practices should be similar in nature and intensity to those present in the area at the time of designation. Generally, uses more intensive than grazing and hay production are incompatible with wild river classification. Rowcrop production and timber harvest may be practice in recreational and scenic river areas. Recreational river areas may contain an even larger range of agricultural and forestry uses. Timber harvest in any river area will be conducted so as to avoid adverse impacts on the river area values.

Other Resource Management Practices. Resource management practices will be limited to those which are necessary for protection, conservation, rehabilitation or enhancement of the river area resources. Such features as trail bridges, fences, water bars and drainage ditches, flow measurement devices and other minor structures or management practices are permitted when compatible with the classification of the river area and provided that the area remains natural in appearance and the practices or structures harmonize with the surrounding environment.

Water Quality. Consistent with the Clean Water Act, water quality in wild, scenic and recreational river areas will be maintained or, where necessary, improved to levels which meet Federal criteria or federally approved State standards for aesthetics and fish and wildlife propagation. River managers will work with local authorities to abate activities within the river area which are degrading or would degrade existing water quality.

Additional management principles stem from other sections of the Act as follows:

Land Acquisition: Section 6
Water Resource Development: Section 7
Mining: Section 9
Management of Adjacent Federal Lands: Section 12(a)
Hunting and Fishing: Section 13(a)
Water Rights: Section 13(b)–(f)
Rights-of-Way: Section 13(g)

The following policies are consistent with and supplement the management principles stated in the Act:

Land Use Controls. Existing patterns of land use and ownership should be maintained, provided they remain consistent with the purposes of the Act. Where land use controls are necessary to protect river area values, the managing agency will utilize a full range of land-use control measures including zoning, easements and fee acquisition.

Rights-of-Way. In the absence of reasonable alternative routes, new public utility rights-of-way on Federal lands affecting a Wild and Scenic River area or study area will be permitted. Where new rights-of-way are unavoidable, locations and construction techniques will be selected to minimize adverse effects on scenic, recreational, fish and wildlife and other values of the river area.

Other legislation applicable to the various managing agencies may also apply to wild and scenic river areas. Where conflicts exist between the provisions of the Wild and Scenic Rivers Act and other acts applicable to lands within the system, the more restrictive provisions providing for protection of the river values shall apply.

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TABLE 1.

ACCELERATED STUDY SCHEDULE

MONTHS

River Study Tasks	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
1. Organize study team Prepare study plan Public information meetings Scope critical issues	▒																													
2. Resource Inventories (a) Study Bndry. Locations (b) River eligibility and classification evalu. (c) Literature search (d) Other agency contacts (e) Resource maps		▒	▒	▒	▒	▒																								
3. Develop alternative (a) Prepare alternatives display (b) Public meetings on findings and alternat. (c) Analyze Public Input (d) Evaluate alternatives							▒	▒	▒	▒																				
4. Complete Preliminay Report/ DEIS							▒	▒	▒	▒																				
5. Review of Draft (a) Internal Review (b) Revise preliminary as needed (c) Prepare camera ready copy (d) Print Draft Report/EIS (e) Distribute for 90-day review (a) Public meetings or formal hearings during review											▒	▒	▒	▒	▒	▒	▒													
6. Analyze Review Input Revise draft as needed. Internal Review																		▒	▒	▒										
7. Print Final Report																					▒	▒	▒	▒						
8. Secretary's decision and transmittal of report w/ recommendations to OMB																					▒	▒	▒	▒						
9. Executive review and transmittal to the Congress																														

This schedule does not take into account the possibility of delays due to Congressional concern, interagency or intradepartmental concerns or other possible outside influences that cannot be planned for.

TABLE 2.

. CLASSIFICATION CRITERIA FOR WILD, SCENIC AND RECREATIONAL RIVER AREAS *

ATTRIBUTE	WILD	SCENIC	RECREATIONAL
Water Resources Development	Free of impoundment.	Free of impoundment.	Some existing impoundment or diversion. The existence of low dams, diversions or other modifications of the waterway is acceptable, provided the waterway remains generally natural and riverine in appearance.
Shoreline Development	Essentially primitive. Little or no evidence of human activity. The presence of a few inconspicuous structures, particularly those of historic or cultural value, is acceptable. A limited amount of domestic livestock grazing or hay production is acceptable. Little or no evidence of past timber harvest. No ongoing timber harvest.	Largely primitive and undeveloped. No substantial evidence of human activity. The presence of small communities or dispersed dwellings or farm structures is acceptable. The presence of grazing, hay production or row crops is acceptable. Evidence of past or ongoing timber harvest is acceptable, provided the forest appears natural from the riverbank.	Some development. Substantial evidence of human activity. The presence of extensive residential development and a few commercial structures is acceptable. Lands may have been developed for the full range of agricultural and forestry uses. May show evidence of past and ongoing timber harvest.
Accessibility	Generally inaccessibile except by trail. No roads, railroads or other provision for vehicular travel within the river area. A few existing roads leading to the boundary of the river area is acceptable.	Accessible in places by road. Roads may occasionally reach or bridge the river. The existence of short stretches of conspicuous or longer stretches of inconspicuous roads or railroads is acceptable.	Readily accessible by road or railroad. The existence of parallel roads or railroads on one or both banks as well as bridge crossings and other river access points is acceptable.
Water Quality	Meets or exceeds Federal criteria or federally approved State standards for aesthetics, for propagation of fish and wildlife normally adapted to the habitat of the river, and for primary contact recreation (swimming) except where exceeded by natural conditions.	No criteria prescribed by the Wild and Scenic Rivers Act. The Federal Water Pollution Control Act Amendments of 1972 have made it a national goal that all waters of the United States be made fishable and swimmable. Therefore, rivers will not be precluded from scenic or recreational classification because of poor water quality at the time of their study, provided a water quality improvement plan exists or is being developed in compliance with applicable Federal and State laws.	

* Table to be used only in conjunction with text.

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federal register

Tuesday
September 7, 1982

Part VIII

Department of Health and Human Services

Food and Drug Administration

Topical Antifungal Drug Products for Over-the-Counter Human Use; Establishment of a Monograph; Reopening of Administrative Record

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 333

[Docket No. 80N-0476]

Topical Antifungal Drug Products for Over-the-Counter Human Use; Establishment of a Monograph; and Reopening of Administrative Record

AGENCY: Food and Drug Administration.

ACTION: Advance notice of proposed rulemaking and reopening of administrative record.

SUMMARY: The Food and Drug Administration (FDA) is issuing an advance notice of proposed rulemaking that would establish conditions under which over-the-counter (OTC) topical antifungal drug products used for the treatment of diaper rash are generally recognized as safe and effective and not misbranded. This notice relates to the development of a monograph for topical antifungal drug products in general, which is part of the ongoing review of OTC drug products conducted by FDA. This notice also reopens the administrative record for OTC topical antifungal drug products to allow for consideration of a statement on drug products for the treatment of diaper rash that has been received from the Advisory Review Panel on OTC Miscellaneous External Drug Products.

DATES: Written comments by December 6, 1982 and reply comments by January 5, 1983.

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

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In accordance with Part 330 (21 CFR Part 330), FDA received on December 14, 1980 a statement from the Advisory Review Panel on OTC Miscellaneous External Drug Products relating to OTC drug products intended for use in the treatment of diaper rash. FDA regulations (21 CFR 330.10(a)(6)) provide that the agency issue in the **Federal Register** a proposed rule containing (1) the monograph recommended by the Panel, which establishes conditions under which these OTC drug products are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph because the Panel determined that they would result in the drugs' not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph because the Panel determined that the available data are insufficient to classify these conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel.

Because some ingredients in drug products for the treatment of diaper rash are marketed in OTC drug products for topical antifungal use, FDA has determined that the Miscellaneous External Panel's recommendations on OTC drug products for the treatment of diaper rash should be included as part of the proposed rulemaking for topical antifungal drug products. Development of this rulemaking has been ongoing for some time.

In the **Federal Register** of March 23, 1982 (47 FR 12480), FDA issued an advance notice of proposed rulemaking to establish a monograph for OTC topical antifungal drug products. FDA advises that it is reopening the administrative record for OTC topical antifungal drug products only as it pertains to drug products for the treatment of diaper rash in order to allow for the consideration of the Miscellaneous External Panel's recommendations on these products. Comments received on this advance notice of proposed rulemaking will be addressed in a future issue of the **Federal Register**. Also, the proceeding to develop a monograph for drug products for the treatment of diaper rash will be merged with the general proceeding to establish a monograph for OTC topical antifungal drug products.

The Panel did not recommend any Category I conditions for topical antifungal ingredients contained in drug products for the treatment of diaper rash. Therefore, no new sections to Subpart C of Part 333 (as set forth in the advance notice of proposed rulemaking that was published in the **Federal Register** of March 23, 1982 (47 FR 12480)) are included in this advance notice of proposed rulemaking for this drug category.

The unaltered statement of the Panel relating to OTC topical antifungal ingredients contained in products for the treatment of diaper rash is issued to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The statement has been prepared independently of FDA, and the agency has not yet fully evaluated the Panel's recommendations. The Panel's findings appear in this document to obtain public comment before the agency reaches any decision on the Panel's statement. This statement represents the best scientific judgment of the Panel members, but does not necessarily reflect the agency's position on any particular matter contained in it.

After reviewing all comments submitted in response to this document, FDA will issue in the **Federal Register** a tentative final monograph for OTC topical antifungal drug products, to include drug products for the treatment of diaper rash. Under the OTC drug review procedures, the agency's position and proposal are first stated in the tentative final monograph, which has the status of a proposed rule. Final agency action occurs in the final monograph, which has the status of a final rule.

The agency's position on OTC topical antifungal drug products will be stated when the tentative final monograph is published in the **Federal Register** as a notice of proposed rulemaking. In that notice of proposed rulemaking, the agency also will announce its initial determination whether the proposed rule is a major rule under Executive Order 12291 and will consider the requirements of the Regulatory Flexibility Act (5 U.S.C. 601-612). The present notice is referred to as an advance notice of proposed rulemaking to reflect its actual status and to clarify that the requirements of the Executive Order and the Regulatory Flexibility Act will be considered in the amended notice of proposed rulemaking. At that time FDA also will consider whether the proposed rule as a significant impact on the human environment under 21 CFR Part 25 (proposed in the **Federal Register** of December 11, 1979; 44 FR 71742).

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC topical antifungal drug products used for the treatment of diaper rash. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on topical antifungal drug products for the treatment of diaper rash should be accompanied by appropriate documentation. Comments will not be accepted at this time on any portion of the OTC topical antifungal rulemaking other than that relating to drug products for the treatment of diaper rash.

In accordance with § 330.10(a) (2), the Panel and FDA have held as confidential all information concerning

OTC drug products for the treatment of diaper rash submitted for consideration by the Panel. All the submitted information will be put on public display in the Dockets Management Branch, Food and Drug Administration, after October 7, 1982, except to the extent that the person submitting it demonstrates that it falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Requests for confidentiality should be submitted to William E. Gilbertson, Bureaus of Drugs and Biologics (HFD–510) (address above).

FDA published in the **Federal Register** of September 29, 1981 (46 FR 47730) a final rule revising the OTC procedural regulations to conform to the decision in *Cutler* v. *Kennedy*, 475 F. Supp. 838 (D.D.C. 1979). The Court in *Cutler* held that the OTC drug review regulations (21 CFR 330.10) were unlawful to the extent that they authorized the marketing of Category III drugs after a final monograph had been established. Accordingly, this provision is now deleted from the regulations. The regulations now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph.

Although it was not required to do so under *Cutler*, FDA will no longer use the terms "Category I," "Category II," and "Category III" at the final monograph stage in favor of the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III because that was the framework in which the Panel conducted its evaluation of the data.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the **Federal Register**. In some advance notices of proposed rulemaking previously published in the OTC drug review, the agency suggested an earlier effective date. However, as explained in the tentative final monograph for OTC topical antimicrobial drug products (published in the **Federal Register** of July 9, 1982; 47 FR 29986), the agency has concluded that, generally, it is more reasonable to have a final monograph be effective 12 months after the date of its publication in the **Federal Register**. This period of time should enable manufacturers to reformulate, relabel, or take other steps to comply with a new monograph with a minimum disruption of the marketplace thereby reducing economic loss and ensuring that consumers have continued access to safe and effective drug products.

On or after the effective date of the monograph, no OTC drug products that are subject to the monograph and that contain nonmonograph conditions, i.e., conditions which would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce. Further, any OTC drug products subject to this monograph which are repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

A proposed review of the safety, effectiveness, and labeling of all OTC drugs by independent advisory review panels was announced in the **Federal Register** of January 5, 1972 (37 FR 85). The final regulations providing for this OTC drug review under § 330.10 were published and made effective in the **Federal Register** of May 11, 1972 (37 FR 9464). In accordance with these regulations, a request for data and information on all active ingredients used in OTC miscellaneous external drug products was issued in the **Federal Register** of November 16, 1973 (38 FR 31697). (In making their categorizations with respect to "active" and "inactive" ingredients, the advisory review panels relied on their expertise and understanding of these terms. FDA has defined "active ingredient" in its current good manufacturing practice regulations (§ 210.3(b)(7), (21 CFR 210.3(b)(7))), as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect." An "inactive ingredient" is defined in § 210.3(b)(8) as "any component other than an 'active ingredient.'") In the **Federal Register** of August 27, 1975 (40 FR 38179), a notice supplemented the original notice with a detailed, but not necessarily all-inclusive, list of ingredients in miscellaneous external drug products to be considered in the OTC drug review. The list, which included "baby cream (diaper rash, rash, prickly heat)" active ingredients, was provided to give guidance on the kinds of active ingredients for which data should be submitted. The notices of November 16, 1973 and August 27, 1975 informed OTC drug product manufacturers of their opportunity to submit data to the review at those times and of the applicability of the monographs from the OTC drug review to all OTC drug products.

Under § 330.10(a)(1) and (5), the Commissioner of Food and Drugs appointed the following Panel to review the information submitted and to prepare a report on the safety, effectiveness, and labeling of the active ingredients in these OTC miscellaneous external drug products:

William E. Lotterhos, M.D., Chairman
Rose Dagirmanjian, Ph.D.
Vincent J. Derbes, M.D. (resigned July 1976)
George C. Cypress, M.D. (resigned November 1978)
Yelva L. Lynfield, M.D. (appointed October 1977)
Harry E. Morton, Sc. D.
Marianne N. O'Donoghue, M.D.
Chester L. Rossi, D.P.M.
J. Robert Hewson, M.D. (appointed September 1978)

Representatives of consumer and industry interests served as nonvoting members of the Panel. Marvin M. Lipman, M.D., of Consumers Union served as the consumer liaison. Gavin Hildick-Smith, M.D., served as industry liaison from January until August 1975, followed by Bruce Semple, M.D., until February 1978. Both were nominated by the Proprietary Association. Saul A. Bell, Pharm. D., nominated by the Cosmetic, Toiletry, and Fragrance Association, also served as an industry liaison since June 1975.

Two nonvoting consultants, Albert A. Belmonte, Ph. D., and Jon J. Tanja, R.Ph., M.S., have provided assistance to the Panel since February 1977.

The following FDA employees assisted the Panel: John M. Davitt served as Executive Secretary until August 1977, followed by Arthur Auer until September 1978, followed by John T. McElroy, J.D. Thomas D. DeCillis, R.Ph., served as Panel Administrator until April 1976, followed by Michael D. Kennedy until January 1978, followed by

John T. McElroy, J.D. Joseph Hussion, R.Ph., served as Drug Information Analyst until April 1976, followed by Victor H. Lindmark, Pharm. D., until March 1978, followed by Thomas J. McGinnis, R. Ph.

The Advisory Review Panel on OTC Miscellaneous External Drug Products was charged with the review of many categories of drugs. Due to the large number of ingredients and varied labeling claims, the Panel decided to review and publish its findings separately for several drug categories and individual drug products. The Panel presents in this statement its conclusions and recommendations on OTC drug products containing topical antifungal ingredients for the treatment of diaper rash. The Panel's findings on other categories of miscellaneous external drug products are being published periodically in the **Federal Register.**

The Panel was first convened on January 13, 1975 in an organizational meeting. Working meetings at which drug products for the treatment of diaper rash were discussed were held on November 12 and 13, 1976; June 5 and 6, 1977; October 5 and 6, November 7 and 8, and December 14, 1980.

The minutes of the Panel meetings are on public display in the Dockets Management Branch (HFA–305), Food and Drug Administration (address above).

No individuals requested to appear before the Panel to discuss topical antifungal ingredients contained in drug products for the treatment of diaper rash, nor was any individual requested to appear by the Panel.

The Panel has reviewed the literature and data submissions, and has considered all pertinent information submitted through December 14, 1980 in arriving at its conclusions and recommendations.

Referenced OTC Volumes

The "OTC Volumes" cited in this document include submissions made by interested persons in response to the call-for-data notices published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179). All of the information included in these volumes, except for those deletions which are made in accordance with confidentiality provisions set forth in § 330.10(a)(2), will be put on public display after October 7, 1982 in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

Statement on OTC Drug Products for the Treatment of Diaper Rash

A. Submissions of Data and Information

In an attempt to make this review as extensive as possible and to aid manufacturers and other interested persons, the agency compiled a list of ingredients recognized, either through historical use or use in marketed products, as baby cream (diaper rash, rash, prickly heat) active ingredients. Fifty ingredients were identified as follows: alkyldimethyl benzylammonium chloride, allantoin (5-ureidohydantoin), aluminum acetate, aluminum hydroxide, amylum, balsam peru, benzethonium chloride, benzocaine, bicarbonate of soda, bismuth subnitrate, boric acid, calamine, calcium carbonate, camphor, casein, cod liver oil, cysteine hydrochloride, dibucaine, diperodon hydrochloride, glycerin, hexachlorophene, 8-hydroxyquinoline, iron oxide, lanolin, menthol, methapyrilene, methionine, methylbenzethonium chloride, oil of eucalyptus, oil of lavender, oil of peppermint, oil of white thyme, panthenol, *para*-chloromercuriphenol, petrolatum, phenol, pramoxine hydrochloride, salicylic acid, silicone, sorbitan monostearate, talc, tetracaine, vitamin A, vitamin A palmitate, vitamin D, vitamin D_2, vitamin E, white petrolatum, zinc oxide, and zinc stearate. Notices were published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) requesting the submission of data and information on these ingredients or any other ingredients used in OTC drug products for the treatment of diaper rash.

1. *Submissions.* Pursuant to the above notices, the following submissions were received:

Firms	Marketed products
Block Drug Co., Inc., Jersey City, NJ 07302..	Tashan Super Skin Cream.
Bristol-Myers Co., New York, NY 10022..	Ammens Powder.
Chesebrough-Pond's, Inc., Trumbull, CT 06611..	Vaseline Pure Petroleum Jelly.
Cooper Laboratories, Inc., Cedar Knolls, NJ 07927..	Aveeno Colloidal Oatmeal.
Corona Manufacturing Co., Atlanta, GA 30301..	Corona Ointment.
Macsil, Inc., Philadelphia, PA 19125..	Balmex Ointment.
Miles Laboratories, Inc., Elkhart, IN 46514..	Acid Mantle Creme, Acid Mantle Lotion.
Pennwalt Corp., Rochester, NY 14603..	Caldesene Powder, Caldesene Ointment, Proposed product containing Calcium Undecylenate and Hydrocortisone Acetate.
Pfizer Pharmaceuticals, New York, NY 10017..	Desitin Ointment.
Resinol Chemical Co., Baltimore, MD 21201..	Resinol Ointment, Resinol Greaseless Cream.
Sterling Drug, Inc., New York, NY 10016..	Diaparene Ointment, Diaparene Peri Anal, Diaparene Baby Lotion, Diaparene Medicated Baby Powder, Diaparene Diaper Rinse Solution, Diaparene Diaper Rinse (Tablets), Diaparene Diaper Rinse (Granules).
Stiefel Laboratories, Inc., Oak Hill, NY 12460..	Zeasorb Super Absorbent Medicated Powder.
Syntex Laboratories, Inc., Palo Alto, CA 94304..	Methakote Diaper Rash Cream.
The Upjohn Co., Kalamazoo, MI 49001..	Colcream Skin Cream.
USV Pharmaceutical Corp., Tuckahoe, NY 10707..	Panthoderm Cream, Panthoderm Lotion.
Whitehall Laboratories, Inc., New York, NY 10017..	Sperti Healing Ointment.
Warren-Teed Pharmaceuticals, Inc., Columbus, OH 43215..	Taloin diaper Rash Ointment.

2. *Related submissions.* The Panel received data on the role of corn starch as a nutrient for *Candida albicans* from the Department of Dermatology, University of Pennsylvania. Data on the safety of 100 percent corn starch as a dusting powder and an evaluation of the effectiveness of methylbenzethonium chloride in diaper rash remedies were received from Glenbrook Laboratories (a Division of Sterling Drug, Inc.).

3. *Ingredients.* The following list contains ingredients in marketed products submitted to the Panel or ingredients that appeared in the call-for-data notice published in the **Federal Register** of August 27, 1975 (40 FR 38179):

Alkyldimethyl benzylammonium chloride
Allantoin (5-ureidohydantoin)
Aluminum acetate
Aluminum hydroxide
Aluminum dihydroxy allantoinate
Amylum
Aromatic oils
Balsam peru
Balsam peru oil
Beeswax
Benzethonium chloride
Benzocaine
Bicarbonate of soda
Bismuth subcarbonate
Bismuth subnitrate
Boric acid
Calamine (prepared calamine)
Calcium carbonate
Calcium undecylenate
Camphor
Casein
Cellulose
Chloroxylenol (*p*-cholo-*m*-xylenol)
Cod liver oil
Corn starch
Cysteine hydrochloride
Dexpanthenol (*D*-panthenol)
Dibucaine
Diperodon hydrochloride
Eucalyptol
Glycerin
Hexachlorophene
Hydrocortisone acetate
8-Hydroxyquinoline
Iron oxide

Lanolin
Live yeast cell derivative
Magnesium carbonate
Menthol
Methapyrilene
Methionine
DL-Methionine
Methlybenzethonium chloride
Microporous cellulose
Mineral oil
Oil of cade
Oil of eucalyptus
Oil of lavender
Oil of peppermint
Oil of white thyme
Panthenol
Para-chloromercuriphenol
Petrolatum
Phenol
Phenylmercuric nitrate
Pramoxine hydrochloride
Protein hydrolysate (composed of *L*-leucine, *L*-isoleucine, *L*-methionine, *L*-phenylalanine, and *L*-tyrosine)
Resorcinol (resorcin)
Salicylic acid
Shark liver oil
Silicone
Sorbitan monostearate
Starch
Talc
Tetracaine
Vitamin A
Vitamin A palmitate
Vitamin D
Vitamin D_2
Vitamin E (*DL-alpha*-tocopheryl acetate))
White petrolatum
Zinc oxide
Zinc stearate

B. General Discussion

The Panel has determined that many of the ingredients contained in products with "diaper rash" claims submitted to this Panel (Ref. 1), or labeling claims related to diaper rash (skin irritation), have previously been reviewed by other OTC advisory review panels. In this statement, the Panel presents some general comments on OTC drug products for the treatment of diaper rash.

In the **Federal Register** of March 23, 1982 (47 FR 12480), FDA published a proposed monograph (advance notice of proposed rulemaking) on OTC topical antifungal drug products. The OTC drug products subject to this rulemaking include products used for the treatment of athlete's foot, ringworm, jock itch, and the control of *Candida*. The Miscellaneous External Panel believes that the use of these products to control fungus may prevent further skin irritation associated with diaper rash. Furthermore, the Panel notes that benzethonium chloride, boric acid, calcium undecylenate, camphor, chloroxylenol, (*p*-chloro-*m*-xylenol), 8-hydroxyquinoline, menthol, phenol, resorcinol (resorcin), and salicylic acid are included in the antifungal rulemaking and therefore recommends that the use of these ingredients for "diaper rash" be referred to that rulemaking.

The Panel recommends that the other ingredients listed above be referred to the rulemaking(s) that FDA considers most appropriate. (Note: In order to assure that these ingredients are referred to the most appropriate rulemakings, FDA is seeking public comment from any interested person. Written comments should be submitted in the manner described at the end of this document.) The Panel also recommends that FDA develop labeling for diaper rash drug products by reviewing the Category I labeling already developed in other rulemakings for possible modification to include "diaper rash." (Note: Elsewhere in this issue of the **Federal Register**, the Panel's statement on OTC drug products for the treatment of diaper rash is included in the rulemakings for topical antimicrobial drug products, external analgesic drug products, and skin protectant drug products.)

The Panel further notes that hexachlorophene is included in the above list of ingredients. However, the use of hexachlorophene as a component of OTC drug products is restricted by 21 CFR 250.250(d). Hexachlorophene is limited to situations where an alternative preservative has not yet been shown to be as effective or where aedquate integrity and stability data for the reformulated product are not yet available. Use of hexachlorophene as a preservative at a level higher than 0.1 percent is regarded as a new drug use requiring an approved new drug application.

The Panel did not review any individual ingredients. Instead, the Panel presents the following general comments on the use of OTC diaper rash drug products.

Diaper rash is a common skin problem of infancy, caused by contact with urine and feces, worsened by occlusion with plastic pants, and often secondarily infected with *Candida albicans*. It has an excellent prognosis for permanent cure after an infant is toilet trained. Incontinent adults may get similar irritant contact dermatitis.

The skin under the diaper is macerated by prolonged wetness. Disposable diapers with a plastic backing, or plastic pants used over regular diapers, keep heat as well as moisture in, causing miliaria (prickly heat) as well as more maceration than occurs with the use of regular diapers alone. Bacteria proliferate in this warm, moist environment, thriving on nutrients in feces and metabolizing urine to produce ammonia, an irritant. *Candida albicans*, often present in feces, also proliferates to produce a characteristic bright red, sharply marginated rash with satellite pustules and erosions. Other exacerbating factors are mechanical irritation (chafing) from rough cloth or tight or stiff plastic, chemical irritation from detergent and bleach in diapers or from soap used to cleanse the baby, diarrhea, and heat.

Ordinary mild diaper rash, characterized by erythema of the buttocks, perineum, and lower abdomen, responds to very frequent diaper changes, cleansing with water, and removal of plastic occlusion (switching to cloth diapers, often two at the same time). Most treatments help by protecting the skin, acting as a physical barrier to irritants, and absorbing or absorbing moisture. Examples are talc and zinc oxide ointment and paste.

The Panel wishes to point out that physicians treat severe diaper rash with topical antifungal and anticandidal drugs such as iodochlorhydroxyquin, nystatin, amphotericin B, miconazole nitrate, and clotrimazole, often in combination with a topical steroid (Refs. 2 and 3). Potent fluorinated steroids, such as 0.1 percent triamcinolone cream, should not be used on diaper rash because, when applied under occlusive dressings, these steroids can produce local thinning of the skin, with striae and easy bruising, but 0.5 to 1 percent hydrocortisone cream is recommended.

References

(1) OTC Volumes 160021, 160025, 160027, 160028, 160038, 160040, 160041, 160042, 160053, 160067, 160069, 160070, 160077, 160088, 160091, 160104, 160204, 160236, 160242 through 160247, 160271, 160272, 160277, 160357, 160362, and 160427.

(2) Weston, W. L., "Practical Pediatric Dermatology," Little, Brown and Co., Boston, pp. 51–53, 1979.

(3) Weinberg, S., and R. Hoekelman, "Pediatric Dermatology for the Primary Care Practitioner," McGraw Hill, New York, p. 121, 1979.

Interested persons may, on or before December 6, 1982, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600

Fishers Lane, Rockville, MD 20857, written comments on this advance notice of proposed rulemaking. Three copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments replying to comments may also be submitted on or before January 5, 1983. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 333

Labeling, Over-the-counter drugs.

Mark Novitch,

Acting Commissioner of Food and Drugs.

Dated: August 27, 1982.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82-24424 Filed 9-3-82; 8:45 am]

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federal register

Tuesday
September 7, 1982

Part IX

Department of Health and Human Services

Food and Drug Administration

Over-the-Counter Human Drugs Which Are Generally Recognized as Safe and Effective and Not Misbranded; Proposed Amendment of General Provisions

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 330

[Docket No. 82N-0050]

Over-the-Counter Human Drugs Which Are Generally Recognized as Safe and Effective and Not Misbranded; Proposed Amendment of General Provisions

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the general provisions for all over-the-counter (OTC) drugs in Part 330 (21 CFR Part 330) to include a warning concerning the use of systematically absorbed OTC drugs by pregnant or nursing women. FDA believes that it is in the interest of the public health to require OTC drugs to bear a warning against use by pregnant or nursing women in the absence of professional advice.

DATES: Written comments by October 7, 1982. The agency proposed that any final rule that may issue based upon this proposal become effective 30 days following publication of the final rule, except that manufacturers will be provided up to one year for label changes. See "Supplementary Information" for a full discussion of the proposed effective date.

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

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, National Center for Drugs and Biologics (HFD-510), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: FDA is proposing to amend the general provisions for OTC drugs to include a requirement that OTC drug labels contain a statement advising pregnant or nursing women to seek professional advice before using any drug. The proposed warning would apply to all OTC drugs that are systemically absorbed and would state, "As with any drug, if you are pregnant or nursing a baby, seek professional advice before using this product." However, where a specific warning concerning possible adverse effects on pregnant or nursing women is established for an ingredient during the OTC drug review, the specific warning listed in an OTC drug final monograph would apply rather than the general warning proposed in this document. The proposed rule also provides for exemption from the general warning requirement, when appropriate, through petitioning the agency.

FDA and the State of California Department of Health Services have corresponded about the need for warnings concerning the use of OTC drugs by pregnant or nursing women. There has been agreement about the importance of informing these women of the need to exercise caution in using OTC drug products, but there have been differences about the best means of accomplishing this goal. FDA has opposed California's requirement of a general pregnancy/nursing warning because of concern that a general warning would not be consistent with specific warnings developed during the OTC drug review.

Recently, the State of California enacted legislation (section 10381 of Title 17 of the California Health and Safety Code) requiring that any OTC drug intended for systemic absorption into the human body that is not specifically exempted under the State's Health and Safety Code must include a pregnancy warning on the label. The warning states: "Caution: If pregnant or nursing a baby, consult your physician or pharmacist before using this product." The new California statute also provides that this specific warning is not required for an OTC drug that is "labeled with information regarding use in pregnancy and nursing which is substantially similar to (this) statement * * *." Any OTC drug manufactured and labeled after November 18, 1982, will be required to comply with the new California labeling. FDA is aware that similar legislation is also under consideration by other States.

FDA believes that it is in the interest of the public health to require OTC drugs to bear a warning against use by pregnant or nursing women in the absence of professional advice. Drugs taken by pregnant women pose the risk that they may affect the growth and developent of the human fetus. Drugs taken by nursing women may be transferred by the mother's milk to the newborn child for whom they are not intended, and at this stage in a child's life its enzyme system is not fully mature and its kidney function not fully developed so that it is easy for toxic levels of drugs to accumulate in its body (Ref. 1). Although only a small number of drugs have been conclusively shown to have adverse effects on the developing human fetus or newborn, information of this type is inadequate to establish safety for most drugs (Refs. 2 through 7). There is evidence, however, that the developing human organism is most susceptible to the effects of teratogenic drugs or other agents from about 2 weeks to 8 weeks after fertilization when the major organ systems are developing (Refs. 3, 5, 7, and 8). Exposure of the fetus to toxic agents after the embryo stage (i.e., after the basic structures of the organ systems have developed), while not likely to cause major anatomical abnormalities, may result in reductions in cell size or number, or alterations in functional capacity (Refs. 3, 5, and 8). The central nervous system appears to be especially susceptible to changes in functional capacity during the last trimester of pregnancy when the rate of brain growth is normally rapid.

In the course of FDA's OTC drug review, the advisory review panels gave particular consideration to evidence of teratogenicity in evaluating the safety of ingredients. For ingredients for which there were data to suggest a potential hazard, the panels recommended specific pregnancy warnings. For example, the panels recommended pregnancy warnings for aspirin use in the last 3 months of pregnancy and for anthelmintics. However, the agency recognizes that even where there are no data to suggest that particular OTC drugs present a potential hazard, there also may be no data demonstrating that such drugs are safe when used by pregnant or nursing women. Because any drug taken during pregnancy or while nursing may pose some risk to the fetus or newborn child, the agency concludes that in order to minimize this risk the labels of systemically absorbed OTC drug products should advise pregnant or nursing women that professional advice should be sought before using OTC drug products.

The agency has reviewed the labeling adopted by the State of California, which advises pregnant and nursing women to "consult your physician or pharmacist before using this product." Although the agency agrees with the concept of encouraging these women to seek professional assistance before using drug products, the agency does not believe that the warning should specify physicians and pharmacists. Many professional groups, such as nurses, nurse practitioners, certified nurse midwives, and physician's assistants, are also sources of sound information on OTC drugs. The woman who is considering taking an OTC drug is in the best position to choose the appropriate health professional to help her assess the risks and benefits of taking the drug for the medical condition for which she seeks relief. Therefore, the agency is

proposing that the warning advise women to "seek professional advice."

The proposed regulation allows a general warning to be superseded by a specific one where information on the extent of the risk is available. FDA considers that the inclusion of a specific warning instead of a general warning will serve to identify those products for which there are data suggesting a particular risk in pregnant or nursing women. The requirement for a general warning is supported by the need to inform pregnant or nursing women of the advisability of minimizing exposure of the fetus or newborn child to drugs, since a drug taken during pregnancy or while nursing may pose some risk. Because this proposed general warning is based on a lack of data demonstrating that OTC drugs are safe for use by pregnant or nursing women, rather than on data demonstrating that the specific product is unsafe, the proposed warning begins with the phrase "as with any drug." This phrase makes it clear that the general warning applies to all drugs and will help to enhance the effect of those specific warnings that represent demonstrated risks of particular drugs.

If the proposed warning is adopted, the agency will continue to review the scientific data concerning the use of OTC drugs by pregnant and nursing women and will give careful consideration to the need for the warning both generally and for specific classes of OTC drugs. Should it appear, based on these data, that the warning is no longer justified, the agency will propose to revoke the requirement.

References

1. Hecht, A., "Advice on Breast-Feeding and Drugs," *FDA Consumer*, 13:21–22, 1979.

2. Heinonen, O. P., D. Slone, and S. Shapiro, "The Teratogenic Role of Drugs in Humans," *in* "Birth Defects and Drugs in Pregnancy," PSG Publishing Company, Littleton, MA, pp. 1–7, 1977.

3. Howard, F. M., and J. M. Hill, "Drugs in Pregnancy," *Obstetrical and Gynecological Survey*, 34:643–653, 1979.

4. Oakley, G. P., Jr., "Drug Influences on Malformations," *Clinics in Perinatology*, 6:403–414, 1979.

5. Shepard, T. H., "Teratogenicity of Therapeutic Agents," *Current Problems in Pediatrics*, 10:1–42, 1979.

6. Hays, D. P., "Teratogenesis: A review of the Basic Principles with a Discussion of Selected Agents: Part I," *Drug Intelligence and Clinical Pharmacy*, 15:562–566, 1981.

7. Hays, D. P., "Teratogenesis: A review of the Basic Principles with a Discussion of Selected Agents: Part II," *Drug Intelligence and Clinical Pharmacy*, 15:542–561, 1981.

8. Goldman, A. S., "Critical Periods of Prenatal Toxic Insults," *in* "Drug and Chemical Risks to the Fetus and Newborn," edited by R. H. Schwarz and S. J. Yaffe, Alan R. Liss, Inc., New York, pp. 9–31, 1980.

The agency invites comments on the preemptive effect the warning required by this proposal have on State OTC drug labeling requirements such as California's and those under consideration by other States. See *Jones* v. *Rath Packing Co.*, 430 U.S. 519 (1977). The Commissioner notes that the warning proposed in this notice is similar to the California warning and, therefore, might fall within the California law's exception for warnings that are "substantially similar." If the warning were determined to be "substantially similar," the question of preemption would not arise; manufacturers who used the warning required by this proposal would also be in compliance with the California law. However, one of the express purposes of the proposed regulation is to establish a national pregnancy/nursing warning requirement with a specified text. Thus, a State labeling requirement that specified wording for an OTC drug pregnancy/nursing warning that was different from the wording proposed here would prevent the accomplishment and execution of the full purpose and objectives of the agency in issuing the regulation. Therefore, in the opinion of FDA, such a State requirement would be preempted. *Jones* v. *Rath Packing Co.*, *supra* at 521.

The present proposal deals only with pregnancy/nursing warning requirements for OTC drugs. Accordingly, the proposal will affect only related or similar State requirements. FDA is aware, however, that there are a number of State requirements, either in force or pending before the State legislatures, relating to other aspects of OTC drug labeling. The agency believes that it has the authority to preempt State-imposed OTC drug labeling requirements regardless of whether it issues specific, conflicting labeling requirements of its own. See *Brookhaven Cable TV, Inc.* v. *Kelly*, 573 F. 2d 765 (2d Cir.), *cert. denied*, 441 U.S. 904 (1978). There is a substantial federal interest in having clear, unambiguous, and consistent information in the labeling of OTC drugs. FDA is concerned that a proliferation of State labeling requirements may weaken FDA's efforts to develop comprehensive national labeling requirements for OTC drugs. While the regulation proposed in this notice relates only to one labeling requirement, FDA in the future may consider whether State requirements should be generally preempted to preserve the integrity of FDA-mandated labeling requirements.

The agency believes that good cause exists for shortening the usual 60-day comment period provided in 21 CFR 10.40(b). The California requirement will take effect on November 18, 1982, unless preempted by FDA regulations. The 30-day comment period will give the agency additional time to analyze comments and to take appropriate action so as to minimize confusion concerning manufacturers' obligations under State and Federal law.

The agency proposes that any final rule that may issue based upon this proposal become effective 30 days following publication of the final rule. This early effective date will preempt any differing State requirements and will allow manufacturers first marketing in States with differing requirements to use only the new FDA labeling. The agency is aware that manufacturers may be revising their labeling in anticipation of the effective date of the California law, or for other reasons. Therefore, although the regulation will become effective 30 days after publication of the final rule, manufacturers will be permitted to defer labeling changes until present supplies of labels are exhausted, or until one year after publication of the final rule, whichever first occurs. Thereafter, covered OTC drugs initially introduced or initially delivered for introduction into interstate commerce would be required to comply with the new labeling requirements. The agency will consider requests for additional time to comply with the requirements based on a showing of good cause.

The agency has examined the regulatory impact and regulatory flexibility implications of the proposed regulation in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354). The proposed rule is estimated to generate one-time label modification costs of $3.8 to $5.7 million to marketers of systemically absorbed OTC drugs, and annual costs of $0.7 to $8 million for consultations between pregnant, and nursing women and health professionals. Thus, first year impacts of the label warning are expected to total $4.5 to $11.7 million. The net cost impact attributable to the proposed rule is less than this because, absent federal action, firms would have to comply with State requirements that would also produce both label modification and consultation costs. These costs are well below the thresholds for a major rule in Executive Order 12291.

Similarly, the costs incurred by small businesses are estimated to be insufficient to warrant a regulatory flexibility anlaysis. Label change costs will be dominated by private label (store brand) OTC drugs which FDA believes to be heavily marketed by larger firms.

FDA further believes that small marketers use relatively simple and inexpensive packaging and labeling. Hence, label change costs to small firms are not expected to be substantial. Costs for additional health care consultants will mainly affect small entities, but will be spread over so many of them, e.g., 47,000 drug stores and 24,000 obstetrician/gynecologist practices, that the average burden per entity appears trivial. Therefore, the agency certifies that the proposal, if adopted, would not have a significant economic impact on a substantial number of small entities. A copy of the threshold assessment for this proposed regulation is on file in the Dockets Management Branch (address above).

The agency has determined that under 21 CFR 25.24(d)(13) (proposed in the **Federal Register** of December 11, 1979; 44 FR 71742) this approval is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 330

OTC drugs.

PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(p), 502, 505, 701, 52 Stat. 1041–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321(p), 352, 355, 371)), under the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)), and under 21 CFR 5.11 as revised (see 47 FR 16010; April 14, 1982), it is proposed that Part 330 be amended by adding a new § 330.2, to read as follows:

§ 330.2 Pregnancy/nursing warning.

(a) The labels for all drugs that are systemically absorbed into the body contains a general warning as follows: "As with any drug, if you are pregnant or nursing a baby, seek professional advice before using this product."

(b) Where a specific warning relating to use during pregnancy or while nursing has been established for an ingredient listed in an OTC drug final monograph, the specific warning shall be used in place of the warning in paragraph (a) of this section.

(c) The food and Drug Administration will grant an exemption from § 330.2(a) where appropriate upon petition under the provisions of § 10.30. Exemption shall be maintained in a permanent file for public review by the Dockets Management Branch, Food and Drug Administration, Room 4–62, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

* * * * *

The agency has determined under § 10.40(d) (21 CFR 10.40(d)) that good cause exists for a comment period of 30 days rather than the usual 60 days. As discussed in this document, the State of California has adopted a labeling requirement and other States have legislative proposals under consideration. Therefore, it is incumbent on the agency to complete promptly this rulemaking to ensure an orderly and uniform labeling requirement, if deemed appropriate as a result of this rulemaking proceeding. Accordingly, a 30-day comment period is justified.

Interested persons may submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, by October 7, 1982. Three copies of all comments shall be submitted, except that individuals may submit single copies of comments. The comments are to be identified withe the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Arthur Hull Hayse, Jr.,

Commissioner of Food and Drugs.

Dated: August 12, 1982.

Richard S. Schweiker,

Secretary of Health and Human Services.

[FR Doc. 82-24452 Filed 9-3-82; 8:45 am]

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Federal Register

Vol. 47, No. 173

Tuesday, September 7, 1982

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Incorporation by reference	523-4534
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Federal Register

Corrections	523-5237
Daily Issue Unit	523-5237
General information, index, and finding aids	523-5227
Privacy Act	523-5237
Public Inspection Desk	523-5215
Scheduling of documents	523-3187

Laws

Indexes	523-5282
Law numbers and dates	523-5282 523-5266
Slip law orders (GPO)	275-3030

Presidential Documents

Executive orders and proclamations	523-5233
Public Papers of the President	523-5235
Weekly Compilation of Presidential Documents	523-5235

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FEDERAL REGISTER PAGES AND DATES, SEPTEMBER

38493-38672.....1
38673-38860.....2
38861-39126.....3
39127-39472.....7

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

Executive Orders:
April 19, 1912
(Amended by PLO 6315).....38891

7 CFR

301.....38861
910.....38862
946.....38493
967.....38494
1004.....38495
1076.....38863
1139.....38496
1701.....38864
1901.....39127
2700.....39128
2710.....39128

Proposed Rules:
278.....38905

8 CFR

332c.....38673
238.....38864

9 CFR

92.....38673
94.....38497

Proposed Rules:
74.....38704

10 CFR

10.....38675
11.....38675
25.....38675
95.....38675
460.....38498
461.....38500

12 CFR

201.....39129
309.....39130
545.....38865
618.....38865

Proposed Rules:
226.....38548

14 CFR

39.....38683, 39133-39136
71.....38684-38687, 39137-39141
73.....39142-39145
75.....38687
97.....39145
103.....38770
1201.....38867

Proposed Rules:
Ch. I.....38705
39.....39189
71.....38706, 39190

15 CFR

369.....38501

Proposed Rules:
922.....39191

17 CFR

200.....38505
211.....38868

18 CFR

4.....38506
141.....38869
157.....38871
271.....38877-38881
274.....38882
282.....38513

Proposed Rules:
271.....38906, 38907

21 CFR

14.....38883
74.....38883
81.....38883
82.....38883
177.....38884
203.....39147
314.....39155
433.....39155
510.....39155
809.....39155

Proposed Rules:
148.....38909, 38912
158.....38915
182.....38917
184.....38917, 39199
186.....39199
330.....39470
333.....38917, 39406, 39464
347.....39436
348.....39412
358.....39906, 39102, 39108, 39120

22 CFR

Proposed Rules:
11.....38548

26 CFR

1.....38514
5c.....38688
30.....38515
31.....38515

Proposed Rules:
1.....38918
31.....38552

27 CFR

9.....38516, 38519
19.....38521
240.....38521

245.....38521
270.....38521
285.....38521
Proposed Rules:
5.....38553
9.....38553

28 CFR

60.....39161

29 CFR

1601.....38885
1910.....39161
1852.....39164

30 CFR

935.....38886
Proposed Rules:
700.....39201
701.....39201
715.....39201
717.....39201
736.....39201
760.....39201
762.....39201
769.....39201
770.....39201
771.....39201
772.....39201
773.....39201
775.....39201
776.....39201
778.....39201
779.....39201
780.....39201
782.....39201
783.....39201
784.....39201
785.....39201
786.....39201
787.....39201
788.....39201
815.....39201
816.....39201
817.....39201
818.....39201
819.....39201
822.....39201
823.....39201
824.....39201
826.....39201
827.....39201
843.....39201
850.....39201
886.....38556
913.....38555
931.....38706
936.....38556

32 CFR

724.....39166
890.....38524
989.....38524
Proposed Rules
292a.....38921

33 CFR

320.....38530
321.....38530
322.....38530
323.....38530
324.....38530
325.....38530
326.....38530
327.....38530
328.....38530
329.....38530
330.....38530

37 CFR

2.....38693

40 CFR

52.....38531, 38532, 38886, 38887, 39167
61.....39168
81.....38888, 38890
180.....38533, 38534
410.....38810
716.....38780
763.....38535
Proposed Rules:
52.....39202, 39203
55.....38557
60.....38832, 39204, 39205
65.....38557
81.....38922
123.....38922
716.....38800

42 CFR

421.....38535

43 CFR

2800.....38804, 38806
5440.....38695
5450.....38695
5460.....38695
Proposed Rules:
3100.....38923
3110.....38923
3120.....38923
3130.....38923
Public Land Orders:
6315.....38891

44 CFR

64.....38891
65.....38893, 39179
67.....38894
70.....38894–38901
Proposed Rules:
67.....38923–38926

46 CFR

Proposed Rules:
Ch. I.....38707
32.....38707

47 CFR

73.....38902, 38903, 39185
Proposed Rules:
1.....38927
2.....38561
34.....38927
35.....38927
43.....38927
73.....38930–38937, 39207
74.....38561
76.....39207, 39212
94.....38561

49 CFR

179.....38697
213.....39398
571.....38698
1039.....38904
1057.....39185
1090.....38904
1300.....38904
Proposed Rules:
173.....38708
178.....38708
1102.....38946

50 CFR

17.....38540
611.....38543, 39186
652.....38544
661.....38545
Proposed Rules:
23.....39219
611.....38947
645.....38948
654.....39221

AGENCY PUBLICATION ON ASSIGNED DAYS OF THE WEEK

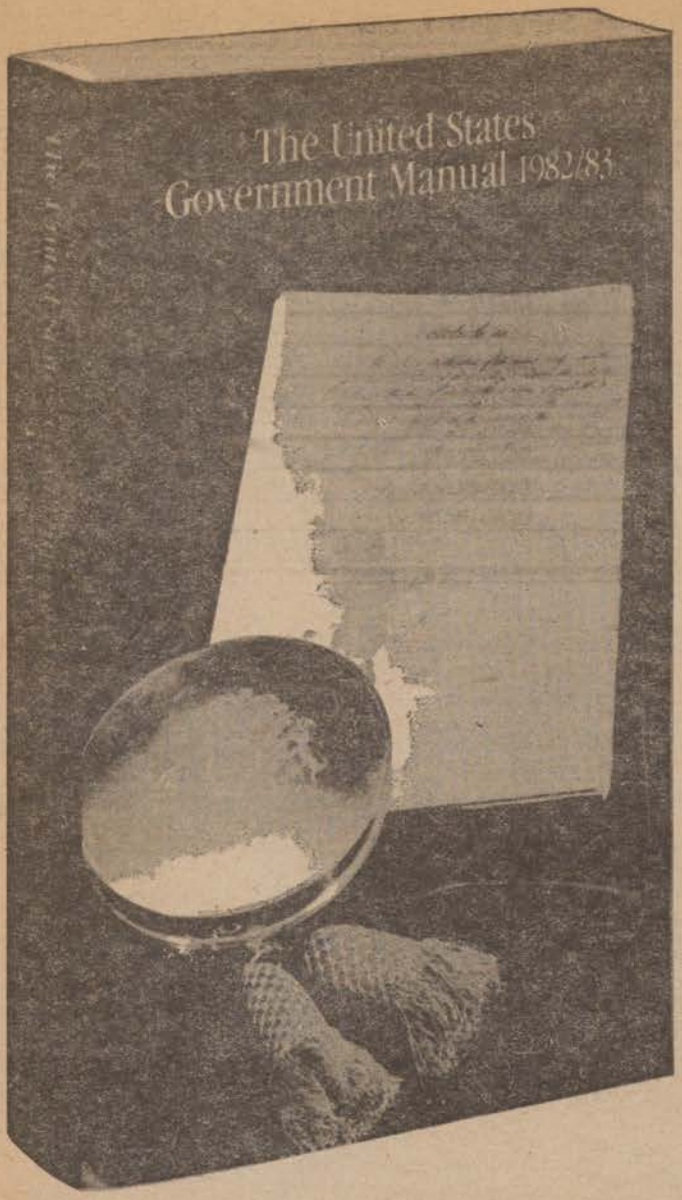
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Monday	Tuesday	Wednesday	Thursday	Friday
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DOT/FAA	USDA/REA		DOT/FAA	USDA/REA
DOT/FHWA	USDA/SCS		DOT/FHWA	USDA/SCS
DOT/FRA	MSPB/OPM		DOT/FRA	MSPB/OPM
DOT/MA	LABOR		DOT/MA	LABOR
DOT/NHTSA	HHS/FDA		DOT/NHTSA	HHS/FDA
DOT/RSPA			DOT/RSPA	
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List of Public Laws

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws.**

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