AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

Vol. 43—No. 229
11-28-78
PAGES
55333-55739

federal register

TUESDAY, NOVEMBER 28, 1978



highlights

SUNSHINE ACT MEETINGS 55559

See Table of Contents under specific agencies.

SOCIAL SECURITY

HEW/SSA adopts rules for adjudicating disability claims in which vocational factors must be considered; effective 2-26-79 55349

HEW/SSA issues rules on eligibility of individuals residing in publicly operated community residences for supplemental security income benefits; effective 11-28-78 55379

FOOD STAMP ACT OF 1977

USDA/FNS adopts rules on the Workfare Demonstration Project; effective 11-28-78 55334

VETERANS BENEFITS

VA proposes to amend regulations to increase the rate of disability compensation, comments by 12-28-78 55420

FARMER'S LOANS

USDA/FmHA amends regulations on guaranteed loans; effective 11-28-78 55345

FEDERAL SAVINGS AND LOAN INSURANCE CORPORATION

FHLBB proposes rules regarding forward commitments to purchase securities, comments by 1-15-79 55413

RUNAWAY YOUTH PROGRAM

HEW/HDSO issues regulations which will provide information necessary for grantees, potential grantees, runaways and their families; effective 11-28-78 (Part II of this issue) 55634

EDUCATIONAL INFORMATION CENTERS PROGRAM

HEW/OE establishes final rules to govern administration 55404

CANADIAN ALLOCATION PROGRAM

DOE/ERA proposes to make amendments reflective of current conditions in the Northern Tier petroleum supply situation; comments by 1-26-79; hearing 1-25-79; request to speak by 1-8-79 (Part IV of this issue) 55734

"OPERATION COMMON SENSE"

HEW/SSA proposes to revise the regulations on earnings records; comments by 1-29-79 55414

PESTICIDES

EPA establishes exemptions from the requirement of a tolerance for two new inert (or occasional active) ingredients in pesticide formulations and changes the use pattern of a third; effective 11-28-78 55403

CONTINUED INSIDE

AGENCY PUBLICATION ON ASSIGNED DAYS OF THE WEEK

The following agencies have agreed to publish all documents on two assigned days of the week (Monday/Thursday or Tuesday/Friday). This is a voluntary program. (See OFR notice 41 FR 32914, August 6, 1976.)

Monday	Tuesday	Wednesday	Thursday	Friday
DOT/COAST GUARD	USDA/ASCS		DOT/COAST GUARD	USDA/ASCS
DOT/NHTSA	USDA/APHIS		DOT/NHTSA	USDA/APHIS
DOT/FAA	USDA/FNS		DOT/FAA	USDA/FNS
DOT/OHMO	USDA/FSQS		DOT/OHMO	USDA/FSQS
DOT/OPSO	USDA/REA		DOT/OPSO	USDA/REA
CSA	CSC		CSA	CSC
	LABOR			LABOR
	HEW/FDA			HEW/FDA

Documents normally scheduled for publication on a day that will be a Federal holiday will be published the next work day following the holiday.

Comments on this program are still invited. Comments should be submitted to the Day-of-the-Week Program Coordinator, Office of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408

NOTE: As of August 14, 1978, Community Services Administration (CSA) documents are being assigned to the Monday/Thursday schedule.

federal register
Area Code 202 Phone 523-5240

Published daily, Monday through Friday (no publication on Saturdays, Sundays, or on official Federal holidays), by the Office of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408, under the Federal Register Act (49 Stat. 500, as amended; 44 U.S.C., Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). Distribution is made only by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

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

The FEDERAL REGISTER will be furnished by mail to subscribers, free of postage, for $5.00 per month or $50 per year, payable in advance. The charge for individual copies is 75 cents for each issue, or 75 cents for each group of pages as actually bound. Remit check or money order, made payable to the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

There are no restrictions on the republication of material appearing in the FEDERAL REGISTER.

INFORMATION AND ASSISTANCE

Questions and requests for specific information may be directed to the following numbers. General inquiries may be made by dialing **202-523-5240.**

FEDERAL REGISTER, Daily Issue:

Subscription orders (GPO)	**202**-783-3238
Subscription problems (GPO)	**202**-275-3050
"Dial - a - Reg" (recorded summary of highlighted documents appearing in next day's issue).	
Washington, D.C.	**202**-523-5022
Chicago, Ill	**312**-663-0884
Los Angeles, Calif	**213**-688-6694
Scheduling of documents for publication.	**202**-523-3187
Photo copies of documents appearing in the Federal Register.	523-5240
Corrections	523-5237
Public Inspection Desk	523-5215
Finding Aids	523-5227
Public Briefings: "How To Use the Federal Register."	523-5235
Code of Federal Regulations (CFR)	523-3419
	523-3517
Finding Aids	523-5227

PRESIDENTIAL PAPERS:

Executive Orders and Proclamations.	523-5233
Weekly Compilation of Presidential Documents.	523-5235
Public Papers of the Presidents	523-5235
Index	523-5235

PUBLIC LAWS:

Public Law dates and numbers	523-5266
	523-5282
Slip Laws	523-5266
	523-5282
U.S. Statutes at Large	523-5266
	523-5282
Index	523-5266
	523-5282
U.S. Government Manual	523-5230
Automation	523-3408
Special Projects	523-4534

HIGHLIGHTS—Continued

EPA establishes tolerances for residues of the fungicide thiabendazole on bananas from preharvest application; effective 11-28-78 ..... **55402**

ANTIBIOTIC DRUGS

HEW/FDA provides certification for natamycin; effective 11-28-78; comments by 1-29-79 ..... **55382**

ANIMAL DRUGS

HEW/FDA establishes promazine hydrochloride tablets as a safe and effective tranquilizer in dogs and cats; effective 11-28-78 ..... **55386**

HEW/FDA approves safe and effective use of caramiphen ethanedisulfonate and ammonium chloride tablets; effective 11-28-78 ..... **55385**

HEW/FDA approves safe and effective use of primidone tablets for treating convulsions; effective 11-28-78 ..... **55385**

HEW/FDA gives notice of withdrawing and withdraws approval of application providing for use of Boost-O-Iron (20 percent ferrous fumarate); effective 11-28-78 (2 documents) **55386**

COMBINATION DRUGS

HEW/FDA announces availability of guidelines on over-the-counter products **55466**

HUMAN DRUGS

HEW/FDA announces that tolbutamide is now eligible for abbreviated new drug applications; supplements to approved new drug applications by 1-29-79 ..... **55465**

MEDICAL DEVICES

HEW/FDA issues proposals on development of classification of neurological devices; comments by 1-29-79 (104 documents) (Part III of this issue) **55640**

CANCER TESTING

HEW/NIH gives notice of availability of bioassay reports on several chemicals for possible carcinogenicity (3 documents). **55467**

LASER PRODUCTS

HEW/FDA revises certain emission and labeling requirements of performance standard; effective 12-8-78; comments by 1-29-79 ..... **55387**

IMPROVING GOVERNMENT REGULATIONS

NASA describes procedures for developing new regulations; effective 11-28-78 ..... **55491**

INDUSTRYWIDE OCCUPATIONAL HEALTH RESEARCH STUDIES

HEW/PHS issues notice requesting information concerning certain substances and industries; information by 1-28-79 ..... **55469**

OLEORESINS FROM INDIA

Treasury/Customs issues notice of preliminary countervailing duty determination; effective 11-28-78 ..... **55512**

AMPICILLIN TRIHYDRATE FROM SPAIN

Treasury/Customs issues notice of preliminary countervailing duty determination; effective 11-28-78 ..... **55512**

TREASURY NOTICES—SERIES V-1980

Treasury announces interest rate of 9¼ percent **55513**

RADIATION THERAPY

NRC adopts rule requiring licensees to confirm the removal of implants at the end of treatment, effective 12-28-78 ..... **55346**

CERTAIN CIGARETTE HOLDERS

ITC holds hearing on 2-21-79 ..... **55472**

FOREIGN RELATIONS

State establishes regulations governing the acceptance of employment from foreign governments by members of the uniformed services; effective 11-28-78 55393

MEETINGS—

CRC: Regional Advisory Committees, 12-15-78 55435
Commerce/NOAA: Mid-Atlantic Fishery Management Council, 12-11-78 55436
USTS: Travel Advisory Board, 12-5-78 55436
DOD/Army: Army Science Board, 12-18 and 12-19-78 55436
DOE: National Petroleum Council, Coordinating Subcommittee and Task Groups of the Subcommittee on Petroleum Inventories and Storage and Transportation Capabilities, 11-28, 11-29, 12-4 and 12-12-78 55436
National Petroleum Council, Subcommittee on Petroleum Inventories and Storage and Transportation Capacities, 12-13-78 55449
FCC: Radio Technical Commission for Marine Services Executive Committee, 12-14-78 55462
GSA: Regional Public Adivsory Panel on Architectural and Engineering Services, 12-11 and 12-12-78 55464
HEW/ADAMHA: National Advisory Council on Drug Abuse, 1-25 and 1-26-79 55464
OE: Advisory Committee on Accreditation and Institutional Eligibility, 12-12, 12-13, 12-14 and 12-15-78 55467
National Advisory Council on Bilingual Education, 12-7 and 12-8-78, hearing 12-6-78 55469
National Advisory Council on Extension and Continuing Education, 12-13, 12-14 and 12-15-78 55468
Justice: United States Circuit Judge Nominating Commission, Third Circuit 55473
NSF: Advisory Committee for Materials Research, National Magnet Laboratory Visiting Subcommittee, 12-14 and 12-15-78 55493

CHANGED MEETINGS—

HEW/ADAMHA: Biological Sciences Training Review Committee, changed from 11-8-78 to 12-20 through 12-22-78 55464

SEPARATE PARTS OF THIS ISSUE

Part II, HEW/HDSO 55634
Part III, HEW/FDA 55640
Part IV, DOE/ERA 55734

reminders

(The items in this list were editorially compiled as an aid to FEDERAL REGISTER users. Inclusion or exclusion from this list has no legal significance. Since this list is intended as a reminder, it does not include effective dates that occur within 14 days of publication.)

Rules Going Into Effect Today

HEW/FDA—Repeal of identity standard for sour half-and-half dressing 44833; 9-29-78

List of Public Laws

All public laws from the second session of the 95th Congress have been received and assigned law numbers by the Office of the Federal Register. The last listing appeared in the issue of November 15, 1978.

A complete listing for the full session will be published on or before December 1, 1978.

contents

AGRICULTURE DEPARTMENT

See Commodity Credit Corporation; Farmers Home Administration; Food and Nutrition Service; Forest Service.

ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

Notices

Meetings:
- Advisory Committees; January 55464
- Biological Sciences Training Review Committee; date change 55464

ARMY DEPARTMENT

Notices

Meetings:
- Army Science Board 55436

CENTER FOR DISEASE CONTROL

See Disease Control Center.

CHILD, INTERAGENCY COMMITTEE FOR INTERNATIONAL YEAR OF

Notices

Child health record card; development of a portable cumulative 55470

CIVIL AERONAUTICS BOARD

Notices

Mail rates, domestic service priority and nonpriority 55430

CIVIL RIGHTS COMMISSION

Notices

Meetings, State advisory committees:
- Illinois et al 55435

CIVIL SERVICE COMMISSION

Rules

Excepted service:
- Franklin Delano Roosevelt and James Madison Memorial Commissions 55333
- Justice Department 55333
- Temporary boards and commissions 55333

Health benefits, Federal employees:
- Second review cycle and mini open season, elimination; correction 55333

COMMERCE DEPARTMENT

See Maritime Administration; National Bureau of Standards; National Oceanic and Atmospheric Administration; Patent and Trademark Office; Travel Service.

COMMODITY CREDIT CORPORATION

Notices

Meetings; Sunshine Act 55559

COMMODITY FUTURES TRADING COMMISSION

Rules

Investigation rules; authority delegations 55348

Notices

Meetings; Sunshine Act 55559

CONSUMER PRODUCTS SAFETY COMMISSION

Notices

Meetings; Sunshine Act (2 documents) 55559

CUSTOMS SERVICE

Notices

Countervailing duty petitions and preliminary determinations:
- Ampicillin trihydrate from Spain 55512
- Oleoresins from India 55512

DEFENSE DEPARTMENT

See also Army Department.

Rules

Removal of obsolete CFR parts 55334

DISEASE CONTROL CENTER

Notices

Occupational health research studies, 1979 FY; inquiry 55469

ECONOMIC REGULATORY ADMINISTRATION

Proposed Rules

Canadian crude oil, mandatory allocation:
- Northern tier shortages 55734

Notices

Powerplant and Industrial Fuel Use Act; early filing procedure 55449

EDUCATION OFFICE

Rules

Educational information centers program 55404

Notices

Meetings:
- Accreditation and Institutional Eligibility Advisory Committee 55467
- Bilingual Education National Advisory Council 55469
- Extension and Continuing Education National Advisory Council 55468

ENERGY DEPARTMENT

See also Economic Regulatory Administration; Energy Information Administration; Federal Energy Regulatory Commission; Hearings and Appeals Office, Energy Department.

Notices

Meetings:
- National Petroleum Council ... 55436

Meetings:
- Petroleum Inventories and Storage and Transportation Capacities Subcommittee, National Petroleum Council 55449

ENERGY INFORMATION ADMINISTRATION

Notices

Energy information reporting requirements; inventory 55437

ENVIRONMENTAL PROTECTION AGENCY

Rules

Pesticide chemicals in or on raw agricultural commodities; tolerances and exemptions, etc.:
- Inert ingredients 55403
- Thiabendazole 55402

Proposed Rules

Air quality implementation plans; delayed compliance orders:
- Illinois 55427
- Tennessee 55427

Notices

Pesticide applicator certification and interim certification; State plans:
- Wisconsin 55462

Pesticides; tolerances, registration, petitions, etc.:
- 5-Chloro-3-methyl-4-nitro-1*h*-pyrazole 55461
- Propylene 55462
- Sodium chlorate 55461

FARMERS HOME ADMINISTRATION

Rules

Guaranteed loan programs:
- Economic emergency loans 55345
- Full faith and credit provisions 55346

FEDERAL COMMUNICATIONS COMMISSION

Proposed Rules

FM broadcast stations; table of assignments:
- Virginia; extension of time 55428

Notices

Meetings:
- Radio Technical Commission for Marine Services 55462
- Sunshine Act (4 documents) .. 55560, 55561

FEDERAL DEPOSIT INSURANCE CORPORATION

Notices

Meetings; Sunshine Act (2 documents) 55561

FEDERAL ENERGY REGULATORY COMMISSION

Notices

Hearings, etc.:
- Sabine River Authority of Texas et al 55449

Meetings; Sunshine Act 55562

FEDERAL HOME LOAN BANK BOARD

Proposed Rules

Federal Savings and Loan Insurance Corporation:
- Forward commitments to purchase securities 55413

FEDERAL MARITIME COMMISSION

Notices

Agreements filed, etc 55463

Complaints filed:
- Allied Chemical International Corp. v. Farrell Lines, Inc ... 55463

FEDERAL RESERVE SYSTEM
Notices
Meetings; Sunshine Act 55562

FEDERAL TRADE COMMISSION
Rules
Prohibited trade practices:
Coventry Builders, Inc., et al.. 55347
Moore & Associates, Inc., et al 55348

FISH AND WILDLIFE SERVICE
Rules
Fishing:
Charles Sheldon Antelope Range, Nev., et al..... 55410
Colusa National Wildlife Refuge, Calif., et al 55411
Notices
Endangered and threatened species permits applications:
Ringling Bros.-Barnum & Bailey Combined Shows, Inc 55470

FOOD AND DRUG ADMINISTRATION
Rules
Animal drugs, feeds, and related products:
Caramiphen ethanedisulfonate and ammonium chloride tablets 55385
Ferrous fumarate..... 55386
Primidone tablets 55385
Promazine hydrochloride tablets..... 55386
Human drugs:
Natamycin 55382
Radiological health:
Laser products; performance standards; emission and labeling requirements 55387
Proposed Rules
Human drugs:
Over-the-counter drugs; emetic products; monograph establishment; correction 55417
Medical devices:
Neurological devices; classification (104 documents; *see* Preamble of first document for complete listing)..... 55640
Notices
Animal drugs, feeds, and related products:
Boost-O-Iron; approval withdrawn 55465
Human drugs:
Antacid products, over-the-counter; classification and labeling; correction..... 55464
Tolbutamide; efficacy study implementation..... 55465
Over-the-counter drug products, guidelines; availability.... 55466

FOOD AND NUTRITION SERVICE
Rules
Food stamp program:
Workfare demonstration project 55334

FOREST SERVICE
Notices
Environmental statements; availability, etc.:
Tongass National Forest, Ketchikan area timber sale, Alaska 55430

GENERAL SERVICES ADMINISTRATION
Rules
Property management, Federal:
ADP and telecommunications; standard terminology 55404
Notices
Authority delegations:
Defense Department Secretary..... 55464
Meetings:
Architectural and Engineering Services Regional Public Advisory Panel 55464
Procurement, Federal:
Furniture trade associations; discussion 55463

HEALTH, EDUCATION, AND WELFARE DEPARTMENT
See Alcohol, Drug Abuse, and Mental Health Administration; Disease Control Center; Education Office; Food and Drug Administration; Health Services Administration; Human Development Services Office; National Institutes of Health; Public Health Service; Social Security Administration.

HEALTH SERVICES ADMINISTRATION
Notices
Advisory committees; annual reports filed, availability 55466

HEARINGS AND APPEALS OFFICE, ENERGY DEPARTMENT
Notices
Applications for exception:
Cases filed (3 documents) 55450, 55458, 55460
Decisions and orders (4 documents)..... 55451, 55452, 55453, 55455
Home heating oil; allocation and pricing regulations; hearing procedure rules..... 55450

HERITAGE CONSERVATION AND RECREATION SERVICE
Notices
Historic Places National Register; additions, deletions, etc.:
California et al 55470

HISTORIC PRESERVATION, ADVISORY COUNCIL
Proposed Rules
Historic and cultural properties protection; briefing and extension of time 55417

HUMAN DEVELOPMENT SERVICES OFFICE
Rules
Runaway youth program..... 55634

INTERIOR DEPARTMENT
See also Fish and Wildlife Service; Heritage Conservation and Recreation Service.
Rules
Procurement; ocean transportation on privately owned U.S. flag vessels; correction 55404
Notices
Environmental statements; availability, etc.:
Alaska National Interest Lands 55471

INTERNATIONAL TRADE COMMISSION
Notices
Import investigations:
Cigarette holders 55472
Meetings; Sunshine Act 55562

INTERSTATE COMMERCE COMMISSION
Rules
Railroad car service orders; various companies:
Chicago & North Western Transportation Co..... 55409
Hillsdale County Railway Co., Inc 55409
Notices
Motor carrier, broker, water carrier, and freight forwarder applications 55540
Motor carriers:
Griffin Transportation, Inc.; temporary operating authority 55539
Permanent authority applications (2 documents 55513
Temporary authority applications (2 documents) ... 55540, 55550
Transfer proceedings (2 documents)..... 55540, 55555
Railroad car service orders; various companies:
Chicago, Milwaukee, St. Paul & Pacific Railroad Co..... 55557
Maryland & Pennsylvania Railroad Co 55557
St. Louis Southwestern Railway Co. et al 55557
Railroad operaton, acquistion, construction, etc.:
Atchison, Topeka & Santa Fe Railway Co 55556
Chicago, Milwaukee, St. Paul Pacific Railroad Co 55556

JUSTICE DEPARTMENT
See also Parole Commission.
Rules
Organization, functions, and authority delegations:
Land and Natural Resources Division; assignment of responsibility under the Surface Mining Control and Reclamation Act 55394
Assistant Attorney General, Administration; audiovisual activities 55395
Notices
Meetings:
Circuit Judge nominating Commission, U.S 55473

LABOR DEPARTMENT
See also Mine Safety and Health Administration.
Notices
Adjustment assistance:
Allstate Lawn Product, Inc 55476
American Pillow Co., Inc 55476
Andrex Industries Corp 55477
Brentwood Fabrics Corp 55490

Central Slipper Co. of New York, Inc 55477
Coblentz Bags Co 55478
Conval Penn, Inc 55481
Craig Byron Co 55478
David Hober and Co., Inc 55479
Dorel Group Co 55479
Duval Corp 55480
Erie Technological Products, Inc 55480
Flora Fashions, Inc 55481
GTE Sylvania, Inc 55482
Galeton Production Co 55482
Genesco Inc. (2 documents) ... 55483
Igualdad Tractor Shop 55483
Intercontinental Petroleum Corp., Inc 55483
J.P. Stevens Co 55484
Morris White Fashions 55484
Northern Ohio Sugar Co 55484
Progressive Uniform Manufacturing Corp 55485
Riddell, Inc. 55491
Rite Coat Inc 55486
Rosemer Manufacturing Co ... 55486
SKF Industries, Inc 55486
Sarajo Manufacturing Co 55487
SCM Corp 55477
Speed Tex Corp 55488
U.S. Steel Corp. (2 documents) 55488
Universal Data Services 55489
White Pine Copper Div 55489
Whitmo Handbags, Inc 55490

MARITIME ADMINISTRATION

Notices

Applications:
Great Lakes-Atlantic Steamship Co 55435

MINE SAFETY AND HEALTH ADMINISTRATION

Notices

Petitions for mandatory safety standard modification:
Bethlehem Mines Corp 55473
Consolidation Coal Co. (3 documents) 55474
Marrowbone Development Co 55475
Portland-Monson Slate Co 55475
Rio Algom Corp 55475
Rio Blanco Shale Co 55475
United Pocahontas Coal Co ... 55476

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

Notices

Improving Government regulations 55491

NATIONAL BUREAU OF STANDARDS

Notices

Information processing standards, Federal:
COBOL; interpretations; correction (2 documents) 55435

NATIONAL INSTITUTES OF HEALTH

Notices

Carcinogenisis bioassay reports; availability:
Parathion 55467
Phosphamidon 55467
Piperonyl butoxide 55467

NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION

Rules

Fishery conservation and management:
Atlantic groundfish; emergency regulations and correction of closure notice 55411

Notices

Meetings:
Mid-Atlantic Fishery Management Council 55436

NATIONAL SCIENCE FOUNDATION

Notices

Meetings:
Materials Research Advisory Committee, National Magnet Laboratory Visiting Subcommittee 55493

NUCLEAR REGULATORY COMMISSION

Rules

Byproduct material, human uses:
Radiation surveys and source count of therapy patients 55346

Notices

Applications, etc.:
Consumers Power Co. (2 documents) 55493
Edlow International et al 55494
Florida Power & Light Co 55494
Jersey Central Power & Light Co 55495
Midland Plant 55495
Tennessee Valley Authority ... 55496
Meetings; Sunshine Act 55563
Regulatory guides; issuance and availability 55495

PAROLE COMMISSION

Notices

Meetings; Sunshine Act 55563

PATENT AND TRADEMARK OFFICE

Rules

Trademark cases:
Forms 55395

Proposed Rules

Patent cases:
Forms and practice rules; application oath or declaration requirements 55417

POSTAL RATE COMMISSION

Notices

Meetings; Sunshine Act 55563

PUBLIC HEALTH SERVICE

Notices

Occupational Health Studies 55469

RAILROAD RETIREMENT BOARD

Notices

Meetings; Sunshine Act 55563
Supplemental annuity program; determination of quarterly rate of excise tax 55496

SECURITIES AND EXCHANGE COMMISSION

Notices

Hearings, etc.:
Appalachian Power Co. et al .. 55496
Bayrock Capital Series, Inc 55497
Boston Stock Exchange, Inc .. 55498
Columbia Gas System, Inc., et al 55498
Developing Growth Shares, Inc., et al 55499
General Public Utilities Corp 55501
Indiana & Michigan Electric Co 55502
Jet Capital Corp 55503
Kentucky Power Co 55505
Louisiana Power & Light Co .. 55506
Marathon Securities Corp 55507
Maryland Tax Exempt Trust Series 1 et al 55507
Merrill Lynch, Pierce, Fenner & Smith Inc. et al 55509

SOCIAL SECURITY ADMINISTRATION

Rules

Aged, blind, and disabled; supplemental security income for:
Eligibility; individuals in publicly operated community residences 55379
Old-age, survivors, and disability insurance, etc.:
Disability claims, vocational evaluation policy 55349

Proposed Rules

Old-age, survivors, and disability insurance:
Earnings records; correction procedures 55414

STATE DEPARTMENT

Rules

Employment, civilian; acceptance from foreign governments by members of uniformed services; procedures for approval 55393

TENNESSEE VALLEY AUTHORITY

Notices

Meetings; Sunshine Act 55563

TRAVEL SERVICE

Notices

Meetings:
Travel Advisory Board 55436

TREASURY DEPARTMENT

See also Customs Service.

Notices

Notes, Treasury:
V-1980 series 55513

VETERANS ADMINISTRATION

Proposed Rules

Adjudication; pensions, compensation, dependency, etc.:
Rate increase 55420

list of cfr parts affected in this issue

The following numerical guide is a list of the parts of each title of the Code of Federal Regulations affected by documents published in today's issue. A cumulative list of parts affected, covering the current month to date, follows beginning with the second issue of the month.

A Cumulative List of CFR Sections Affected is published separately at the end of each month. The guide lists the parts and sections affected by documents published since the revision date of each title.

5 CFR

213 (3 documents) 55333
890 55333
1601 55334
1602 55334

7 CFR

282 55334
1980 (2 documents) 55345, 55346

10 CFR

35 55346

PROPOSED RULES:

214 55734

12 CFR

PROPOSED RULES:

563 55413

16 CFR

13 (2 documents) 55347, 55348

17 CFR

11 55348

20 CFR

404 55349
416 ..... 55349, 55379

20 CFR—Continued

PROPOSED RULES:

404 55414

21 CFR

430 55382
436 55382
449 55384
520 (3 documents) 55385, 55386
558 55386
1040 55387

PROPOSED RULES:

337 55417
882 55640

22 CFR

3a 55393

28 CFR

0 (2 documents) 55394, 55395

36 CFR

PROPOSED RULES:

800 55417

37 CFR

4 55395

37 CFR—Continued

PROPOSED RULES:

1 ..... 55417, 55419
3 ..... 55417, 55419

38 CFR

PROPOSED RULES:

3 55420

40 CFR

180 (2 documents) 55402, 55403

PROPOSED RULES:

65 (2 documents) 55427

41 CFR

14–19 55404
101–36 55404

45 CFR

137 55404
1351 55414

47 CFR

PROPOSED RULES:

73 55428

49 CFR

1033 (2 documents) 55409

50 CFR

651 55411

CUMULATIVE LIST OF CFR PARTS AFFECTED DURING NOVEMBER

The following numerical guide is a list of parts of each title of the Code of Federal Regulations affected by documents published to date during November.

1 CFR

Ch. 1 50845
462 52457

3 CFR

EXECUTIVE ORDERS:

11157 (Amended by EO 12094) .. 51379
11562 (Amended by EO 12098) .. 53411
11846 (Amended by EO 12102) .. 54197
11945 (See EO 12098) 53411
12054 (Amended by EO 12090) .. 50997
12059 (Amended by EO 12097) .. 52455
12061 (Amended by EO 12091) .. 51373
12071 (Amended by EO 12100) .. 54193
12076 (Amended by EO 12099) .. 54191
12084 (Amended by EO 12097) .. 52455
12090 50997
12091 51373
12092 51375
12093 51377
12094 51379
12097 52455
12098 53411
12099 54191
12100 54193
12101 54195
12102 54197

MEMORANDUMS:

October 30, 1978 50995
November 22, 1978 55233

PROCLAMATIONS:

4608 53701

4 CFR

331 52693

5 CFR

213 ..... 51381–51383, 51753, 53703, 53704, 55333
300 51753
713 52694
890 ..... 52459, 52460, 55333
1601 55334
1602 55334

PROPOSED RULES:

334 53761

6 CFR

PROPOSED RULES:

705 51938

7 CFR

6 ..... 50999, 54900
26 52019
271 54199
273 54199
282 ..... 54215, 55334
331 54919
634 50845
722 54216
905 ..... 52197, 53027, 54217, 54617
906 ..... 50866, 51000
907 54618
910 ..... 52462, 53705, 54934
944 52197
946 52199
966 52199
971 53704

7 CFR—Continued

989 50866
1004 53413
1030 51383
1099 54920
1207 51000
1464 54218
1822 ..... 51385, 55235
1823 ..... 55236, 55237
1900 52462
1933 ..... 52462, 55237
1980 ..... 53413, 55345, 55346
2852 51753
2880 54921

PROPOSED RULES:

225 51806
273 54253
301 54936
401 52722
416 52723
651 53443
906 54254
917 52728
981 51405
1062 54642
1099 51405
1135 52496
1435 51026
1496 51406
1804 52496
1933 54652
2900 54938

8 CFR

103 55238
214 54618

9 CFR

73 52466
92 53706
97 ..... 52466, 53706
307 ..... 51386, 51754
350 51386
351 51386
354 51386
355 51386
362 51386
381 ..... 51386, 51754

10 CFR

Ch. II 53414
Ch. III 53414
20 ..... 52202, 54081
21 52202
35 55346
40 52202
51 53027
73 52202
205 51755
211 55322
300 51956
473 55228
515 54912

PROPOSED RULES:

40 54255
50 54255
70 54255
75 54255
150 54255
205 53256

10 CFR—Continued

PROPOSED RULES—Continued

211 ..... 52104, 52186, 54081, 54652
212 ..... 52186, 54256
214 55734
435 54512
500 53974
501 53974
502 53974
503 53974
505 53974
580 54660
1040 53658

12 CFR

201 ..... 50867, 53707, 53708
204 52202
205 53708
211 55238
226 ..... 52695, 52696, 54924
250 53414
262 52203
265 52203
329 54081
526 53415
545 ..... 53415, 54622
563 53415
564 53415
615 55239
701 54220

PROPOSED RULES:

Ch. V 54942
12 50917
208 50914
302 ..... 53042, 54665
344 51638
526 52254
545 52254
552 ..... 53762, 54664
563 55413
563b 54664
701 ..... 51407, 54100

13 CFR

107 54924
309 54924

PROPOSED RULES:

120 53765
308 52432

14 CFR

11 52203
23 52495
25 ..... 52495, 54082
39 ..... 51001, 51004, 52207–52213, 53415–53417, 54082
71 ..... 51005–51010, 53418, 53419, 54925
73 ..... 51010, 51011, 52214, 52467
75 51012
97 53419
121 52205
127 52206
133 52206
137 52206
139 52206
221 52697
241 53647
242 53649
249 53649
250 53028

14 CFR—Continued

291 53628
302 52021
384 54622
385 ..... 53649, 54623
1208 52214

PROPOSED RULES:

39 54100
47 54101
71 ..... 51026, 51029, 52496, 53446-53449, 54943
73 52496
75 51030
91 54101
213 54665
221 54102
298 52182
302 54102
380 53450
399 54102

15 CFR

16 51615
371 52215
376 52215
399 52215
806 54623

PROPOSED RULES:

15 53765
90 51806

16 CFR

2 51757
3 51757
13 ..... 51013, 52216, 52467, 55347, 55348
1202 53709
1701 53711

PROPOSED RULES:

Ch. II 54944
13 ..... 51031, 53450, 53767, 54944
433 54950
440 54103
447 54951
455 52729
460 51038
1205 51038

17 CFR

11 55348
32 ..... 52467, 54220
201 52216
211 ..... 50868, 52217, 54228, 55239
230 ..... 52022, 54229
231 ..... 52022, 53246
239 54229
241 ..... 52697, 53246
270 50869
271 52022

PROPOSED RULES:

1 53450
30 52729
230 ..... 53251, 55254
240 ..... 53251, 54256
250 53251
260 53251

18 CFR

1 52219

PROPOSED RULES:

Ch. I 55257
2 53270
154 53770
157 53270
270 53270

18 CFR—Continued

PROPOSED RULES—Continued

271 53270
273 53270
274 53270
275 53270
276 53270
284 53270
703 54262
707 54262

19 CFR

4 54234
153 ..... 52022, 55240
158 ..... 53713, 54925
159 ..... 52485, 53421-53425

PROPOSED RULES:

4 53453
6 53453
10 53453
11 53461
111 53461
123 53453
133 53461
148 53461
162 ..... 53453, 53461
171 53453

20 CFR

404 ..... 53713, 54083, 54087, 55349
416 ..... 54235, 55349, 55379

PROPOSED RULES:

404 ..... 51410, 52936, 54666, 55414
416 51410

21 CFR

5 51758
73 54235
81 ..... 54235, 54236
105 52690
155 54925
173 ..... 54237, 54926
177 54927
178 54927
184 54238
430 55382
436 55382
449 55384
520 ..... 52700, 55385, 55386
540 52700
558 ..... 52701, 53716, 54240, 55386
561 54088
809 52701
820 52701
1040 55387

PROPOSED RULES:

10 51966
12 51966
13 51966
14 51966
15 51966
16 ..... 51966, 52731
54 52731
71 52731
170 52731
171 52731
180 52731
310 ..... 52731, 52732
312 52731
314 52731
320 52731
330 52731
337 55417
350 51806
358 51546
361 52731

21 CFR—Continued

PROPOSED RULES—Continued

430 52731
431 52731
510 52731
511 52731
514 52731
570 52731
571 52731
601 52731
630 52731
882 55640
1003 52731
1010 52731

22 CFR

3a 55393
41 54928
42 51013

PROPOSED RULES:

51 51410

23 CFR

480 54074
635 53717

PROPOSED RULES:

170 51040
173 51040
420 51040
620 51040

24 CFR

1914 ..... 50874, 51013
1915 50879
1917 ..... 50879-50903, 51386, 51617-51628

PROPOSED RULES:

Ch.XX 54951
1917 51411-51427

25 CFR

20 52227
36 52023

PROPOSED RULES:

231 51806

26 CFR

1 ..... 51387, 54089
6 ..... 52027, 54090
54 53718
141 53718
601 53029

PROPOSED RULES:

1 ..... 50920, 51428, 52734, 53045, 54103, 54265
7 50920
55 54103

27 CFR

4 54264

PROPOSED RULES:

4 54266
5 54266
7 54266
194 51808
197 51808
201 51808
250 51808
251 51808
252 51808

28 CFR

0 ..... 54929, 55394, 55395
45 52702

28 CFR—Continued

PROPOSED RULES:

16 51816
301 52498

29 CFR

Ch. XVI 53426
1910 ..... 51760, 52952, 54354
1953 51761
1956 51389
2610 55240

PROPOSED RULES:

56 53771
1202 52032
1206 54267
1404 ..... 52500, 53466
1910 54955
2200 53774
2201 53774
2520 54268
2700 53045
2701 53470

30 CFR

41 51761
55 54065
56 54066
57 54067
75 54241
250 50903

PROPOSED RULES:

46 53774
715 ..... 50921, 52734
717 52734

31 CFR

129 51629
500 51763
515 51762

PROPOSED RULES:

500 53016
515 53021
520 53023

32 CFR

Ch. I 51391
361 52228
362 52230
832 ..... 51763, 51765
862 54625

PROPOSED RULES:

Ch. I 52032

33 CFR

1 54186
6 53427
117 ..... 52235, 54929
121 53427
125 53427
165 53427
223 52236

PROPOSED RULES:

117 ..... 53472, 54957
183 53471
207 53045
209 54269

36 CFR

PROPOSED RULES:

219 54958
800 55417

37 CFR

4 55395
201 54247
301 53719

PROPOSED RULES:

1 ..... 55417, 55419
3 ..... 55417, 55419

38 CFR

3 51015
21 52486
36 ..... 51015, 53728

PROPOSED RULES:

2 54104
3 55420
21 ..... 54104, 54666

39 CFR

111 ..... 51016, 51017
257 53428

40 CFR

52 ..... 51393, 51767–51780, 52029, 52237, 52239, 52702, 53031, 53035, 53439, 54247
55 54248
62 ..... 51393, 52241
65 ..... 51782, 51783, 52030, 52031, 52241, 52242, 52704–52706, 53037, 54273–54278, 54627
86 52914
162 52031
180 ..... 50904, 51018, 52486, 54090, 55402, 55403
600 52914
750 50905
762 55241

PROPOSED RULES:

52 ..... 51817, 52033, 52747, 53472, 54269
60 ..... 54959, 55258
65 ..... 50921, 51042, 52255, 52500, 52748–52753, 53473, 54273–54278, 55427
81 54960

41 CFR

Ch. 101 54632
1–1 53729
1–9 53440
3–1 54250
3–3 54250
5A–1 51395
5A–2 51396
5A–3 51397
5A–6 51398
5A–7 51398
5A–16 51398
5A–19 51398
5A–72 51399
5A–73 51399
5A–76 51399
5B–2 53440
5B–3 50907
14–19 55404
60–1 51400
60–2 51400
60–4 51401
60–30 51401
60–40 51401
60–50 51401

41 CFR—Continued

60–60 51401
60–250 51402
60–741 51402
101–36 55404

PROPOSED RULES:

Ch. I 52032
101–17 52502
101–26 51429
101–29 52503
101–38 51429
101–40 51817

42 CFR

50 52146
51b 52707
56a 51532
57 ..... 52487, 54929, 55242
71 53039
441 52071

PROPOSED RULES:

57 55261
405 ..... 51822, 52256
419 52256
456 50922

43 CFR

2650 55326

PROPOSED RULES:

2540 51043
2740 51043
9180 51043

45 CFR

46 ..... 51559, 53652
64 45933
95 53039
116d 52676
137 55404
205 52174
220 52174
222 52174
228 52174
282 53730
801 51784
1067 55247
1068 52438
1350 51785
1351 55414
1602 51785
1609 51788
1620 51789

PROPOSED RULES:

46 53950
114 51431
115 51431
139 53781
144 52128
160b 51431
160i 51432
161j 53046
169 51260
175 52128
176 52128
186 51432
187 51432
188 51432
205 54105
224 53778
1062 55263
1069 53474
1321 53782

46 CFR

197 53678
308 54090
390 51636

PROPOSED RULES:

Ch. IV 53046
25 52261
32 53474
34 52261
76 52261
95 52261
108 52261
151 53474
162 52261
181 52261
193 52261
276 51045
502 54960

47 CFR

Ch. II 53440
0 ..... 51791, 52243, 52244, 54096
1 ..... 53733, 54096
15 54097
21 ..... 52245, 52246
23 52245
25 52245
73 ..... 51790, 53733, 53742, 54097
74 51790
76 ..... 51791, 53742
78 52245
81 52246
83 ..... 51790, 52492
87 52245
89 54788
90 54788
91 ..... 51018, 53040, 54788
93 54788

47 CFR—Continued

PROPOSED RULES:

0 54106
1 53474
2 51649
5 54106
15 ..... 51650, 51652
21 54106
23 54106
25 54106
42 52263
43 52263
68 54666
73 ..... 51655, 53475, 54106, 54109, 54110, 54111, 54279, 55428
74 54106
78 54106
81 ..... 51047, 51048, 54106
87 54106
89 54106
91 54106
93 54106
94 54106
95 ..... 51048, 54106
97 ..... 51048, 54106
99 54106

48 CFR

PROPOSED RULES:

9 54962
28 51432

49 CFR

99 54251
106 51020
107 51020
171 51020
172 51020
173 51020
174 51020
175 51020
177 51020

49 CFR—Continued

178 51020
225 51020
395 52246
501 51022
571 ... 52246, 52493, 53440, 54933, 55248
1033 ..... 50907, 51023-51025, 51402, 54098, 55409
1034 51404
1056 51805
1100 50908
1331 55252

PROPOSED RULES:

195 52504
571 ..... 51657, 51677, 52264, 52268
572 53478
576 53479
1201 51052

50 CFR

32 51025
33 ..... 54098, 54639, 54933, 54934
222 54639
227 54639
611 ..... 51637, 52709, 54636
651 ..... 52252, 53040, 55411
652 ..... 54252, 54638
672 52709

PROPOSED RULES:

23 ..... 50928, 55314
26 54963
222 55267
226 55267
227 55267
260 53047
611 ..... 50928, 51053, 52034, 54964, 55268
671 52034

FEDERAL REGISTER PAGES AND DATES—NOVEMBER

Pages	*Date*	*Pages*	*Date*	*Pages*	*Date*
50845-50994	Nov. 1	52197-52454	9	54081-54189	20
50995-51372	2	52455-52692	13	54191-54716	21
51373-51594	3	52693-53025	14	54717-54918	22
51595-51751	6	53027-53410	15	54919-55232	24
51753-52017	7	53411-53699	16	55233-55331	27
52019-52196	8	53701-54079	17	55333-55739	28

rules and regulations

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.

[6325-01-M]

Title 5—Administrative Personnel

CHAPTER I—CIVIL SERVICE COMMISSION

PART 213—EXCEPTED SERVICE

Department of Justice

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: Position of Information Officer in the Immigration and Naturalization Service of the Department of Justice is no longer excepted under Schedule A because examination is practicable for this position.

EFFECTIVE DATE: October 28, 1978.

FOR FURTHER INFORMATION CONTACT:

James R. Edman, 202-632-4533.

Accordingly, 5 CFR 213.3110(b)(1) is revoked as set out below:

§ 213.3110 **Department of Justice**

* * * * *

(b) *Immigration and Naturalization Service.*

(1) [Revoked].

* * * * *

(5 U.S.C. 3301, 3302; E.O. 10577, 3 CFR 1954-1958 Comp., p. 218.)

UNITED STATES CIVIL SERVICE COMMISSION,
JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc. 78-33183 Filed 11-27-78; 8:45 am]

[6325-01-M]

PART 213—EXCEPTED SERVICE

Franklin Delano Roosevelt Memorial Commission and James Madison Memorial Commission

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: The amendment revokes the Schedule A authority for all positions on the staff of the Franklin Delano Roosevelt Memorial Commission because the authority is not being used and is no longer needed. This amendment also revokes the Schedule A authority for one executive secretary position in the James Madison Memorial Commission because that organization no longer exists.

EFFECTIVE DATE: October 24, 1978.

FOR FURTHER INFORMATION CONTACT:

James R. Edman, 202-632-4533.

Accordingly, 5 CFR 213.3158 and 5 CFR 213.3161 are revoked, as follows:

§ 213.3158 [Revoked]

§ 213.3161 [Revoked]

(5 U.S.C. 3301, 3302; E.O. 10577, 3 CFR 1954-1958 Comp., p. 218.)

UNITED STATES CIVIL SERVICE COMMISSION,
JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc. 78-33180 Filed 11-27-78; 8:45 am]

[6325-01-M]

PART 213—EXCEPTED SERVICE

Temporary Boards and Commissions

AGENCY: Civil Service Commission.

ACTION: Final Rule.

SUMMARY: This amendment revokes the Schedule A authority for the Micronesian Claims Commission because this organization no longer exists.

EFFECTIVE DATE: November 9, 1978.

FOR FURTHER INFORMATION CONTACT:

James R. Edman, 202-632-4533.

Accordingly, 5 CFR 213.3199(p) is revoked, as follows:

§ 213.3199 **Temporary boards and commissions.**

* * * * *

(p) [Revoked].

* * * * *

(5 U.S.C. 3301, 3302; E.O. 10577, 3 CFR 1954-1958 Comp., p. 218)

UNITED STATES CIVIL SERVICE COMMISSION,
JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc. 78-33186 Filed 11-27-78; 8:45 am]

[6325-01-M]

PART 890—FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM

Elimination of the Second Review Cycle and Mini Open Season

CORRECTION

AGENCY: Civil Service Commission.

ACTION: Correction to final rule.

SUMMARY: In the FEDERAL REGISTER of November 13, 1978 (43 FR 52460) the Commission published final rulemaking eliminating the second review cycle and mini open season for comprehensive medical plans desiring access to the Federal Employees Health Benefits Program. The effective date for the elimination of the second review cycle and mini open season is October 1, 1979. However, subparagrah 890.203(a)(2) which was added in this regulation pertains to a limited application opportunity for employee organization plans and is effective January 1, 1979.

DATES: Section 890.203(a)(2) is effective January 1, 1979.

FOR FURTHER INFORMATION CONTACT:

Craig Pettibone—202-632-4682, Office of Policy Development and Technical Services, Bureau of Retirement, Insurance and Occupational Health

UNITED STATES CIVIL SERVICE COMMISSION,
JAMES C. SPRY,
Executive Assistant to the Commissioners.

[FR Doc. 78-33254 Filed 11-27-78; 8:45 am]

[3810-70-M]

CHAPTER VI—DEPARTMENT OF DEFENSE

SUBCHAPTER A—OFFICE OF THE SECRETARY OF DEFENSE

PART 1601—SALARIES AND PERSONNEL PRACTICES APPLICABLE TO TEACHERS, CERTAIN SCHOOL OFFICERS, AND OTHER EMPLOYEES OF THE OVERSEAS DEPENDENTS' SCHOOLS OF THE DEPARTMENT OF DEFENSE

PART 1602—ABSENTEE VOTING

Deletion of Parts

AGENCY: Office of the Secretary of Defense.

ACTION: Deletion of Parts.

SUMMARY: The Office of the Secretary of Defense is reviewing its directives and instructions, including those published in the Code of Federal Regulations, as part of the effort to meet Presidential objectives to improve Government regulations. The review resulted in identifying in Title 5 CFR two parts, one of whose source document has been superseded (5 CFR Part 1601); and the other (5 CFR Part 1602) whose subject matter is duplicated in 32 CFR Part 46. Deleting these parts will eliminate obsolescence and duplication.

EFFECTIVE DATE: November 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. M. S. Healy, telephone 202-697-4111.

SUPPLEMENTARY INFORMATION: Using guidelines issued by the General Counsel, DoD, the Office of the Secretary of Defense has determined that Part 1601 does not have sufficient impact on the public to warrant publication in the FEDERAL REGISTER and the CFR. Regarding Part 1602, it is contemplated to update it, revising 32 CFR Part 46 appropriately.

Accordingly, 5 CFR Chapter VI is amended by revoking Parts 1601 and 1602.

MAURICE W. ROCHE,
Director, Correspondence and Directives, Washington Headquarters Services, Department of Defense.

NOVEMBER 22, 1978.

[FR Doc. 78-33276 Filed 11-27-78; 8:45 am]

[3410-30-M]

Title 7—Agriculture

CHAPTER II—FOOD AND NUTRITION SERVICE, DEPARTMENT OF AGRICULTURE

[Amendment No. 139]

PART 282—DEMONSTRATION, RESEARCH, AND EVALUATION PROJECTS

Food Stamp Program

AGENCY: Food and Nutrition Service, USDA.

ACTION: Final rules and Notice of Intent.

SUMMARY: On July 12, 1978, the Department published in the FEDERAL REGISTER proposed rulemaking and a Notice of Intent for the Food Stamp Workfare Demonstration Project which is mandated by Subsection 17(b)(2) of the Food Stamp Act of 1977. Under this project, food stamp work registrants will be required to perform work in a public service capacity in exchange for the coupon allotment to which their household is otherwise normally entitled. The Notice of Intent announces the intention of the Departments of agriculture and Labor to jointly conduct the project and further seeks proposals for project operation from eligible political subdivisions or groupings thereof wishing to take part in the project.

EFFECTIVE DATE: November 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Keith Spinner, Acting Division Director, Program Development Division, U.S. Department of Agriculture, Washington, D.C. 20250.

SUPPLEMENTARY INFORMATION: As a result of the proposed rule making, close to 100 comment letters were received. Based on these comments, the Department is hereby making some modifications in the final rule and Notice of Intent. Letters received are available for public inspection and copying during regular business hours in Room 672, 500 12th Street, SW., Washington, D.C.

Concept of workfare. About 50 individuals addressed the statutory requirement for project operations, some in support and others in opposition. Some commenters offered alternatives to the workfare concept. Adoption of these alternatives is not within the legislative authority of the Department. Conduct of the workfare demonstration project is mandated by the Act.

Project purpose. Approximately 10 individuals and groups requested clarification of the purpose of the project. The major concern expressed was the lack of criteria for determining "feasibility." Suggestions included adding criteria for determining the cost-effectiveness of administering workfare (the concern of one State welfare agency) and the benefits accruing to participants. In addition, it was recommended that ongoing reports be developed for monitoring project performance, and that an evaluation be done to determine "feasibility" and practicality of the workfare concept as applied to the Food Stamp Program. To determine the feasibility of this concept in Food Stamp Program administration, the Departments of Agriculture and Labor have established evaluative criteria by which such feasibility will be measured. The evaluation of the project will be performed by an independent contractor, and will run concurrently with the project. There will be a process evaluation, related to the operational features of the project, and an impact evaluation, to analyze the project's effect on participants and local labor markets. The impact evaluation will also include an analysis of the costs and benefits of the project to participants, site communities, and sponsors. A Request for Proposal (RFP) for the evaluation contract will be announced in *Commerce Business Daily* shortly after this rulemaking, and copies of the RFP will be available to the public on request as in all competitive contract proceedings.

Other recommendations included: not limiting workfare to public service; permitting volunteer service in a public or private agency; and revising the regulations to reflect how long the workfare project will last. The Act states that this project is to involve the performance of work in a public service capacity in return for food stamp benefits. Regulations clarify that such public service employment may be for either State and local public service agencies or, under specific conditions, for private nonprofit agencies. Actual project operations will commence in conjunction with the implementation of the benefit computation provisions of Pub. L. 95-113 and, with the extension provided by Pub. L. 95-400, will last approximately one year. The evaluation process will take place concurrently with project operations and then extend for six months beyond to allow for a complete impact analysis.

Limits on use of Federal funds. Approximately 30 persons commented on the lack of Federal funding. Of those commenting, over half were State and local agencies who believed that the Federal government should absorb

some or all of the cost of administering the project.

The legislative history clearly states (House Report No. 95-464, 95th Congress, 1st session, p. 370) that there will be no Food Stamp Program funds used in the administration of the project and that Food Stamp Program funding for project operations would be limited to the payment of the coupon allotment to which the household is normally entitled. The Solicitor of the Department of Labor has issued an opinion that funds available for the administration of public service employment through the Comprehensive Employment and Training Act of 1973, as amended, generally cannot legally be used for this project.

The final Notice of Intent clarifies that no Department of Agriculture funds may be used by the workfare sponsor for project operation. However, other funds which may have originated with the Federal Government (such as revenue sharing funds) may be used to defray the costs of administering workfare. In addition, the final Notice of Intent includes one significant provision omitted from the Notice published with the proposed regulations: Full Federal funding for sponsor costs incurred in connection with project evaluation. Since this issue was omitted from the proposed regulations, some commenters believed that the workfare sponsors would be required to fund evaluation costs in addition to costs of project operation. The final Notice distinguishes between sponsor costs in operating workfare and sponsor costs incurred in tasks necessary for the evaluation that are undertaken at the direction of the evaluation contractor. The contractor will request data compilations from the workfare sponsor's records on workfare participants and assignments, and may request some additional evaluation related activities from sponsors. Such compilations (and any other evaluation activities that the workfare sponsor agrees to undertake at the request of the contractor) are considered to be part of the evaluation and shall be performed entirely at the expense of the contractor, not at the expense of the sponsor. These compilations are not to be confused with the recordkeeping and administrative reporting requirements (such as reporting to the food stamp office that a participant has refused to comply with workfare) of normal day-to-day operations of workfare, which are to be conducted at the expense of the sponsor.

In addition to concern over Federal support for administrative costs, approximately 10 advocate groups and 3 State and local agencies expressed concern about participant's work-related expenses. They believed that either the sponsor or FNS should reimburse participants for project-related expenses, such as transportation costs, or that FNS should allow a deduction for work-related expenses. The Department is constrained by the Act from reimbursement of participants' expenses. Moreover, there is no provision which requires sponsors to pay any work-related costs incurred by project participants, and sponsors do not receive Federal administrative funding for this purpose. One organization suggested dealing with this issue by providing a 20 percent earned income deduction for work performed by a workfare participant. However, under Section 8 of the Act, food stamps are not considered earned income and do not qualify for such a deduction. Further, the application of such a deduction would result in an increase in the household's coupon allotment; thus increasing the workfare hour requirements and subsequently increasing the household's earned income deduction. The continuing application of such deductions with the consequent fluctuation in benefit levels would be impractical if not impossible.

A flat grant to participants to cover work-related expenses was also suggested. The Department of Agriculture has no fiscal authority to make such expenditures either from program or administrative funds. The Departments recognize that the lack of reimbursement for work-related expenses could cause hardships on project participants. Thus, in selecting among competing applications for project sponsorship, the Departments will consider the provision of transportation to work sites, and/or reimbursement for work-related expenses (although there is no requirement that a workfare sponsor provide such transportation or expenses). In addition, the Notice of Intent has been revised to instruct workfare sponsors to schedule, where possible, the work hours in blocks of time equivalent to an eight hour work day, so long as such scheduling does not conflict with other employment scheduled by the participant. Such action will provide controls over excessive participant transportation costs, and will also be less disruptive of normal job search activities.

Several commenters requested clarification concerning the employee benefits that are to be provided to workfare participants. The workfare sponsor will be required to make available to participants the same benefits made available to others similarly employed. Since workfare participants will generally be employed on a part-time basis, benefits accruing to similar part-time employees must be made available to workfare participants. For example, if it is customary for the sponsor to pay half of any medical insurance costs, the workfare participant must be given the option of such coverage. The participant would be free to refuse such coverage but would be equally free to pay his share from other available household funds at his or her option.

Criteria for participation. Approximately 10 individuals had questions concerning the identification of households and household members subject to participation in workfare. All such commenters recommended that the regulations clearly indicate who must participate in the project. It was suggested that the work registration exemptions be incorporated into the regulations so it will be evident who will be subject to the workfare provisions. The Act makes clear that only those households members subject to the full-time work requirements of Pub. L. 95-113 would be potentially subject to workfare if such household's non-excluded earned income does not exceed the value of the household's coupon allotment. The workfare requirements do not apply to households whose earned income exceeds the value of the coupon allotment or to household members who are exempted by law from work registration. Clarification of these issues has been added to the regulations.

Suggestions offered to improve the clarity of the language were: (1) to clearly indicate that only one household member who qualifies for work registration must participate in workfare; (2) to allow two household members to split the workfare hours; and (3) to add mechanics for designation of a second household member when the first household member fails to comply with the workfare provisions.

The final regulations clarify that if more than one member of a household is subject to the work registration requirement, the household shall designate which member will complete the workfare requirement and "work off" the household's food stamp allotment. The member designated by the household (referred to as the prime designee) may divide his or her work hours with another household member if this arrangement is acceptable to the workfare sponsor. However, in the event of split work, the prime designee remains principally responsible for completion of the workfare obligation. In the event that the household's full workfare obligation is not met, it shall always be the prime designee who is disqualified. Thus, if the second member does not fulfill his or her share of the work hours (and those hours are not completed by the prime designee either), the prime designee will be disqualified because the workfare requirement was not completed by the household.

The prime designee shall not be disqualified if the full workfare requirement is completed. Thus, if the prime designee and a second household member work out an arrangement with a sponsor whereby each will work 10 hours a week, the household will not be disqualified if one member works fewer than 10 hours but the other member arranges with the sponsor to make up the difference so that the full 20 hours of work are still performed.

The final regulations also clarify procedures to be followed when a household member is disqualified. If no other household member is registered for work (or if the household's reduced allotment during the month of disqualification does not exceed the household's earned income), the household does not have a workfare obligation during the month of disqualification. However, if there is another member subject to the work registration requirements, and the reduced allotment exceeds the household's earned income, this member shall be subject to the workfare requirements during the month that the initial household member is disqualified.

Federal minimum wage. Approximately 15 comment letters were received in opposition to limiting compensation for workfare employment to 100 percent of the Federal minimum wage. The most prevalent concern was that the use of the Federal minimum wage as the level of compensation may result in the depression of wages for similar jobs in the community. Other individuals believed this form of compensation to be an exploitation of workfare participants who perhaps could receive higher pay. Suggested alternatives included either the use of the prevailing wage for similar jobs, or the use of the Federal minimum wage if there are no similar jobs in the community. Use of the Federal minimum wage is mandated by the Act. Workfare jobs will be designed as entry level positions and are intended to increase work opportunities in the community by supplementing existing employment. Workfare sponsors will be prohibited from using workfare jobs to replace existing jobs or to displace employed workers. The evaluation of the project will analyze the impact of workfare employment on the labor market and the wage structure of similar jobs which exist in the community.

Relationship of workfare to CETA public service employment. Nearly twenty individuals and groups commented on the Department's interpretation of the Act which states that no workfare job offer is to be made until all public service jobs supported under the Comprehensive Employment and Training Act of 1973 (CETA), as amended, are filled. The legislative history (see H.R. 95-464, 95th Congress, 1st Session, p. 371) emphasizes that the purpose of this provision is to assure that workfare jobs supplement, rather than supplant, other job programs. In order to ensure the continuing operation of the workfare project, and to provide maximum validity to project results, while at the same time carrying out the intent of Congress that workfare employment supplement and not supplant other job programs, the Department proposed that a workfare job could only be offered if the CETA sponsor is making every effort to fill all available public service job openings and the potential workfare participant is found to be unqualified for available CETA job slots. This caveat on the offer of workfare employment, taken in conjunction with the requirement contained in the Notice of Intent that the workfare sponsor be located where a CETA prime sponsor is basically fulfilling its public service employment hiring schedule, was intended to insure increased job availability. Of those who commented, only two program administrators favored the Department's proposal. Numerous recipients, advocates and legal services organizations objected to the Department's interpretation of the law. They argued that the legislation requires that every CETA slot be filled before a workfare sponsor could make any offer of workfare employment. A few individuals requested clarification of the phrase "every effort" as used in § 282.10(d)(1)(iv): "* * * the CETA sponsor is making every effort to fill all available openings." The American Federation of State, County and Municipal Employees (AFSCME) suggested that the prime sponsor report weekly to the Regional Office of the Department of Labor so that compliance can be monitored.

The Department has deleted the language related to "making every effort to fill" since such a determination would be difficult, if not impossible, to make. The proposed regulations and Notice of Intent have been revised to a degree to ensure that Congressional intent in expanding employment opportunities is met. A workfare job will not be offered unless it is determined that: the CETA prime sponsor is basically fulfilling its public service employment hiring schedule (i.e., openings which exist are due to normal attrition or the unavailability of qualified technical personnel); and the potential workfare participant is not found qualified for available CETA openings, or, available CETA openings for which the participant is qualified are refused by the participant for good cause. The Department would like to point out that a workfare participant may initially be found unqualified for CETA openings, but later be found qualified for a CETA job that subsequently becomes available. The determination regarding whether a workfare job may be offered to a particular participant may need to be reassessed if new CETA jobs become available after the participant has begun workfare activity. CETA prime sponsor activities will be monitored to ensure: (1) the continued basic fulfillment of the CETA public service employment hiring schedule; and (2) the validity of determinations made regarding potential workfare participants' qualifications for available CETA public service employment slots.

Relationship of workfare to job search. Approximately twenty individuals addressed this subject. Of the comments received, nearly all were negative and over half represented the comments of organizations representing the interests of participants. Opposition centered, to varying degrees, around the rule which requires workfare participants to engage in job search unless they are working an average of at least 30 hours per week (workfare plus other employment). Suggested alternatives included exempting all workfare participants from the job search requirement or modifying the average number of work hours per week which would exempt a participant from job search. One individual suggested the number of hours be set at 20, while another believed it would be more effective to establish a maximum limit of 25 hours per week. The Department established the average 30-hour work week exemption from job search taking into consideration various factors. First, persons working less than 30 hours a week are subject to the food stamp work registration requirement. This level of effort in terms of work hours has been logically extended to workfare for the purposes of the job search exemption. Total exemption from the job search requirements due to workfare employment, as suggested by some comments, has not been incorporated into these rules. Most workfare participants will be employed by a workfare sponsor for less than half-time and will still have time to engage in job search.

Another area of concern to two individuals was the length of time required to find a job in the private or public sector before the workfare requirement becomes effective. Both individuals believed 30 days was not enough time to find a job and one of the individuals recommended this time period be increased to 90 days. The Act prescribes the 30-day interval between initial work registration and potential workfare participation, so no change has been made.

Training/meaningful employment. Approximately twenty individuals and groups commented on this subject. Most of those commenting were State and local program administrators and advocate groups who believed that it is questionable whether career development can take place as a result of workfare. According to a few of these individuals, workfare fails to provide "real" jobs, teach marketable skills, provide training to all participants, or provide incentives for good work performance. One program administrator questioned how opportunities for promotion would be handled when the workfare provisions are implemented. It was suggested that built-in incentives be added to the workfare provision to encourage upward mobility. One incentive mentioned was "preferential hiring" of qualified workfare participants for salaried positions when they become available at the job site. The Department does not believe a Federal requirement for preferential hiring is appropriate or authorized under the Act. However, the Department will consider the training and developmental aspects of proposed workfare operations in making selections for project sponsorship. The evaluation will examine the impact of workfare on future employment.

Other individuals questioned how meaningful such short-term jobs could be and recommended that final regulations set a minimum number of participant work hours, with participants excused from workfare if their obligation was less than the minimum number of hours. On the other hand, some individuals questioned whether households participating in workfare would have enough time or resources left over for real job search, and suggested that the maximum work week limit be set at less than the forty hours established in the proposed regulations.

The Act is explicit in both establishing 40 hours a week as the maximum workfare obligation and in providing that the hours to be worked shall be determined with reference to the household's coupon allotment. Thus, there is no authority under the legislation for altering the maximum 40-hour limit or setting a minimum number of participant work hours.

Disqualification. Approximately 30 individuals or groups commented on the disqualification procedures established in the proposed regulations. The large majority opposed some aspect of these procedures.

Five advocacy groups indicated their opposition to the withholding of food stamp benefits for noncompliance and requested that this penalty be deleted from the final regulations. The requirement regarding disqualification in instances of refusal is specifically mandated by the statute. Other commenters suggested that noncompletion of workfare requirements not be classified as a refusal to meet workfare obligations. Other than minor modifications in language for the purpose of clarity, the original definition of refusal has been retained since the Department believes that it was Congressional intent to apply the disqualification penalty to all persons refusing to comply with the workfare requirement.

Of concern to seven advocate groups and three State and local agencies was the definition of "good cause." The majority of these individuals recommended that the definition be clarified by including additional examples of circumstances beyond the member's control, such as lack of suitable child care, lack of transportation (including public transportation) or refusal of the sponsor to pay transportation costs, and discrimination in employment. One State agency recommended that this section be revised to require that "good cause" not cover those instances where public transportation is available but the participant refuses to use it. Another area of concern to some of these commenters was the impact this compliance requirement could have on migrant farmworkers. It was suggested that the Department add to the definition of "good cause," "households moving to seek more gainful employment" in order that migrant farmworkers not be disqualified because they move to find agricultural labor elsewhere. The Department has clarified the "good cause" definition section of the regulations to clarify what is and what is not an example of "good cause." The Department never intended that a participant's refusal to use available public transportation be considered as "good cause," and has made this clear. A grievance procedure related to both workfare sponsor employment practices and alleged violations of project requirements has been added.

Comments were also received on the proposed one-month period for disqualification should the workfare member refuse to comply with program requirements. One individual supported this provision as written. One individual supported the right of clients to receive benefits when a hearing is requested. Approximately 10 others, however, expressed concerns regarding these proposed procedures. One program administrator requested that the regulations clarify whether or not a workfare participant may be disqualified more than once, and, whether the fair hearing procedures afford the participant protection from disqualification for further instances of noncompliance during the period of advance notice or pending the outcome of the hearing. In response to these comments, the regulatory language has been clarified. Refusal either to accept workfare employment, to report for job scheduling, or to complete the entire work hour requirement will result in disqualification for a one-month period. Subsequent refusals to comply with the workfare requirement in another month will result in another one-month disqualification. Disqualification will not take effect until after a fair hearing decision is reached, if such a hearing has been requested. Until the fair hearing decision is reached the household member may continue to be offered appropriate workfare employment. For each month of refusal without good cause, a penalty of a one-month disqualification will be assessed against the noncompliant member. Any disqualification will be effective during the month following expiration of the notice of adverse action, or, the month following a negative fair hearing decision.

One objection to the one-month disqualification period came from a lawyer involved in litigation of joint Department of Health, Education, and Welfare and the Department of Labor regulations on the WIN Program. He believed that the proposed one-month disqualification was arbitrary and capricious, citing the *McLean vs. Matthews* case on a disqualification issue which was decided in favor of the client. The *McLean vs. Matthews* litigation dealt with statutory language providing for disqualification ". . . if and for so long as" an individual refused employment (42 U.S.C. § 602(a)(19)(f)) while subsection 17(b)(2) of the Food Stamp Act requires a disqualification for one month when the individual refuses workfare employment. Since workfare legislation provides that the disqualification period shall be for one month, the proposed regulations seem neither arbitrary nor capricious on this point. One program administrator contended that the Departments had deviated from the language of the Act which states that a household member is ineligible *during* the month in which he or she refuses to comply with workfare requirements. This individual objected to the Department's proposal to disqualify the noncomplying household member in a month following the actual month of refusal. The proposed procedures have been retained for the same reasons discussed in the supplementary information to the proposed regulations. First, it would be administratively impossible to take action during the month of refusal since in virtually all instances the household would have already received its allotment by the time refusal takes place. Second, the proposed procedure com-

plies with constitutional requirements concerning due process under law by allowing time to notify the participant of the adverse action to be taken, and by allowing time for a participant to exercise his or her right to appeal the decision through the food stamp fair hearing process.

Approximately 10 comments were received on the Department's proposed procedures for determining a household's food stamp entitlement in those instances where a household member has been disqualified but has partially completed the assigned hours of work (§ 282.10(f)(3)). Most of the comments received were from State and local agencies who indicated that the calculations to be made are too complicated. This section has been reworded for clarity. Language has been added related to calculating the income and resources of the remaining household members during the month of disqualification of the noncompliant workfare participant.

Language clarification. More than 10 individuals and groups offered suggestions relative to language clarification, miscellaneous corrections and/or editing needed in the proposed regulations.

Most of these suggestions were made by FNS Regional Offices and State and local welfare agencies. Clarification on a number of points has been supplied.

One issue on which clarification was sought was on how to detemine what month's allotment the participant is working off if he/she has been waiting several months for a workfare assignment. The month's allotment used for workfare will always be the current month. Language has been added to the regulations to clarify that uncompleted work hours will not be carried forward from one month to another. Failure on the part of the sponsor to provide a work assignment or to schedule sufficient work to complete the required number of hours within the month will not subject the workfare participant to a penalty, or to an increase in the required number of work hours in a subsequent month.

Clarification was also sought regarding the phrase "initial registration" for work, and, what procedures to follow when a person's work registration status changes. Section 273.7(a) defines initial registration for work as the completion of the work regislation form during the food stamp application process. During the initial phases of project operations, household members may be immediately subject to workfare participation if an existing food stamp work registration has not lapsed or has simply been renewed. In addition, the final regulations note that if a household member registered for work should become exempt due to employment or other circumstances, and then later should become subject to work registration again, the 30-day waiting period would begin at the time that subsequent work registration takes place.

Public review of proposals and comment on project sites. More than 10 persons, mostly advocates, commented on the need for broader review of project proposals. Only one State commented and this was on the need for clarification and research on labor contract issues. The major comment was that parties other than labor organizations, such as community action and advocacy groups, should be able to comment on workfare proposals. Some comments suggested that no parties should have this right to comment and that the proposed regulations affording this right to labor organizations should be deleted. Other persons recommended that the "local" public in proposed workfare pilot project sites be invited to comment since workfare could affect them directly. Publication of notices in newspapers, creation of citizen advisory boards, and public hearings were among the methods most often recommended to accomplish the objective.

The Act, in citing CETA legislation, specified that labor organizations must be given the opportunity to comment on proposals for workfare sponsorship before the proposals are submitted. No other group is mentioned in either the Act, legislative history or pertinent CETA legislation. Due to the pilot project character of workfare, the Department does not believe requirements for other groups to comment on proposals are necessary.

Site and sponsor selection. Approximately 10 individuals commented on the criteria for workfare site and sponsor selection. Most of these comments came from advocate groups. Several individuals requested clarification of "sufficient number and variety of public service jobs" as a criterion for site selection. In addition, one commenter was opposed to the selection of project sites with heavy concentrations of seasonal workers, and one was opposed to the selection of sponsors in States with more than 6 percent unemployment. The major recommendation was that the criteria for sponsor selection be strengthened by making the likelihood of permanent work resulting from workfare a factor to be used in evaluating applications. Another recommendation was that preference be given to sponsors who are willing to supplement the hours of work and/or the expenses of the participants.

The Department has added to Part G of the Notice of Intent additional critieria by which applications will be ranked. As previously mentioned, location with a CETA prime sponsor who is basically fulfilling its public service employment hiring schedule or location in an area not served by CETA is mandatory. The additional, nonmandatory selection criteria include the extent to which a sponsor provides for: (1) transportation of workfare participants or reimbursement of work-related travel expenses; (2) payment of other work-related expenses; (3) training and skill development; (4) permanent employment resulting from the workfare assignments; and (5) supplementation of the hours required under workfare with additional hours of paid employment. The failure of a potential sponsor to make positive proposals with regard to one or more of these criteria will not preclude the potential sponsor from consideration or selection. The ability of the applicant sponsor to develop jobs for all or most of the potential participants will be weighed during selection. Suggested selection criteria which would delete from consideration sites with particular labor or racial or ethnic minority characteristics have not been adopted. Given the existence of such characteristics in various locations throughout the country, their categorical exclusion as demonstration projects sites would restrict the validity of project findings. Demographic and economic characteristics will be considered in project evaluation.

Administrative requirements. Approximately twenty individuals and groups commented on the administrative requirements established in the proposed regulations and Notice of Intent. Of particular interest were the comments received from the National Association of Counties which surveyed both rural and urban counties. Some urban counties believed a workfare program would not be administratively feasible. They were principally concerned about the problems involved in monitoring and supervising participants who will work only an average of 2 to 5 days per month. Rural counties had different concerns. One rural county analyzed its food stamp rolls and found that only a very small number of participants would be subject to workfare. Transportation in rural areas was presented as a problem, as was finding jobs suitable for participants.

The administrative feasibility of the workfare concept from the sponsor's point of view will be evaluated in detail. The process evaluation phase, running concurrently with project operations, calls for documentation by the contractor of the operational design established by each workfare sponsor. Administrative procedures and changes made thereto during the demonstration project year are to be recorded and evaluated by the con-

tractor for their impact on successful or unsuccessful project operations. The 14 demonstration projects will provide a mix of administrative designs, including representation of urban and rural sites. The contractor's final report will include findings on the administrative components of workfare not only for the sponsors, but also for State welfare agencies and other cooperating agencies and employers.

A few commenters believed that the recordkeeping requirements contained in the proposed workfare regulations were too minimal to evaluate the project effectively. Suggestions offered for additional reporting included: (1) reports and evaluations which provide information on the administrative feasibility and practicality of the project; (2) records indicating the number and percentages of workfare participants obtaining permanent employment as a direct or indirect result of workfare placements; and (3) a cost/benefit analysis showing any reductions in benefits or caseloads resulting from salaried employment obtained as a result of workfare, and comparing these reductions to the additional costs involved in administering workfare projects. One individual recommended that the regulations impose a definite time limit for submittal of the monthly report and suggested 10 days following the end of the report month as an appropriate time limit. Two State agencies objected to the additional reports the workfare regulations would generate. One State recommended that statistics not be collected and reported unless they are absolutely necessary, that report formats be simple and instructions easy to understand, that deadlines be reasonable, and that agencies not be held accountable for errors caused by untimely or inaccurate reporting by workfare sponsors.

Most of the data collection will take place as part of the evaluation contract. The evaluation will include analysis of the three areas listed above. Submission of monthly reports will be required by the 15th day following the end of the report month. State agencies will be required to exclude errors resulting from workfare requirements from State Quality Control error rates, according to new language added to § 282.10(g).

Two State agencies were concerned that sufficient time be provided to select sites, plan, and implement workfare. One State agency felt that the 30-day timeframe for submitting sponsor applications was inadequate because of the approvals and coordination necessary between the various agencies required to run the program. The final Notice of Intent provides that project operations will begin at the same time as implementation of the benefit computation provisions of the Food Stamp Act of 1977. The Notice of Intent has been changed to give potential sponsors 45 days for formal proposal submission in recognition of the number of agencies involved in approvals and clearances.

Clarification was also sought concerning timeliness standards for the exchange of information between State agencies and workfare sponsors. Procedures will be developed by the Departments with sponsors and State welfare agencies to ensure timely submission and processing of reports on workfare participation. The sponsor will report noncompliance to the State agency as it occurs. Changes in a household's allotment or earnings that affect the number of hours to be worked, or affect a participant's workfare status, will be reported as soon as they are known.

Some commenters stated that some of the responsibilities they thought had been assigned to State agencies would be more appropriately assigned to Employment Service Offices. These include employment screening and placement mechanics and determinations of whether a specific job is suitable for a participant. In addition, the recommendation was made that participants unable to obtain a job after 30 days be referred to a workfare project by the local Employment Service Office rather than the State agency which is not otherwise involved. For the purpose of this demonstration project, these responsibilities have been assigned not to the State agency, but to the workfare sponsor. The State welfare agency's role is to maintain the food stamp case status current under the additional requirements of workfare. Referral activities, other than those for work registration, are limited to referral of the household's eligible workfare participant to the sponsor. The responsibility has been given to the sponsor to contact the potentially eligible workfare participant after 30 days from initial registration to verify whether or not the work registrant has obtained employment, whether CETA employment has been sought, and whether the participant will be available for workfare scheduling. Employment screening will be performed by the sponsor or his designee, who will, to the extent possible, match participants with jobs by skills and experience. If an individual contests the suitability of the job to which he or she is assigned and alleges "good cause" for refusal to comply with the workfare requirements, then the sponsor's responsibility is to report the refusal to the State welfare agency for final determination. Whether or not there is "good cause" is a determination to be made by the State agency. Where "good cause" is established, no disqualification will result. The participant will remain subject to workfare and available for scheduling for another job. The Department has added new language under § 282.10(g) to incorporate into State welfare agency responsibilities the obligation to report to DOL/USDA any alleged or actual sponsor violations of the requirements of this project.

Commenters pointed out that no provision has been made for the months in which the number of workfare jobs is less than the number of participants eligible for workfare. One State agency recommended that each participant have an equal opportunity to be chosen for work. The Department recognizes that a workfare sponsor may not be able to find slots for all persons potentially subject to workfare. Therefore, the regulations clarify that a participant shall not be disqualified if he or she receives no job offer from the sponsor. The workfare sponsor is responsible for providing jobs and filling them according to the assurances made in response to the Notice of Intent, including giving special consideration to those persons who have been unemployed the longest and to those who have the least prospect of finding employment without assistance. These situations will be evaluated and the Departments will take prompt action on any complaints of discrimination in job placement or scheduling of work hours. A suggestion was made that the concept of rescheduling not be addressed because of the amount of paperwork involved. However, every opportunity must be provided for fulfillment of the workfare obligation.

Compliance monitoring and evaluation. A need for strong enforcement of labor standards laws and project requirements, through complaint and hearing procedures, was expressed by several groups. One suggestion involved establishing a complaint procedure through DOL's regional offices. An appeal procedure was also recommended for participants who questioned their inclusion in a workfare project, their ability to perform assigned work, or the suitability of the work assigned. In addition, three advocate groups voiced the need for a monitoring system to assure compliance with the workfare regulations and to guard against potential sponsor abuses. Advocate groups also expressed the need for a fiscal penalty to deter workfare sponsors from displacing regular employees with workfare employees.

The Departments of Agriculture and Labor are developing a monitoring system to ensure sponsor compliance with appropriate provisions of the

CETA Act, these regulations, and the Notice of Intent, and a grievance system for workfare participants, labor organizations, and other groups alleging sponsor violation of the requirements of the regulations and Notice of Intent or discrimination in employment practices. A new section has been added to the regulations at § 282.10(h) on compliance monitoring and grievance procedures and a similar section added to the Notice of Intent. The regulations oblige State agencies and workfare sponsors to cooperate with the Departments by making participants aware of their rights to appeal noncompliance of workfare requirements on grounds of alleged violations of the regulations and Notice of Intent through both the fair hearing process and by referring such grievances to DOL/USDA for investigation. Guarantees similar to those stipulated in the CETA regulations, § 96.24(d), which prohibit hiring of participants when any other employee is on layoff from the same or any substantially equivalent job, and § 96.24(g), which prohibits participants from working in any position substantially equivalent to a position which is vacant due to a hiring freeze, were also recommended. These guarantees have been incorporated into the Notice of Intent as assurances to be provided by a the workfare sponsor to the Departments as a condition of participation. Compliance with these assurances will be monitored by the Departments who have agreed to designate staff to perform this function as well as to ensure that individual grievances receive prompt attention. The monitoring system will include on-going administrative reviews of project site operations. Project operations will be designed to ensure that the food stamp fair hearing system is used to promptly resolve workfare related issues which are contested by participants.

Accordingly a new § 282.10 of Chapter II, Title 7, Code of Federal Regulations, is promulgated as follows:

§ 282.10 Workfare demonstration project.

(a) *Authority.* Subsection 17(b)(2) of the Act mandates that the Secretaries of the United States Department of Agriculture and Labor jointly conduct a demonstration project involving the performance of public service work by food stamp participants subject to the work registration requirement.

(b) *Purpose.* The purpose of the workfare demonstration project is to determine the feasibility of having food stamp participants perform work in a public service capacity in return for the food stamp benefits to which the household is otherwise entitled. The project will be analyzed and evaluated on the basis of both operational feasibility and economic impact.

(c) *Areas of Operation.* A workfare demonstration project will be conducted in one urban and one rural area in each of the seven FNS administrative regions. The selection of project sponsors will be made by the Departments of Agriculture and Labor based on applications submitted by political subdivisions or groupings thereof wishing to participate in the project.

(d) *Criteria for Participation.* (1) A food stamp household member in a selected demonstration project area will be potentially subject to participation in the workfare project if the member meets the following criteria:

(i) He or she is required to register for full-time work under the terms of § 273.7(a). The normal exemptions from the work registration requirement, § 273.7(b), will be in effect for the purposes of this project;

(ii) The household's total non-excludable earned income, as defined in §273.9(b)(1), is less than the household's coupon allotment. Work registrants who are members of households which receive unearned income shall be subject to participation in workfare if the household's non-excludable earned income does not exceed the value of the coupon allotment;

(iii) He or she has been unable to secure a job in the private or public sector after 30 days from the date of initial registration for work as required in § 273.7(a). Household members becoming exempt from work registration during this 30 day period shall not be subject to workfare participation until such exemption ceases, the member reregisters and 30 days lapse; and

(iv) All public service jobs supported under the Comprehensive Employment and Training Act of 1973 (CETA) have been filled. For the purpose of this project all CETA jobs will be considered filled if:

(A) the CETA prime sponsor is basically fulfilling its hiring schedule (i.e., any openings are due to either normal attrition or the unavailability of qualified technical personnel); and

(B) with respect to any individual potentially subject to workfare:

(*1*) that the CETA sponsor has determined that such individual is not suitable for CETA jobs that are open; or

(*2*) that available openings for which the participant is qualified are not accepted by the participant because these openings do not constitute suitable employment in accordance with § 273.7(i)(1) and (2) (i) through (v). The continued basic fulfillment of the CETA public service employment hiring schedule and the determinations made under (B) (i) and (ii) above will be monitored by the Departments of Agriculture and Labor as described in § 282.10(h);

(2) Households containing more than one work registrant will have the option of deciding which member or members will fulfill the workfare requirement. At the time of application, or upon subsequent notification that the household is subject to workfare requirements, the household shall name one of its members as a prime designee to fulfill the workfare requirements. If acceptable to the workfare sponsor, the household may divide the workfare requirements among work registrants, but shall still designate one registrant as the prime designee. In such circumstances, the prime designee shall be disqualified if the household's workfare obligation is not completed since the second household member is considered to be acting in a proxy capacity for the prime designee. If either the prime designee or the other household member fails to complete his or her share of the workfare obligation but the other member is able to satisfy in full the remaining workfare hour obligation, the prime designee shall not be disqualified.

(3) If a household member is disqualified for refusal to comply with the workfare requirements, the remaining household members shall, if otherwise eligible, continue to receive food stamp benefits. The household shall still be subject to the workfare requirement during the month of disqualification if: the household contains another member subject to the work registration requirement, and, the household's non-excludable earned income (as computed for purposes of determining the household's allotment during the month of disqualification) is less than the reduced allotment the household receives during the month of disqualification. In such a circumstance, a household member who has not been disqualified and who is subject to work registration shall be subject to workfare participation during this month.

(e) *Conditions of employment.* (1) No participant shall be required to accept an offer of workfare employment if such employment fails to meet the criteria established in § 273.7(i)(1) (iii) and (iv); and § 273.7(i)(2) (i), (ii), (iv), and (v);

(2) The total number of required work hours each month will be determined by subtracting the household's monthly earned income, as defined in § 273.9(b)(1), from the household's coupon allotment, and dividing the remainder by the Federal minimum wage. For computational purposes, this earned income figure shall be rounded up to the next highest dollar amount. Fractions of hours to be worked shall be disregarded;

(3) In no instances shall the total number of hours worked under workfare, combined with any other employ-

ment, exceed 40 hours a week for any participant;

(4) If the workfare participant is unable to report for job scheduling, to appear for scheduled workfare employment, or to complete the entire workfare obligation due to compliance with the additional work requirements established in § 273.7(e) (1), (2), (3), or (4), such inability shall not be considered a refusal to accept workfare employment. The workfare participant shall inform the workfare sponsor of the time conflict to avoid disqualification and the workfare sponsor shall reschedule the missed activity if possible. If such rescheduling cannot be completed before the end of the month, this shall not be cause for disqualification. The State Employment Service Office shall make every effort not to schedule the additional work requirements established in § 273.7(e) (1), (2), (3), or (4) to conflict with workfare job scheduling, workfare employment or travel time necessary to reach or return from workfare employment. If the State employment office does not avert such a conflict, however, and the participant does not comply with the additional work requirements because he or she is fulfilling a workfare obligation, the noncompliance with the additional work requirement shall be considered to be for good cause;

(5) The workfare sponsor shall schedule employment for eight hour intervals whenever possible so long as such intervals do not conflict with other employment in which a workfare participant is engaged;

(6) If the workfare sponsor is unable to schedule the workfare participant for employment or is unable to provide the required work hours, the workfare participant shall not be disqualified;

(7) During any month in which the average hours of workfare employment combined with any other hours of employment equal 30 hours or more per week, the workfare participant shall not be subject to the job search activity requirements of § 273.7(d);

(8) Compensation for workfare employment shall be paid in the form of the food stamp allotment to which the household is otherwise entitled. Such employment shall be required until the household's coupon allotment (minus any nonexcludable earned income the household receives) is earned;

(9) The workfare sponsor shall assure that all persons employed in workfare jobs receive job related benefits at the same levels and to the same extent as similar non-workfare employees. Any elective benefit which requires a cash contribution by the participant shall be optional at the discretion of the participant;

(10) All persons employed in workfare jobs will be assured by the workfare sponsor of working conditions and promotional opportunities neither more nor less favorable than those provided other employees similarly employed;

(11) The provisions of section 2(a)(3) of Pub. L. 89-286 (relating to health and safety conditions) shall apply to the workfare program;

(12) Where a labor organization represents employees who are engaged in similar work in the same area to that proposed to be performed under this program for which an application is being developed for submission, such organization shall be notified and afforded a reasonable period of time prior to the submission of the application in which to make comments to the applicant and to the Secretary of Labor;

(13) Special consideration in filling workfare jobs will be given to unemployed persons who are the most severely disadvantaged in terms of the length of time they have been unemployed and their prospects for finding employment without assistance. However, such special consideration shall not authorize the placement of any workfare participant when any other person is on lay-off from the same or any substantially equivalent job slot at the job site;

(14) That no workfare participant will be placed or remain working in any position substantially equivalent to a position which is vacant due to a hiring freeze unless it can be demonstrated that the job slot open due to the freeze resulted from a lack of funds to sustain former staff levels and was not established because of the availability of workfare participants;

(15) That no job vacancy will be created by the action of an employer in laying off or terminating the employment of any regular employee in anticipation of filling the vacancy with a workfare participant;

(16) That the workfare jobs in each promotional line in no way infringe upon the promotional opportunities which would otherwise be available to regular employees, and, that no job will be filled in other than an entry level position in each promotional line until applicable personnel procedures and collective bargaining agreements have been complied with.

(f) *Refusal to comply.* (1) If a household member subject to the workfare requirement refuses, without good cause, to accept an offer of workfare employment, to report for job scheduling, or to complete the entire workfare requirement, such person shall, after opportunity is given for a fair hearing, be disqualified from participation in the food stamp program for a period of one month. If, during the same month in which the refusal occurs, another household member subject to the work registration requirements completes the required workfare obligation for the household, no disqualification shall result.

(2) If a household member is disqualified, and no other member of the household is subject to the work registration requirements, then the household shall not have a workfare obligation during the month of disqualification. However, if such a household does contain another member subject to the work registration requirements, and the household's earned income (as defined in § 273.9(b)(i)) is less than the reduced allotment it receives during the month of disqualification, then the remaining member who is registered for work shall be subject to workfare during this month.

(3) Good cause, for the purpose of this demonstration project, shall be defined as:

(i) Circumstances beyond the member's control, such as, but not limited to: illness; the illness or incapacitation of another household member requiring the presence of the workfare member; a household emergency; or the unavailability of either public or private transportation; or even of the minimal financial resources to obtain available public transportation when transportation is not provided by the sponsor. Lack of private transportation shall not constitute good cause when public transportation is available and the potential workfare participant has the financial resources to use public transportation;

(ii) Becoming exempt from the work registration requirement under the terms established in § 273.7(b);

(iii) Becoming exempt from workfare participation because the household's earned income exceeds the value of the household's coupon allotment. This includes earned income anticipated by the food stamp eligibility worker; or

(iv) Moving to follow the stream of employment while a part of the migrant labor force.

(4) For those households containing a workfare participant who has been disqualified from program participation, the income and resources of such disqualified persons shall be treated in accordance with § 273.11(c). In determining Food Stamp Program eligibility for the remaining household members, a pro rata share of the income of a disqualified member shall be counted as income to the remaining members and his or her resources shall continue to count in their entirety to the remaining household members.

(5) Households containing a disqualified workfare participant may be entitled to additional benefits during the month of disqualification if such par-

ticipant has completed part of the workfare obligation. Such entitlement shall be established by calculating the household's entitlement without the disqualified member, subtracting from this amount any earned income as defined in § 273.9(b)(1), and then comparing this difference to the value of hours worked by the disqualified workfare participant (computed at the Federal minimum wage). If the value of hours worked is greater, the household shall be entitled to benefits in the amount of the difference. The entitlement thus calculated provides compensation when the value of hours worked by the disqualified member exceeds the household's coupon allotment (as calculated without the disqualified member) minus the household's earned income.

(g) *State agency responsibilities.* The State agency shall be responsible for undertaking the following activities:

(1) Determining, during the certification process, those work registrants subject to participation in workfare;

(2) Informing potential participants about the nature of the project, the options in household member designation, the penalty for noncompliance, their rights, procedures for appeal through the fair hearing process, and grievance procedures as established in § 282.10(h);

(3) Establishing and maintaining a recordkeeping system for each household subject to the workfare requirements;

(4) Forwarding information to the workfare sponsor on required work hours for each workfare participant and any subsequent information affecting a household member's workfare obligation, such as a change in the required work hours, or a change resulting in the inapplicability of the workfare requirement;

(5) Informing a workfare household who reports a change in earned income of the effect this change will have on the workfare hours requirement or the continuing applicability of the workfare requirement;

(6) Taking the following actions, as appropriate, on information received from the workfare sponsor:

(i) Upon notification that the participant has failed to comply with the workfare requirement (see § 282.10(f)(1)), the State agency shall issue a notice of adverse action in accordance with § 273.13 unless good cause has already been established in accordance with § 282.10(f)(2);

(ii) If the household member establishes good cause for noncompliance, as defined in § 282.10(f)(2), the requirement for further workfare participation shall be dependent on the continuing applicability of the workfare requirement;

(iii) If a notice of adverse action is issued and no appeal is filed, the State agency shall take action to disqualify the noncompliant household member for one month following expiration of the notice period. During the month of disqualification, no workfare job referrals shall be made for the disqualified member since this person is not a member of a food stamp household for that month. If, however, in the subsequent month, the household is still certified for participation and the member is still subject to the workfare requirement, the workfare job referral process shall be reinstated;

(iv) If a fair hearing is requested, any action to disqualify the noncomplying household member will be suspended until completion of the hearing. During pendency of the fair hearing, the workfare requirements will continue to apply. If the hearing results in a decision upholding the disqualification, the period of disqualification shall be effective in the first month following the decision;

(v) If disqualification resulted from refusal to complete the entire workfare requirement, the State agency shall provide benefits, where appropriate, under the conditions of § 282.10(f)(4);

(7) Take such action as is necessary to:

(i) Eliminate errors attributable to workfare requirements from the Quality Control error rate computations;

(ii) Establish procedures to refer alleged violations of project requirements by the workfare sponsor to appropriate USDA/DOL officials for investigation and resolution, as established in § 282.10(h);

(iii) Resolve grievances, to the extent possible, related to alleged violations by a sponsor of the requirements of these regulations or the Notice of Intent. In resolving such matters, contact shall first be made with the workfare sponsor. Issues which cannot be resolved at this level shall immediately be forwarded to USDA/DOL as specified in § 282.10(h) below;

(iv) Provide fair hearings in those instances where participants claim that noncompliance resulted from alleged sponsor violations of project requirements. Such alleged violations shall also be forwarded immediately to USDA/DOL for review. Any findings of USDA/DOL officials may be entered into evidence at the fair hearing, so long as all affected parties have been informed of these findings at a reasonable time in advance of the hearing. When a fair hearing official renders a decision in such a case, the hearing decision shall be implemented, but the decision shall also be forwarded to USDA/DOL for review. Subsequent USDA/DOL findings regarding the alleged sponsor violations, if contrary to the evidence presented at the fair hearing, shall be provided to the State agency for a reconsideration of the fair hearing decision in light of the new evidence. If the initial decision is reversed, benefits shall be restored or a claim initiated as appropriate.

(h) *Compliance monitoring and workfare evaluation.* The Departments of Agriculture and Labor will establish procedures for monitoring compliance with the operational requirements of § 282.10 and for the evaluation of the workfare concept as demonstrated by project site operations. Persons, organizations or agencies alleging workfare sponsor noncompliance with the terms of these regulations or the Notice of Intent shall refer such complaints to the National headquarters of the Departments of Agriculture and Labor for investigation and disposition. Compliance monitoring shall include, but not be limited to:

(1) Administrative reviews of project site operations;

(2) Ongoing reviews of workfare sponsors' and related agencies' compliance with the terms of these regulations and the Notice of Intent which follows;

(3) Grievance procedures for resolution of complaints against workfare sponsor operations;

(4) Desk reviews of workfare sponsors' monthly activity reports.

APPENDIX

NOTICE OF INTENT

In accordance with subsection 17(b)(2) of the Food Stamp Act of 1977, (Title XIII, Pub. L. 95-113), the Secretaries of Agriculture and Labor jointly announce their intention to conduct a demonstration project, hereafter called workfare, involving the performance of work in exchange for food stamp benefits. Under this project, members of food stamp households, subject to the work registration requirement, whose total household earned income is less than their household's coupon allotment, will be required to work in a public service capacity if they are unable to secure work in the private or public sector. The required hours of employment will be determined by dividing the household's coupon allotment, minus any nonexcludable earned income the household receives, by the Federal minimum wage. Compensation will be "paid" in the form of the monthly coupon allotment to which the household would normally be entitled. Persons required to participate in the workfare project who refuse to accept workfare employment will not be eligible to participate in the Food Stamp Program for a period of one month following each month in which refusal occurs. The workfare project will be conducted in one urban and one rural political subdivision or groupings thereof in each of the seven FNS/USDA administrative regions. Actual project operations are targeted to begin in conjunction with the implementation of the benefit computation provisions of the Food

Stamp Act of 1977. Regulations issued by the Department on October 17, 1978 require that such provisions be implemented by State agencies no later than March 1, 1979.

This notice further seeks proposals for project operation from political subdivisions or groupings thereof wishing to participate in the Workfare Demonstration Project. Such proposals shall describe in detail how the political subdivision, working with the welfare agency and any other cooperating agencies that may be involved in the project, shall fulfill the provisions of the Act governing the Workfare Demonstration Project, which are enumerated below.

A. Basic Operational Requirements

1. Household members, subject to the full-time work registration requirement, whose total household earned income is less than the household's coupon allotment, and who are unable to find work in the private or public sector after 30 days from initial registration for work, shall be subject to participation in workfare in addition to all other work registration requirements.

2. No workfare job shall be offered until all public service jobs supported under the Comprehensive Employment and Training Act of 1973 (CETA) within that subdivision have been filled. For the purpose of this project all CETA public service jobs will be considered filled if:

(a) The CETA prime sponsor is basically fulfilling its public service employment hiring schedule (i.e., any openings are due either to normal attrition or the unavailability of qualified technical personnel); and

(b) With respect to the individual potentially subject to workfare:

(i) the CETA sponsor has determined that such individual is not qualified for suitable CETA slots that are open; or

(ii) that available CETA openings, for which the participant is qualified, are not refused by the participant for reasons established in § 273.7 (i)(1) and (2) (i) through (v).

3. Compensation for workfare employment shall be paid in the form of the coupon allotment to which the hosehold is normally entitled.

4. The number of hours a workfare participant is required to work shall be determined by dividing the household's total coupon allotment, minus any nonexcludable earned income the household receives, by the Federal minimum wage.

5. A workfare participant shall not be eligible to participate in the Food Stamp Program for a period of one month for each month in which the participant refuses to accept a workfare job offer. Refusal, for the purposes of this demonstration project, shall be defined as actual refusal, without good cause, to accept workfare employment; refusal, without good cause, to report to the workfare sponsor for job scheduling; or refusal, without good cause, to complete the entire workfare hour requirement.

B. Workfare Sponsors

1. *Eligibility.* To participate in the project, potential workfare sponsors must meet the folowing requirements:

(a) Be a political subdivision or grouping thereof (i.e., a State or a unit of local government or a combination of local governments), currently operating a public service employment program under State or local general assistance programs, the Comprehensive Employment and Training Act (CETA), or other legislation. This includes those political subdivisions sponsoring general assistance workfare programs. Political subdivisions who are not now operating a public service employment program may be considered for eligibility if the application is sufficiently detailed to enable the Departments to determine the proposer's administrative ability to sponsor a workfare demonstration project.

(b) Have the capability for effectively operating and administering a workfare project under the terms and conditions established in the Food Stamp Act, this Notice, and regulations established in § 282.10.

2. *Responsibilities.* The workfare sponsor shall be responsible for:

(a) Determining which agencies within its jurisdiction shall be used in the various administrative functions of this project. For administrative simplicity, a workfare sponsor may use a currently operational administrative structure if it can fulfill the requirements of this project.

(b) Establishing an operational system to fulfill the functions of the workfare project. At a minimum, the system shall:

(1) Provide for communication between involved agencies;

(2) Ensure the establishment of a sufficient number and variety of short-term public service jobs to allow testing of the workfare concept. Jobs may be allocated among State and local public service agencies and subdivisions thereof. To the extent consistent with the maintenance of effort requirements of this Notice and with personnel procedures and collective bargaining agreements of the workfare sponsor and cooperating agencies, jobs may also be allocated to private nonprofit agencies;

(3) Before contacting the potential workfare participant, assure that:

(i) 30 days have passed since his or her initial registration for work under the food stamp program; and,

(ii) all public service jobs supported under CETA are filled (see A2). Documentation that all CETA jobs are filled shall be noted in each workfare participant's records;

(4) Notify workfare participants of job scheduling and assure the continuing applicability of the workfare requirement. Such notification shall include the number of hours to be worked (based on the household's monthly food stamp entitlement and earned income) for the month and the penalty for noncompliance;

(5) Provide for monthly work scheduling for each workfare participant based on the number of hours of work each participant is required to perform, as determined by the welfare agency. Such employment shall be scheduled in eight hour increments whenever possible. However, such employment shall not be scheduled to conflict with any other employment scheduled by the participant;

(6) Ensure timely reporting to the welfare agency on those workfare participants failing to report for job scheduling;

(7) Assign workfare participants to workfare jobs and ensure the provision of the necessary supervision;

(8) Monitor the hours of work of workfare participants;

(9) Have records maintained which identify the name of the sponsoring agency; the participant's name and food stamp case file number; the type of work to be performed; the period covered by the time reports and any additional benefits provided by the sponsoring agency, such as transportation, training, upward mobility programs and health benefits;

(10) Ensure monthly reporting on the total number and type of workfare slots available; the number of workfare slots filled by participants in the food stamp workfare project; the total number and names of participants who fully complied with the workfare requirement, including the number of hours worked; the total number and names of persons refusing to participate in workfare; the total number of hours worked; and other information as requested. Such reports shall be directed to the USDA/DOL evaluation contractor and elsewhere, as required, no later than the 15th of the month following the report month; and

(11) Ensure that all necessary reports are submitted as required.

(c) Establish a monitoring system to ensure that cooperating agencies are carrying out their responsibilities as established for the workfare project.

3. *Assurances.* All potential workfare sponsors shall provide the following assurances:

(a) They have the legal authority to conduct the project;

(b) They will be responsible for the development and execution of the project;

(c) They will comply with all requirements of the Civil Rights Act of 1964, of the Food Stamp Act of 1977, the regulations issued pursuant to these Acts which are applicable to the project and this Notice;

(d) That special consideration in filling workfare jobs will be given to unemployed persons who are the most severely disadvantaged in terms of the length of time they have been unemployed and their prospects for finding employment without assistance. However, such special consideration in filling workfare jobs shall not authorize the placement of any workfare participant when any other person is on lay-off from the same or any substantially equivalent job at the job site;

(e) That no workfare participant will be placed or remain working in any position substantially equivalent to a position which is vacant due to a hiring freeze unless it can be demonstrated that the freeze resulted from a lack of funds to sustain former staff levels and was not established because of the availability of workfare participants;

(f) That no job vacancy will be created by the action of an employer in laying off or terminating the employment of any regular employee in anticipation of filling the vacancy with a workfare participant;

(g) That there will be planning for and training of supervisory personnel in working with participants;

(h) That the applicant sponsor will, where appropriate, maintain or provide linkages with upgrading and employment and training programs for the purposes of:

(1) providing those persons employed in workfare jobs who want to pursue work with the employer, in the same or similar work, the opportunities to do so and to find permanent upwardly mobile non-workfare careers in that field; and

(2) providing those persons so employed, who do not wish to pursue permanent careers in such fields, with opportunities to seek, prepare for, and obtain work in other fields; and

(i) That the workfare jobs in each promotional line in no way infringe upon the promotional opportunities which would otherwise be available to regular employees, and,

that no job will be filled in other than an entry level postion in each promotional line until applicable personnel procedures and collective bargaining agreements have been complied with.

4. *Conditions of participation.* Sponsors of workfare shall insure compliance with the following conditions:

(a) Workfare will result in an increase in employment opportunities over those opportunities which would otherwise be available; will not result in the displacement of currently employed workers (including partial displacement such as a reduction in the hours of non-overtime work or wages or employment benefits); will not impair existing contracts for services, or result in the substitution of Federal for other funds in connection with work that would otherwise be performed; and will not substitute public service workfare jobs for existing federally-assisted jobs.

(b) Compensation shall be at 100 percent of the Federal minimum wage, to be paid by the Federal government in food stamps until the household coupon allotment (minus any non-excludable earned income) is earned. However, all persons employed in workfare jobs will be assured of workmen's compensation, health insurance, unemployment insurance and other benefits at the same levels and to the same extent as other similar employees of the employer, and to working conditions and promotional opportunities neither more nor less favorable than other persons similarly employed enjoy. Costs associated with such coverage shall be borne by the workfare sponsor.

(c) Work-related expenses, such as transportation costs, may be provided by workfare sponsors at their descretion.

(d) The cost of any work related supplies, such as uniforms and special equipment, shall be borne by the workfare sponsor if such supplies are necessary to employment.

(e) The provisions of section 2(a)(3) of Public Law 88-286 (relating to health and safety conditions) shall apply to the workfare program.

(f) Where a labor organization represents employees who are engaged in similar work in the same area to that proposed to be performed under this program and for which application is being developed for submission, such organization shall be notified and afforded a reasonable period of time prior to the submission of the application in which to make comments to the applicant and to the Secretary of Labor.

(g) Conditions of employment or training will be appropriate and reasonable in the light of such factors as the type of work, geographical region, and proficiency of the participant.

C. Welfare Agency

1. Responsibilities of the welfare agency in localities in which a workfare project is operating shall be to:

(a) Establish a procedure within the food stamp eligibility determination process to identify potential workfare participants. Explain to such households, at the time of certification, the project's operation, the household's rights, and the penalty for noncompliance.

(b) Identify the total number of hours to be worked based on the household's entitlement minus any non-excludable earned income the household receives. Such information, in addition to any subsequent information affecting the member's workfare obligation, shall be transmitted as directed by the workfare sponsor.

(c) Receive preliminary information on workfare participants reporting to the job site and, at the end of the month, final information on the number of hours worked.

(d) Take action on information received. In instances of refusal without good cause, i.e., refusal to accept a workfare job offer, refusal to report for job scheduling, or refusal to complete the entire work requirement, the noncomplying household member shall be subject to the penalty of a one month disqualification as established in § 282.10(f) of the implementing regulations.

(e) Establish procedures for referral of complaints regarding workfare sponsor's alleged violations of this Notice and the regulations to the appropriate official of DOL and/or USDA for investigation and adjudication.

(f) Resolve, to the extent possible, grievances related to alleged violations of the requirements of this Notice or the implementing regulations. In resolving such matters, contact shall first be made with the workfare sponsor. Issues which cannot be resolved at this level shall be forwarded to USDA/DOL.

(g) Where workfare noncompliance and subsequent fair hearings are based on alleged sponsor noncompliance with project requirements, forward all such fair hearing transcripts to USDA/DOL for review.

(h) Maintain records on workfare activities, including:

(1) Recording in individual case files information on:

(i) Referral to the workfare sponsor; and

(ii) Noncompliance with the workfare requirements.

(2) Fair hearings and disqualifications as a result of workfare noncompliance; and

(3) Such other records as deemed appropriate.

2. *Assurances.* The participating welfare agency shall provide assurances that it will comply with all applicable requirements of the Food Stamp Act, this Notice, and regulations, as promulgated.

D. Funding

Funding for project operations by the Department of Agriculture shall be limited to the payment of the coupon allotment to which the food stamp household is otherwise normally entitled. The workfare sponsor shall be responsible for performing the sponsor's administrative activities and providing employee benefits as prescribed herein. The cost of data compilations (such as the monthly report required in B.2.(b)(10)) performed by the workfare sponsor at the direction of the evaluation contractor shall, however, be fully reimbursed by the evaluation contractor at a rate negotiated between the sponsor and contractor. Additional evaluation activities which the sponsor agrees to undertake at the request of the evaluation contractor shall also be fully reimbursed.

E. Records

All records pertaining to the Workfare Demonstration Project shall be available to USDA and DOL representatives or their designees for purposes of inspection and review. Such records shall be maintained for a period of three years from the date of project completion, or longer if requested in writing by USDA or DOL.

F. Applications

Applications shall be submitted in an original and two copies and shall be received by the Deputy Administrator, Family Nutrition Programs, Food and Nutrition Service, USDA, 500 12th Street, SW., Washington, D.C. 20250, within 45 days following publication of the final regulations governing the workfare project. Applications must be signed by the representative of the potential workfare sponsor having the authority to commit the political subdivision to the project. The workfare sponsor shall insure that all necessary agencies, including the welfare agency, which are either involved or have review authority, have concurred in project operations. In addition to the information on project operations and assurances required above, the application shall contain the following information:

1. A precise description of the administrative procedures to be used and a work plan which establishes a schedule for development and implementation of the project.

2. A description of:

(a) the approximate number of jobs and the types of jobs which will be provided;

(b) training and/or skill development which will be given; and

(c) any employee benefits, including transportation costs, which will be provided to participants.

3. A statement of the qualifications and size of the staff to be used, including a project director, to accomplish the purpose of the project.

G. Selection of Project Sites

1. *Federal procedures.* (a) All applications will be reviewed by a panel comprised equally of representatives from USDA and DOL; and (b) Applications will be ranked based on the criteria established in (2) below.

2. *Criteria for selection.* To be selected, the potential sponsor must be located with a CETA prime sponsor basically fulfilling its public service employment hiring schedule or located in a political subdivision not served by a CETA prime sponsor. Meeting this criterion, the contents of the proposals will be weighted on the following criteria:

(a) Conceptual development and clarity of operational design;

(b) Geographical mix as required by the Food Stamp Act;

(c) Ability of the sponsor to provide a sufficient number and variety of public service jobs to test the feasibility of the workfare concept;

(d) Compliance of the work plan with the provisions governing the project as contained in the Act, this Notice, and applicable regulations;

(e) The adequacy of the work plan;

(f) The capability of the applicant to conduct the project based on:

(1) A description of the qualifications of staff;

(2) Availability of necessary facilities, staff, and other resources;

(3) Administrative and supervisory capacity; and

(4) Previous experience of the workfare employer in administering public service employment.

(g) Additional points shall be given to potential sponsors for the payment of participants' work-related expenses and/or provisions for transportation to the job site(s); the ability to supplement workfare hours with paid employment; the likelihood of an offer of permanent employment following

the workfare employment; the development of new job skills; the career potential of jobs to be offered; and other assurances over and above the minimum levels required in Part B.3 (d) through (g).

3. *Selection.* USDA and DOL shall notify all proposers of those sites selected for project operation. To the extent possible, the Departments will select project sites which represent a cross-section of food stamp household characteristics.

H. MONITORING AND EVALUATION

The Departments of Agriculture and Labor shall establish procedures for monitoring the compliance of the workfare sponsors and related agencies with the requirements of the workfare demonstration project regulations. An evaluation shall be structured to assess both the operational feasibility and economic impact of the project. The cost of the evaluation shall be borne, in its entirety, by the Department of Agriculture. All data compilations performed by the workfare sponsor at the direction of the evaluation contractor, as distinct from the recordkeeping requirements necessary for the operation of the workfare project, shall be fully reimbursed by the evaluation contractor at a rate negotiated between the sponsor and the contractor. Additional evaluation activities undertaken by the sponsor at the request of the evaluation contractor shall also be fully reimbursed by the contractor.

(91 Stat. 950, as amended (7 U.S.C. 2011-2027).)

NOTE.—The Food and Nutrition Service has determined that this document does not contain a major proposal requiring preparation of an Economic Impact Statement under Executive Order 11821 and OMB Circular A-107.

NOTE.—The reporting and/or recordkeeping requirements contained herein have been forwarded to the Office of Management and Budget for approval in accordance with the Federal Reports Act of 1942.

(Catalog of Federal Domestic Assistance Programs No. 10.551, Food Stamps.)

Dated: November 9, 1978.

CAROL TUCKER FOREMAN,
Assistant Secretary of Agriculture.

Dated: November 22, 1978.

ERNEST G. GREEN,
Assistant Secretary of Labor.

[FR Doc. 78-33376 Filed 11-27-78; 8:45 am]

[3410-07-M]

CHAPTER XVIII—FARMERS HOME ADMINISTRATION, DEPARTMENT OF AGRICULTURE

SUBCHAPTER P—GUARANTEED LOANS

[FmHA Instruction 1980-A]

PART 1980—GENERAL

Subpart A—General

AGENCY: Farmers Home Administration, USDA.

ACTION: Final rule.

SUMMARY: The Farmers Home Administration (FmHA) amends its Loan Note Guarantee (Form FmHA 449-34). The intended effect of this action is to make the form applicable to guaranteed economic emergency loans, and to revise the full faith and credit provision of the guarantee. The change is required to make the form applicable to guaranteed economic emergency loans and to make the guarantee unconditional.

EFFECTIVE DATE: November 28, 1978.

FOR FURTHER INFORMATION CONTACT:

William K. Krause, telephone 202-447-7600.

SUPPLEMENTARY INFORMATION: Appendix A of Subpart A of Part 1980 of Chapter XVIII, Title 7, Code of Federal Regulations is amended. These amendments to Form FmHA 449-34, Loan Note Guarantee will (1) make the form applicable to economic emergency loans guaranteed by FmHA pursuant to Pub. L. 95-334, "the Emergency Agricultural Credit Adjustment Act of 1978" enacted August 4, 1978, and (2) change the full faith and credit provision of the guarantee to make it clear that the guarantee is "unconditional" by defining the phrases "use of loan funds for unauthorized purposes" and "unauthorized purpose."

The Comptroller of the Currency advised FmHA that the full faith and credit provision of the Loan Note Guarantee did not meet the requirements of 12 U.S.C. 84 (10) which exempts loans that are guaranteed unconditionally by the Federal Government from the lending limit requirements imposed on national banks. It is the opinion of the Comptroller General that this revision in the full faith and credit provision will make the guarantee "unconditional," as that word is used in 12 U.S.C. 84 (10).

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. These amendments, however, are not published for proposed rulemaking since the first change adapts the form for use in the guaranteed economic emergency loan program and is administrative in nature and the second change will benefit the lending institutions which participate in the FmHA guaranteed loan programs. Therefore, public participation is unnecessary.

APPENDIX A [AMENDED]

Accordingly, Appendix A of Subpart A of Part 1980 of Chapter XVIII, Title 7, Code of Federal Regulations, is amended as follows:

1. The paragraph directly above paragraph A is amended to read as follows:

* * * * *

In consideration of the making of the subject loan by the above named Lender, the United States of America, acting through the Farmers Home Administration of the United States Department of Agriculture (herein called "FmHA"), pursuant to the Consolidated Farm and Rural Development Act (7 U.S.C. 1921 et. seq.), the Emergency Livestock Credit Act of 1974 (7 U.S.C. note preceding 1961, Pub. L. 93-357 as amended), the Emergency Agricultural Credit Adjustment Act of 1978 (7 U.S.C. note preceding 1921, Pub. L. 95-334), or Title V of the Housing Act of 1949 (42 U.S.C. 1471 et. seq.) does hereby agree that in accordance with and subject to the conditions and requirements herein, it will pay to:

* * * * *

2. Paragraph 3 under "Conditions of Guarantee" is amended by adding a sentence to the end of the paragraph as follows:

CONDITIONS OF GUARANTEE

* * * * *

3. *Full Faith and Credit.* * * *

As used herein, the phrase "use of loan funds for unauthorized purposes" refers to the situation in which the lender in fact agrees with the borrower that loan funds are to be so used and the phrase "unauthorized purpose" means any purpose not listed by the lender in the completed application as approved by FmHA.

* * * * *

(7 U.S.C. 1989; 5 U.S.C. 301; Sec. 10 Pub. L. 93-357, 88 Stat. 392; delegation of authority by the Sec. of Agri., 7 CFR 2.23; delegation of authority by the Asst. Sec. for Rural Development, 7 CFR 2.70.)

Dated: November 13, 1978.

GORDON CAVANAUGH,
Administrator, Farmers Home Administration.

[FR Doc. 78-33222 Filed 11-27-78; 8:45 am]

[3410-07-M]

SUBCHAPTER N—OTHER LOAN PROGRAMS

[FmHA Instruction 1980-A]

PART 1980—GUARANTEED LOAN PROGRAMS

Subpart A—General

AMENDMENTS

AGENCY: Farmers Home Administration, USDA.

ACTION: Final rule.

SUMMARY: The Farmers Home Administration (FmHA) amends its regulations to revise the full faith and credit provisions of the guarantee. The effect of these changes is to make clear that the guarantee issued under the FmHA regulations is "unconditional." This change is required to make the guarantee unconditional.

EFFECTIVE DATE: November 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Darryl H. Evans, Loan Specialist, telephone 202-447-4150.

SUPPLEMENTARY INFORMATION: § 1980.11 and Appendix B of Subpart A of Part 1980 of Chapter XVIII, Title 7, Code of Federal Regulations are amended. These amendments clarify the full faith and credit provisions of the Guarantee by defining the phrases "use of loan funds for unauthorized purposes, and "unauthorized purpose."

The Comptroller of the Currency advised FmHA that the full faith and credit provisions of the Loan Note Guarantee did not meet the requirements of 12 U.S.C. § 84 (10) which exempts loans that are guaranteed unconditionally by the Federal Government from the lending limit requirements imposed on national banks. According to the Comptroller under the above cited regulations prior to these revisions, the guarantee was conditional. It is the opinion of the Comptroller General that enactment of these revisions to the full faith and credit sections of the regulations will clearly make the new guarantees and previously issued guarantees which are subject to Subpart A "unconditional," as that word is used in 12 U.S.C. § 84 (10).

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. These amendments, however, are not published for proposed rulemaking since they make clear that the loan guarantee is unconditional, thereby benefitting the lending institutions which participate in the FmHA guaranteed loan programs. Therefore, public participation is unnecessary.

Accordingly, § 1980.11 and Appendix B of Subpart A of Part 1980 of Chapter XVIII, Title 7, Code of Federal Regulations are amended as follows:

1. Section 1980.11 is amended by adding a sentence to the end of the section as follows:

§ 1980.11 Full faith and credit.

* * * As used in this paragraph and in any Loan Note Guarantee (including those now outstanding) in which the phrase appears, "use of loan funds for unauthorized purposes" refers to the situation in which the lender in fact agrees with the borrower that loan funds are to be so used and the phrase "unauthorized purpose" means any purpose not listed by the lender in the completed application as approved by FmHA.

* * * * *

3. Paragraph II under the Parties Agree of Appendix B, Form FmHA 449-35, Lender's Agreement, is amended to add a sentence to the end of the paragraph as follows:

APPENDIX B—FORM FMHA 449-35, LENDER'S AGREEMENT

* * * * *

THE PARTIES AGREE

* * * * *

II. Full Faith and Credit. * * *

As used herein, the phrase "use of loan funds for unauthorized purposes" refers to the situation in which the lender in fact agrees with the borrower that loan funds are to be so used and the phrase "unauthorized purpose" means any purpose not listed by the lender in the completed application as approved by FmHA.

* * * * *

(7 U.S.C. 1989; 5 U.S.C. 301; Sec. 10, Pub. L. 93-357, 88 Stat. 392 delegation of authority by the Sec. of Agri., 7 CFR 2.23; delegation of authority by the Asst. Sec. for Rural Development, 7 CFR 2.70.)

Dated: October 11, 1978.

GORDON CAVANAUGH,
Administrator,
Farmers Home Administration.

[FR Doc. 78-33223 Filed 11-27-78; 8:45 am]

[7590-01-M]

Title 10—Energy

CHAPTER I—NUCLEAR REGULATORY COMMISSION

PART 35—HUMAN USES OF BYPRODUCT MATERIAL

Radiation Surveys of Therapy Patients

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Final rule.

SUMMARY: Certain NRC licensees are authorized to treat patients with temporary implants incorporating radioactive material. NRC will require such licensees to confirm the removal of the implants at the end of the treatment by (1) a source count and (2) a radiation survey of the patient. Failure to account for all implants at the conclusion of patient treatment has resulted in some instances of unnecessary radiation exposure to patients and members of the general public.

EFFECTIVE DATE: The amendment becomes effective on December 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Edward Podolak, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Phone: 301-443-5966).

SUPPLEMENTARY INFORMATION: NRC regulations in § 35.14(b)(5)(vii) require Group VI licensees [1] to assure that patients treated with cobalt-60, cesium-137 or iridium-192 temporary implants remain hospitalized until the implants have been removed. The primary method for confirming that all sources have been removed is to count the sources implanted and count the sources removed. The source counting has not always been performed accurately, or on a timely basis.

Some patients have been discharged from the hospital with radioactive sources still implanted. (It is particu-

[1] The most common types of NRC specific licenses for the medical use of byproduct material are the *Group* medical licenses under § 35.14 that apply to those radioactive materials listed in § 35.100. The radioactive materials listed in § 35.100 are divided into six groups, each group having similar requirements for user training and experience, facilities and equipment, and radiation safety procedures. Groups I, II, and III are lists of radiopharmaceuticals for diagnostic procedures; Groups IV and V are lists of radiopharmaceuticals for therapeutic procedures; and Group VI is a list of radioactive medical devices for both diagnostic and therapeutic procedures.

larly difficult to count iridium-192 seeds, which sometimes become dislodged from their encasement in nylon ribbon). Because a backup radiation survey of the patient could have prevented these incidents, on June 28, 1978 NRC published a proposed rule in the FEDERAL REGISTER adding a requirement for source counting and patient radiation surveys to the existing § 35.14(b)(5)(vii) which prohibits Group VI licensees from discharging patients until all sources are removed. The comment period ended August 14, 1978.

Twenty-one comments were received. Eleven favored the proposal without qualification. Three commenters suggested that bulky afterloaded devices that protrude from the body be exempted from the radiation survey. One commenter suggested that an x-ray be permitted as an alternative to the radiation survey. One commenter asked what was meant by "the end of the treatment" and one commenter, while favoring the proposal, suggested that the radiation survey should be performed within one hour of source removal. Four commenters objected to the proposal because they believe that regulations that define what is already good medical practice are useless. One commenter objected to the proposal because he believes that there are some cases where it would be impossible to survey the patient before discharge.

The wording of the final rule is the same as the proposed and requires a radiation survey of the patient before discharge. The radiation survey is the most positive (active) method of verifying source removal. The x-ray is a passive method. Although good practice would suggest a radiation survey soon after source removal, the regulation has to recognize the realities of the clinical setting where other tasks may have higher priority. Placing a tight time limit on this essentially quality control function may interfere with patient care. However, it is extremely unlikely that the licensee will experience difficulty performing the survey between source removal and discharge of the patient.

The suggestion to exempt afterloaded devices is well made. The devices are bulky relative to the actual source size and it is difficult to imagine that patients would be discharged with these devices in-place. However, NRC inspectors, who are familiar with incidents of overexposure from implants remaining in patients, say that this is an area where the "impossible" happens in spite of great care and precautions. Also, NRC inspectors have investigated an incident where a patient was discharged with an afterloaded device in-place with the sources loaded. The radiation survey is simple and inexpensive and it will also detect any sources lost in the bedclothes or room where the survey is performed. Therefore, the afterloaded devices will not be exempted from the requirements for a radiation survey.

Finally, regulations that define what is generally considered good practice may seem useless or may even dismay conscientious licensees. However, this is insufficient reason to forgo these regulations when there is evidence that the good practices are not universal.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended and sections 552 and 553 of title 5 of the United States Code, notice is hereby given that the following amendment to 10 CFR Part 35 is published as a document subject to codification.

In 10 CFR Part 35, § 35.14(b)(5)(vii) is amended to read as follows:

§ 35.14 Specific licenses for certain groups of medical uses of byproduct material.

* * * * *

(b) Any licensee who is authorized to use byproduct material pursuant to one or more groups in §§ 35.14(a) and 35.100 is subject to the following conditions:

* * * * *

(5) For Group VI any licensee who possesses and uses sources or devices containing byproduct material shall:

* * * * *

(vii) Assure that patients treated with cobalt-60, cesium-137 or iridium-192 implants remain hospitalized until a source count and a radiation survey of the patient confirm that all implants have been removed.

* * * * *

(Sec. 161, Pub. L. 83-703, 68 Stat. 948 (42 U.S.C. 2201); Sec. 201, Pub. L. 93-438, 88 Stat. 1243 (42 U.S.C. 5841).)

Dated at Bethesda, Maryland this 14th day of November 1978.

For the Nuclear Regulatory Commission.

LEE V. GOSSICK,
Executive Director for Operations.

[FR Doc. 78-33229 Filed 11-27-78; 8:45 am]

[6750-01-M]

Title 16—Commercial Practices

CHAPTER I—FEDERAL TRADE COMMISSION

[Docket No. 9042]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

Coventry Builders, Inc., et al.

AGENCY: Federal Trade Commission.

ACTION: Final order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement, among other things, requires a Shaker Heights, Ohio home improvements firm to cease, in connection with the extension of credit, failing to provide consumers with those materials and disclosures required by Federal Reserve System regulations.

DATES: Complaint issued July 15, 1975. Decision issued October 23, 1978.[1]

FOR FURTHER INFORMATION CONTACT:

Paul R. Peterson, Regional Director, 4R, Cleveland Regional Office, Federal Trade Commission, Suite 500, Mall Bldg., 118 St. Clair Ave., Cleveland, Ohio 44114. 216-522-4207.

SUPPLEMENTARY INFORMATION: On Wednesday, August 16, 1978, there was published in the FEDERAL REGISTER, 43 FR 36281, a proposed consent agreement with analysis In the Matter of Coventry Builders, Inc., a corporation, and Louis Galiano, Sr., inidividually and as an officer of said corporation, for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions, or objections regarding the proposed form of order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered its order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

The prohibited trade practices and/or corrective actions, as codified under 16 CFR Part 13, are as follows: Subpart-Advertising Falsely or Misleadingly: § 13.73 Formal regulatory and statutory requirements; 13.73-92 Truth in Lending Act; § 13.155 Prices; 13.155-95 Terms and conditions; 13.155-95(a) Truth in Lending Act.

[1] Copies of the Decision and Order filed with the original document.

Subpart-Misrepresenting Oneself and Goods—Goods: § 13.1623 Formal regulatory and statutory requirements; 13.1623-95 Truth in Lending Act.—Prices: § 13.1823 Terms and conditions; 13.1823-20 Truth in Lending Act. Subpart-Neglecting, Unfairly or Deceptively, To Make Material Disclosure: § 13.1852 Formal regulatory and statutory requirements; 13.1852-75 Truth in Lending Act; § 13.1905 Terms and conditions; 13.1905-60 Truth in Lending Act.

(Sec. 6, 38 Stat. 721; (15 U.S.C. 46). Interpret or apply sec. 5, 38 Stat. 719, as amended; 82 Stat. 146, 147; (15 U.S.C. 45, 1601, *et seq.*).)

CAROL M. THOMAS,
Secretary.

[FR Doc. 78-33271 Filed 11-27-78; 8:45 am]

[6750-01-M]

[Docket No. C-2933]

PART 13—PROHIBITED TRADE PRACTICES, AND AFFIRMATIVE CORRECTIVE ACTIONS

Moore & Associates, Inc., et al., Trading as Uni-Check, et al.

AGENCY: Federal Trade Commission.

ACTION: Final order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement, among other things, will require a Honolulu, Hawaii firm engaged in providing various businesses with consumer credit information and other services, to cease furnishing reports containing obsolete, inaccurate, or disputed information; providing such reports for improper purposes; or otherwise failing to comply with statutory requirements.

DATES: Complaint and order issued October 24, 1978.[1]

FOR FURTHER INFORMATION CONTACT:

William A. Arbitman, Regional Director, 9R, San Francisco Regional Office, Federal Trade Commission, 450 Golden Gate Ave., San Francisco, Calif. 94102. (415) 556-1270.

SUPPLEMENTARY INFORMATION: On Friday, August 18, 1978, there was published in the FEDERAL REGISTER, 43 FR 36642, a proposed consent agreement with analysis In the Matter of Moore & Associates, Inc., a corporation doing business as Uni-Check, and Rentcheck, and R. Donald Moore, individually and as an officer of said corporation, for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions, or objections regarding the proposed form of order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered its order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

The prohibitive trade practices and/or corrective actions, as codified under 16 CFR Part 13, are as follows: Subpart-Collecting, Assembling, Furnishing or Utilizing Consumer Reports: § 13.382 Collecting, assembling, furnishing or utilizing consumer reports; 13.382-1 Confidentiality, accuracy, relevancy, and proper utilization; § 13.382-5 Formal regulatory and/or statutory requirements; 13.382-5(a) Fair Credit Reporting Act. Subpart-Corrective Actions and/or Requirements: § 13.533 Corrective actions and/or requirements; 13.533-37 Formal regulatory and/or statutory requirements.

(Sec. 6, 38 Stat. 721 (15 U.S.C. 46). Interpret or apply sec. 5, 38 Stat. 719, as amended; 82 Stat. 146, 147; 84 Stat. 1127-36 (15 U.S.C. 1601, *et seq.*).)

CAROL M. THOMAS,
Secretary.

[FR Doc. 78-33272 Filed 11-27-78; 8:45 am]

[6351-01-M]

Title 17—Commodity and Securities Exchanges

CHAPTER I—COMMODITY FUTURES TRADING COMMISSION

PART 11—RULES RELATING TO INVESTIGATIONS

Delegation of Authority To Reassign Duties From Persons Named in a Commission Order of Investigation to Other Staff Persons

AGENCY: Commodity Futures Trading Commission.

ACTION: Final Rule.

SUMMARY: The Commission has delegated to the Director of the Division of Enforcement the authority to grant to other members of the Commission staff the authority of persons named in a Commission Order of Investigation.

EFFECTIVE DATE: November 28, 1978.

FOR FURTHER INFORMATION CONTACT:

John A. Field, III, Director, Division of Enforcement, Commodity Futures Trading Commission, 2033 K Street, N.W., Washington, D.C. 20581, 202-254-9501.

SUPPLEMENTARY INFORMATION: The Commission has amended § 11.2 of its regulations under the Commodity Exchange Act to include a new paragraph (b) which authorizes the Director of the Division of Enforcement to grant to any Commission employee under his direction, all or part of the authority which the Commission, by order, has authorized specific employees to perform in connection with a Commission investigation conducted by the Division of Enforcement. With the approval of the Executive Director, the Director of the Division of Enforcement may grant similar authority to any Commission employee under the direction of the Executive Director. This delegation will enable the Director to appoint additional (or substitute) staff persons to issue subpoenas and take testimony without having to obtain an amended order from the Commission.

The Commission finds that the amendment of § 11.2 relates solely to agency practice and procedure and that the provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed rulemaking and other opportunity for public participation are not required.

In consideration of the foregoing, 17 CFR 11.2 is amended by designating the present section as paragraph (a) and by adding a new paragraph (b) as follows:

§ 11.2 Authority to conduct investigations.

* * * * *

(b) The Commission hereby delegates, until the Commission orders otherwise, to the Director of the Division of Enforcement the authority to grant to any Commission employee under his direction all or a portion of the authority which the Commission, by order, has authorized specified employees of the Commission to perform in connection with a Commission investigation conducted by the Division of Enforcement. With the approval of the Executive Director, the Director of the Division of Enforcement may also grant such authority to any Commission employee under the direction of the Executive Director.

(Secs. 2a(11) and 6(b) of the Act, 7 U.S.C. 4a(j) and 15 (1976), as amended by the Futures Trading Act of 1978, Pub. L. 95-405, sec. 13, 92 Stat. 871 (1978)).

[1] Copies of the Complaint and the Decision and Order filed with the original document.

Issued in Washington, D.C. on November 21, 1978, by the Commission.

READ P. DUNN, Jr.,
Commissioner.

[FR Doc. 78-33227 Filed 11-27-78; 8:45 am]

[4110-07-M]

Title 20—Employees' Benefits

CHAPTER III—SOCIAL SECURITY ADMINISTRATION; DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Regulations No. 4, 16]

PART 404—FEDERAL OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE BENEFITS

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Rules for Adjudicating Disability Claims in Which Vocational Factors Must Be Considered

AGENCY: Social Security Administration, HEW.

ACTION: Final rules.

SUMMARY: The amendments will expand existing regulations to include additional detailed criteria for the evaluation of those cases involving claims based on disability under titles II and XVI of the Social Security Act in which the determination as to disability cannot be made on medical severity alone or on the ability to do past work. In those instances the individual's impairment will be considered in conjunction with the individual's age, education and work experience to determine his or her ability to engage in substantial gainful activity. In publishing the amendments, the Social Security Administration intends to consolidate and elaborate upon longstanding medical-vocational evaluation policies for adjudicating disability claims in which an individual's age, education, and work experience must be considered in addition to the medical condition.

DATES: These amendments shall be effective February 26, 1979.

FOR FURTHER INFORMATION CONTACT:

William J. Ziegler, Legal Assistant, Office of Policy and Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, Md. 21235, telephone 301-594-7415.

SUPPLEMENTARY INFORMATION: On March 7, 1978, there was published in the FEDERAL REGISTER (43 FR 9284) a Notice of Proposed Rule Making with proposed amendments providing rules for adjudicating disability claims in which vocational factors must be considered in addition to impairment severity. Interested persons, organizations, and groups were invited to submit data, views, or arguments pertaining to the proposed amendments within a period of 60 days from the date of publication of the notice. The comment period was extended an additional 30 days to allow members of the public more time to submit their comments (43 FR 19238). After careful consideration of all the comments submitted, the proposed amendments are being adopted and shall become effective 90 days after this publication. Many issues identified in the comments received from the public were previously addressed in the NPRM. All issues which were not discussed there are addressed later in this preamble.

The amendments will expand existing regulations to include additional detailed criteria for the evaluation of those cases involving claims based on disability under title II and title XVI of the Social Security Act in which the determination as to disability cannot be made on medical severity alone or on the ability to do past work. In those instances, the individual's impairment will be considered in conjunction with the individual's age, education, and work experience to determine his or her ability to engage in substantial gainful activity. The rules in Appendix 2 consider only impairments which result in exertional limitations. They do not apply where the impairment(s) causes only nonexertional limitations; e.g., certain mental, sensory or skin impairments. The regulations text, however, provides the framework in which to evaluate impairments resulting in nonexertional limitations. In any case where a numbered rule in Appendix 2 does not apply, full consideration must be given to all the facts of the case in accordance with the definitions and discussions of each factor in the regulations.

These amendments do not apply to individuals who are blind as defined under title II or title XVI of the Social Security Act, nor in determining disability for children under age 18 under title XVI or applicants for disabled widow' or widowers' benefits under title II.

In publishing the amendments, the Department intends to consolidate and elaborate upon long standing medical-vocational evaluation policies for adjudicating disability claims in which an individual's age, education, and work experience must be considered in addition to the medical condition. These policies have in the past been reflected in adjudicative guides but have not been available in the same format at all levels of adjudication. While the majority of disability cases are resolved on the basis of medical considerations alone or the ability to do past work, those cases that require the full consideration of an individual's age, education, and work experience are the most difficult to resolve at all levels of adjudication. And, they are more difficult for the general public to understand. Consolidating these policies and incorporating them into the regulations will serve to make clearer to claimants and their representatives how disability is determined where vocational factors must be considered. In addition, it will serve to better assure the soundness and consistency of disability determinations in all claims that are filed regardless of the level at which adjudicated; and finally, it should promote better understanding and acceptance by the public and the courts of disability determinations that are made.

BACKGROUND

Congress first amended the Social Security Act in 1954 to preserve the insurance rights of individuals who have periods of total disability before reaching retirement age. The 1954 provision defined disability, in pertinent part, as:

> "inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or to be of long-continued and indefinite duration * * * (Section 106(d), Pub. L. 761, 83rd Cong., 2d Sess., September 1, 1954, C. 1206, 68 Stat. 1080).

The law, on its face, did not initially mandate consideration of any vocational factors. However, the Congress envisaged that the determination in every case be an individual one. Accordingly, since the inception of the social security disability program in 1954, in the application of the statutory test, consideration has been given to the individual's vocational capacity, where pertinent, in determining whether the individual is disabled. However, because of the clearly limited statutory definition, those factors which relate primarily not to disability but to an individual's ability to obtain employment have been excluded from consideration.

The Social Security Administration's first effort in developing rules for disability determinations was in February 1955 when the Commissioner of Social Security appointed a Medical Advisory Committee to provide technical advice on administrative guides and standards designed to provide equal consideration to all individuals in the evaluation of their disabilities under the 1954 law. This committee suggested that age, education, training, experi-

ence, and other individual factors would need consideration in any case requiring evaluation of facts beyond the medical report and work record even though the law did not specifically require consideration of such factors.

In 1956, the law was further amended to provide for payment of disability insurance benefits to insured individuals who were disabled; the above-quoted statutory definition of disability was adopted for this purpose (Social Security Act as amended by § 103(a) of Pub. L. 84-880, approved August 1, 1956, (C. 836, 70 Stat. 815)). Regulations promulgated in 1957 to implement the statute also provided for the consideration of vocational factors. Section 404.1501 of Regulations No. 4, provided in pertinent part:

(b) In determining whether an individual's impairment makes him unable to engage in such activity [substantial gainful activity] primary consideration is given to the severity of his impairment. *Consideration is also given to such other factors as the individual's education, training and work experience.*

(c) It must be established by medical evidence, and where necessary by appropriate medical tests, that the applicant's impairment results in such a lack of ability to perform significant functions—such as moving about, handling, objects, hearing or speaking, or, in a case of mental impairment, reasoning or understanding—*that he cannot, with his training, education and work experience, engage in any kind of substantial gainful activity.* (Emphasis added.)

The initial years of operation of the disability program were reviewed by the Subcommittee on the Administration of the Social Security Laws of the Committee on Ways and Means. This Subcommittee's Preliminary Report, issued on March 11, 1960, stated, in commenting on "nonmedical standards" in the disability program, that:

"The subcommittee believes it is essential that there be a clear distinction between this program and one concerned with unemployment. It also believes it is desirable that disability determinations be carried out in as realistic a manner as possible, and that theoretical capacity in a severely impaired individual can be somewhat meaningless if it cannot be translated into an ability to compete in the open labor market."

In August 1960 the regulations were further amended. Among other things, the amended regulations continued to provide for the consideration of vocational factors including age, education, training, and work experience in determining disability, and specifically stated:

"The physical or mental impairments must be the primary reason for the individual's inability to engage in substantial gainful activity. Where for instance, an individual remains unemployed for a reason or reasons not due to his physical or mental impairment but because of the hiring practices of certain employers, technological changes in the industry in which he has worked, or local or cyclical conditions, such individual may not be considered under a disability * * *"

Reflecting concern about the disability insurance benefit program and the way the definition was being interpreted by the courts, the 1967 amendments to the law clarified the definition of disability. This legislation emphasized the role of medical standards in determining disability by stating that an individual is not to be considered under a disability unless the individual's impairment is of such severity that he or she is not only unable to do his or her previous work but cannot (considering his or her age, education, and work experience) engage in any other kind of substantial gainful work which exists in the national economy.

Specifically, the statutory definition of disability in section 223 of the Act was amended by the 1967 amendments to read, in pertinent part, as follows:

"(d)(1) the term 'disability' means—

"(A) Inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months; or

"(B) [Blindness].

"(2) For purposes of paragraph (1)(A)—

"(A) An individual (except a widow, surviving divorced wife, or widower for purposes of section 202 (e) or (f)) shall be determined to be under a disability *only if his physical or mental impairment or impairments are of such severity that he is not only unable to do his previous work but cannot, considering his age, education, and work experience, engage in any kind of substantial gainful work which exists in the national economy,* regardless of whether such work exists in the immediate area in which he lives, or whether a specific job vacancy exists for him, or whether he would be hired if he applied for work. For purposes of the preceding sentence (with respect to any individual), 'work which exists in the national economy' means work which exists in significant numbers either in the region where such individual lives or in several regions of the country. (Emphasis added.)

* * * * *

"(3) For purposes of this subsection, a 'physical or mental impairment' is an impairment that results from anatomical, physiological, or psychological abnormalities which are demonstrable by medically acceptable clinical and laboratory diagnostic techniques.

* * * * *

"(5) An individual shall not be considered to be under a disability unless he furnishes such medical and other evidence of the existence thereof as the Secretary may require." (Section 158(b), Pub. L. 90-248, January 2, 1968, 81 Stat. 821.)

The legislative history of this amendment indicates that the Congress clearly intended that medical factors be given predominant importance in making disability determinations. The House Report (H.R. Rep. No. 544, 90th Cong., 1st sess. (1967)) states, at page 30:

"* * * In most cases the decision that an individual is disabled can be made solely on the basis that his impairment or impairments are of a level of severity (as determined by the Secretary) to be sufficient so that, in the absence of an actual demonstration of ability to engage in substantial gainful activity, it may be presumed that he is unable to so engage *because* of the impairment or impairments." (Emphasis in original.)

Further, for the first time, Congress specifically alluded to vocational factors in the statutory language (223(d)(2)(A)) and provided guidance as to their applicability. In discussing the factors which must be applied to individuals whose medical impairments are not of a sufficient level of severity so that the presumption of disability would apply, the House Report went on to state, at page 30:

"* * * that such an individual would be disabled only if it is shown that he has a severe medically determinable physical or mental impairment or impairments; that if, despite his impairment or impairments, an individual still can do his previous work, he is not under a disability; and that if, considering the severity of his impairment together with his age, education, and experience, he has the ability to engage in some other type of substantial gainful work that exists in the national economy even though he can no longer do his previous work, he also is not under a disability regardless of whether or not such work exists in the general area in which he lives or whether he would be hired to do such work. It is not intended, however, that a type of job which exists only in very limited numbers or in relatively few geographic locations would be considered as existing in the national economy. While such factors as whether the work he could do exists in his local area, or whether there are job openings, or whether he would or would not actually be hired may be pertinent in relation to other forms of protection, they may not be used as a basis for finding an individual to be disabled under this definition. It is, and has been, the intent of the statute to provide a definition of disability which can be applied with uniformity and consistency throughout the nation, without regard to where a particular individual may reside, to local hiring practices or employer preferences or to the state of the local or national economy."

Except for the existing appendix to the regulations listing specific medical impairments which are presumptive of disability due to the severity involved, the existing regulations have provided general guidance in the determination of disability. They have been supported by a wide array of specific administrative materials which have been used primarily at the initial and reconsideration levels in the making of each decision. Such materials (provided primarily from surveys of industry by the Department of Labor, the Bureau of

the Census and State employment services) include a variety of specific, published documentations of jobs existing in the local and national economy and specific physical, mental and skill requirements of such jobs (e.g., the *County Business Patterns*, published by the Bureau of the Census, which show distribution of employment in the United States by locality and by industry; the *Census Reports*, published by the Bureau of the Census, which give detailed characteristics of the working population on a national, regional, and local level; occupational analyses of light and sedentary jobs prepared for the Social Security Administration by various State employment agencies; the *Occupational Outlook Handbook*, published by the Bureau of Labor Statistics, which shows the nature of work, the training and other qualifications needed and working conditions and employment outlook for certain occupations; and the third edition of the *Dictionary of Occupational Titles*, published by the Department of Labor, which provides job definitions, requirements, worker traits, industry designations and indicators of skills). Thus, the relationship between the physical abilities of specific individuals and the physical, mental, and skill requirements of specific jobs available in the national economy has been administratively determined. The administrative notice which is taken of the mentioned reference materials is based on the fact that they are generally recognized in business, industry, and government as representing authoritative sources on jobs throughout the national economy. As later editions are published, e.g., the fourth edition of the *Dictionary of Occupational Titles* now being prepared by the Department of Labor, they will be used in the same manner.

Consistent with the definition of disability prescribed by the law and regulations, and the relationship between the physical abilities of specific individuals and the physical, mental, and skill requirements of specific jobs available in the national economy, detailed guides for determining whether disability exists have been developed by the Social Security Administration and have been provided in the form of administrative issuances at the initial and reconsideration levels for use in the adjudication of each case. Hundreds of thousands of such cases are adjudicated each year under these evaluation guides. These guides are now being incorporated into the regulations as rules. Their publication in this form will facilitate a sound determination of disability in those cases where the vocational impact of age, education, and work experience must be assessed in conjunction with the severity of an individual's medical impairment(s), better assure consistency of determinations, and better serve to advise the public, adjudicatory personnel within the Social Security Administration, and the courts, of the specific rules followed by the Social Security Administration.

This need for publication of additional, more definitive medical vocational rules has been further heightened by the advent of the recent title XVI (Supplemental Security Income) legislation, which introduced into general adjudicative consideration for the first time, a factor not normally present in the title II disability program—the vocational impact upon adult individuals who have no relevant work experience.

Under title II, the "insured status" requirement, which applies to most disability claimants, requires that the claimant have a significant and recent work history covered under the title II program. Under title XVI, the same test of disability is used as under title II, but the collateral requirements are directed to financial need rather than participation in a work-related contributory system. Therefore, needy disabled individuals may qualify under title XVI even if they have no work history.

Amendments Expanding the Regulations

General

For consistency with the statutory definition of disability, the regulations contain a technical clarification of the language in Regulations No. 4 and Regulations No. 16 to reflect that an impairment that is "not severe" would support a finding that an individual is not disabled.

The regulations specifically define the adjudicative weight to be given to impairment severity, age, education, and work experience. They emphasize that the adjudicative judgment is to be based on consideration of the interaction of all of the individual factors. They also add a new Appendix 2 which is composed of rules that reflect the major functional and vocational patterns that are encountered in cases where an individual with a severe medically determinable physical or mental impairment(s) is not engaging in substantial gainful activity and the individual's impairment(s) prevents the performance of his or her vocationally relevant past work. The rules in Appendix 2 also reflect the analysis of the various vocational factors in combination with the individual's residual functional capacity in evaluating the individual's ability to engage in substantial gainful activity in other than vocationally relevant past work.

These rules are not presumptive, but are conclusive where the necessary findings with regard to each individual establish that a particular rule is met. That is, where the findings of fact made with respect to a particular individual's vocational factors and residual functional capacity coincide with all of the criteria of a particular rule, the rule directs a conclusion as to whether the individual is or is not disabled. However, these individual findings of fact are subject to rebuttal and the individual may present evidence to refute the findings. Where any one of the findings of fact does not coincide with the corresponding criterion of a rule, the rule does not apply in that particular case and, accordingly, does not direct a conclusion.

Because the rules consider only impairments which result in exertional limitations, they are not applicable where an individual's impairment(s) causes only non-exertional limitations, e.g., certain mental, sensory, or skin impairments. Further, the rules may not apply where a combination of impairments significantly limits the range of work an individual can perform at a given exertional level; nor do the rules apply where a finding of fact concerning age, education, or work experience differs from the vocational characteristics covered by a rule. The rules, however, are useful as adjudicative guides in considering borderline cases and cases involving combinations of impairments. In any case where a rule does not apply, full consideration must be given to all the facts of the case in accordance with the definitions and discussions of each factor in the regulations.

The criteria are considered in appropriate sequence in the context of the overall disability sequential evaluation process. This sequence, conforming to existing social security regulations, and left substantially unchanged by the amendments, is applied in the following manner.

1. *Determinations based on an individual engaging in substantial gainful activity.*

Where an individual is actually engaging in substantial gainful activity, a finding will be made that the individual is not under a disability without consideration of either medical or vocational factors.

2. *Determinations based solely on the medical severity of impairments.*

a. Medical considerations alone can justify a finding that the individual is not under a disability where the medically determinable physical or mental impairment(s) is not severe, e.g., does not significantly limit the individual's physical or mental capacity to perform basic work-related functions.

b. On the other hand, medical consideration alone would justify a finding of disability where:

(i) The impairment meets the duration requirement (i.e., is expected to

last at least 12 months or result in death);

(ii) The impairment meets or equals the severity of a listed impairment published in the Appendix (now designated "Appendix") of the disability regulations; and

(iii) Other evidence does not rebut a finding of disability, e.g., the individual is not actually engaging in substantial gainful activity.

3. *Determinations based on vocational as well as medical considerations.*

a. Where an individual with a marginal education and long work experience (e.g., 35 to 40 years or more) limited to the performance of arduous unskilled physical labor, is not working and is no longer able to perform such labor because of a significant impairment or impairments, the individual may be found to be under a disability.

b. Where a finding of disability (or its absence) is not made under any of the foregoing steps, the individual's impairment(s) is evaluated in terms of physical and mental demands of the individual's past relevant work. If the impairment(s) does not prevent the performance of past relevant work, disability will be found not to exist.

c. If an individual cannot perform his or her past relevant work but the individual's physical and mental capacities are consistent with his or her meeting the demands of a significant number of jobs in the national economy and the individual has the vocational capabilities (considering his or her age, education, and past work experience) to make an adjustment to work different from that which the individual has performed in the past, it will be determined that the individual is not under a disability. However, if the individual's physical and mental capacities in conjunction with his or her vocational capabilities (considering his or her age, education, and work experience) are not consistent with making an adjustment to work differing from that which the individual has performed in the past, it will be determined that the individual is under a disability.

The amendments and the addition of Appendix 2 primarily concern the last two steps of the process (3 b and c above) and principally the last step (3c above). They provide a logical sequence for evaluating disability within the last step the step where it is necessary to evaluate the impact of the individual's severe impairment(s) in conjunction with his or her vocational profile (i.e., age, education, and work experience). These rules apply only after a determination has been made that the individual's impairment(s), although severe, does not meet or equal the listing of impairments in Appendix 1 and the individual is unable to perform past relevant work. Moreover, the rules apply only after the impairments have been translated into the individual's physical and mental ability to perform functions necessary for the performance of work.

In the determination of the individual's impairments and ability to function, all medical evidence is evaluated. The individual has the burden of proving his or her case by furnishing evidence of disability, but all evidence adduced in the case from any source is fully considered. If, however, nothing in the evidence raises a question regarding a particular impairment or function, such as seeing or hearing, the individual is considered to be able, in that respect, to perform work activities.

The amendments focus on the vocational factors of age, education, and work experience. They are premised on the necessity to adjudicate each case individually to determine what work a specific individual is able to do. This includes a specific consideration of the individual's vocational profile. In making determinations of disability, administrative notice is taken of authoritative publications and studies which identify the kinds and numbers of jobs that exist in the national economy and their skill and exertional requirements.

Most sources not connected with the Social Security Administration which deal with the vocational implications of limitations resulting from impairments, age, education, and work experience do so from the standpoint of job placement rather than the social security concept of disability, which is concerned with the physical and mental ability to engage in jobs that exist. Such sources entail consideration of elements such as employer hiring practices which the law excludes from consideration in social security disability adjudication. Thus, most of their findings are not directly applicable. Such data do, however, provide an overview of the realities of the labor market and some specific reference points that can be utilized. The extensive experience of the Social Security Administration is also used as a basis for consideration of vocational factors.

Recognizing the primary importance of the individual's impairment(s) and any limitations resulting therefrom, the amendments require first that sound professional judgments be made as to an individual's residual functional capacity. Then, a reliable basis is needed to relate the individual's resiual, functional capacity to what he or she could be expected to do in terms of work at various exertional levels. The individual has the burden of proving that he or she is disabled and where no issue is raised by his or her allegations or the evidence adduced as to specific physical or mental capacities, findings as to such capacities are not required.

In order to consider the individual's residual functional capacity in terms of the level of work his or her exertional capabilities would represent, the definitions of sedentary, light, medium, heavy and very heavy work are use as those terms are defined in the third edition of the *Dictionary of Occupational Titles* published by the Department of Labor. This provides a "bridge" between assessment of residual functional capacity and the identification of ranges of work and types of jobs that remain within the individual's functional capabilities. The rules attach vocational significance to the functional capability for various ranges of work in terms of the relative numbers of jobs represented by the various capabilities.

The functional ability to perform heavy work, which includes the functional capability for work at all of the lesser functional levels as well, indicates the functional capability for almost all work that is listed in the third edition of the *Dictionary of Occupational Titles.* The functional ability to perform very heavy work includes the functional capability for all work that is listed in the third edition of the *Dictionary of Occupational Titles.*

The functional capacity to perform medium work includes the functional capacity to perform sedentary, light, and medium work and indicates a substantial work capability. Approximately 2,500 separate unskilled sedentary, light and medium occupations are identified in the *Selected Characteristics of Occupations,* a supplement to the third edition of the *Dictionary of Occupational Titles.* Each occupation represents numerous jobs found throughout the national economy.

The functional ability to perform a full or wide range of light work represents substantial work capability in diverse jobs and industries at all skill levels. Approximately 1,600 separate unskilled light and sedentary occupations can be identified in the *Supplement to the Dictionary of Occupational Titles* (third edition), each occupation representing numerous jobs found throughout the national economy.

Most sedentary occupations are skilled or semi-skilled, and fall within the professional, administrative, technical, clerical, machine trade, and benchwork classifications. There are also approximately 200 separate unskilled sedentary occupations which can be identified in the *Supplement to the Dictionary of Occupational Titles* (third edition), each occupation representing numerous jobs found throughout the national economy. While sed-

entary work represents a significantly restricted range of work, this range itself is not so restricted as to negate work capability for substantial gainful activity. As with the other factors, the functional level of work which an individual can perform is not, in itself, determinative of disability but must be considered in conjunction with the individual's age, education and work experience.

Appendix 2 considers the functional level of work which an individual can perform in relation to the individual's age, education, and work experience. Various combinations of these functions are arranged to direct a conclusion as to whether the individual is disabled. Where findings of fact as to the individual's remaining functional capacity, age, education and work experience coincide with the criteria of a specific rule, the indicated conclusion obtains. Where any one of the individual findings of fact does not coincide with a criterion specified in a particular rule, the rule does not apply in that particular case and, therefore, does not direct a conclusion of disabled or not disabled. In those instances the Appendix 2 rules will provide a guide for decisionmaking along with the discussions of each factor in the body of the regulations.

If it is found that an individual does not have the physical-mental capacity to perform work even at a sedentary level—the level requiring the least exertion—disability will be determined to exist, absent specific evidence to the contrary (e.g., the individual is working in substantial gainful activity). (In such a situation, the individual should ordinarily have been determined to be disabled based solely on consideration of the medical severity of impairment under Step 2b in the sequential process described above.) If, on the other hand it is found that the individual, although severely impaired, does have the physical-mental capacity to perform work at some exertional level (i.e., sedentary through heavy), consideration then must be given, as provided in the law, to whether "jobs exist in the national economy" that are within the individual's capability, considering his or her residual functional capacity in the light of his or her age, education, and work experience.

As previously set out, the law provides that "jobs exist in the national economy" when they exist in significant numbers either in the region where an individual lives or in several regions of the country. Further, in defining what constitutes disability, under sections 223(d) and 1614(a)(3) of the Social Security Act, the Congressional intent is that where an individual's physical or mental impairment(s) and his or her age, education, and past work experience are compatible with the performance of substantial gainful activity, the individual cannot be considered under a disability because he or she is unsuccessful in obtaining work he or she can do; or because work he or she could do does not exist in his or her local area; or because of the hiring practices of employers, technological changes in the industry in which the individual has worked, or cyclical economic conditions; or because there are no job openings for the individual or the individual would not actually be hired to do work he or she could otherwise perform. On the other hand, an individual may be determined to be under a disability if the individual's physical or mental impairments are of such severity that the individual is not only unable to do his or her previous work but cannot, considering his or her age, education, and work experience, engage in any other kind of substantial gainful work which exists in the national economy.

In view of the provisions of the law and data which show that significant numbers of unskilled jobs do exist in the "national economy" at each of the levels of required exertion from sedentary through heavy and very heavy, an individual would not meet the requirements for disability if the individual has the residual functional capacity to do work at any of these levels and the individual's vocational capabilities, considering his or her age, education, and work experience, are not so adverse as to preclude his or her ability to engage in such work. Thus, for example, an individual who retains the physical ability to do a wide range of light work, who is not of advanced age, and is able to communicate, read, and write on an elementary level, would generally be considered to still be in the competitive labor market for light, unskilled work, despite the absence of special experience or skills. This is a longstanding guide used by social security disability program adjudicators and has been available in administrative issuances.

Within the context of the preceding discussion concerning the overall impact of vocational considerations in assessing disability, the expanded regulations also provide specific rules for assessing each of the vocational factors of age, education, and work experience. The bases for these rules are discussed below:

AGE

Reference sources and materials dealing with chronological age in terms of vocational relationship deal principally with employment and rehabilitation activities, basing their conclusions mainly on the rate of participation in the labor force, the unemployment rate, duration of unemployment, and the proportion of hires to applicants. It appears from such materials that the "older worker" is usually considered as an individual 45 years of age and older. See, for example *"Services to Older Workers"* by the Public Employment Service (May 1957), page 9; *Training and Employment of the Older Worker, Recent Findings and Recommendations Based on Older Worker Experimental and Demonstration Projects* by Sarah F. Leiter (February 1968), page 1 and 2; *The Productive Years Age 45-65* (undated) published by the National Association of Manufacturers; *Meeting the Manpower Challenge of the Sixties with 40-plus Workers,* a November 1960 Department of Labor publication, page 12.

It is further noted in publications that age 55 represents a critical point in the attempts of "older workers" to obtain employment. See, for example, *A Survey of the Employment of Older Workers* (1965) by the State of California, Department of Employment and Citizens' Advisory Committee on Aging, page 96; *The Vocational Adjustment of the Older Disabled Worker, A Selective Review of the Recent Literature,* by Herbert Rusalen, Ed. D (a study for the Vocational Rehabilitation Administration), pages 9, 10, and 12; *Services to Older Workers* by the Public Employment Service (May 1957).

In viewing the overall implications of the data in the sources cited, it must be recognized that there is a direct relationship between age and the likelihood of employment. However, the statutory definition of disability provides specifically that vocational factors must be viewed in terms of their effect on the ability to perform jobs rather than the ability to obtain jobs—in essence, in terms of how the progressive deteriorative changes which occur as individuals get older affect their vocational capacities to perform jobs. Since no data or sources are available which relate varing specific chronological ages to specific vocational limitations for performing jobs, it has been necessary to analyze and interpret the available age—employment data to ascertain a point where it would be realistic to ascribe vocational limitations based on chronological age.

Prior experience of the Social Security Administration in determining when age makes a difference in disability determinations has also been considered, e.g., as shown in the *Social Security Disability Applicant Statistics/1970* published by the U.S. Department of Health, Education, and Welfare, Social Security Administration, Office of Research and Statistics, September 1974, as well as the Veter-

ans Administration Schedul› for rating disabilities (38 CFR 4.17).

In this respect, while the data reflect employment problems as developing at age 45, they recognize that this problem becomes significantly intensified at age 55. It is at this point, age 55, where it can reasonably be anticipated, therefore, that the deteriorative changes which occur in older persons which affect vocational capacities would most likely occur. Further, the vocational adversity of age 55 was recognized in *Report of the 1971 Advisory Council on Social Security* published by the U.S. Government Printing Office, April 5, 1971; and age 55 has already gained Congressional recognition in legislation establishing special provisions for disability because of blindness (see section 223(d)(1)(B) of the Social Security Act).

Thus, from the standpoint of chronological age, the proposed amendments reflect age 55 and over as advanced age representing the point when age could be expected to be an adverse consideration in determining an individual's vocational adaptability to work differing from that of his or her past experience. This designation of age is an expectancy only and not an arbitrary limit and may not be crucial in a particular case. Indeed, whatever disadvantage "advanced age" may have generally may be offset in a specific case by an advantage such as skills or training. Further, no general application or inferences are intended regarding employer hiring practices with respect to age. (The Age Discrimination in Employment Act of 1967 prohibits discrimination in hiring practices because of age.) As noted earlier, employer hiring practices, regardless of their legality, are excluded from consideration in social security disability adjudication. The ultimate finding of whether an individual of advanced age can or cannot reasonably be expected to adjust to work other than that which the individual has performed in the past, is dependent upon an evaluation of the extent of the individual's limitations resulting from medically determinable impairments in interaction with his or her age, education, training, past work experience (or lack of work experience), and skills.

In addition, these amendments take cognizance of the fact that the vocational impact of age does not abruptly change from a favorable to an adverse vocational consideration precisely at the point of attaining age 55. Therefore, the proposed amendments provide for consideration of a lesser, but nevertheless significant, degree of vocational adversity as advanced age is approached. The chronological ages shown in the Appendix 2 Rules (45, 50, 55, 60) as representative of the increasing adversity of age within the scope of consideration of this factor in social security disability adjudication are intended as specific indicators, but are not intended to be applied mechanically in borderline situations.

EDUCATION

Formal education is given adjudicative weight to the extent that it relates to an individual's ability to meet reasoning abilities, language, and arithmetical requirements of jobs. Reasoning ability would affect the individual's ability to follow instructions and make judgments in a work situation. Language competence relates to ability to read, write, and speak. The inability to meet the language requirements at an elementary level would restrict even the number of unskilled jobs a person would be able to do. Similarly, the inability to perform simple calculations in addition and subtraction would represent vocational restrictions in performing some unskilled jobs. On the other hand, the *Dictionary of Occupational Titles*, third edition, and particularly the supplement thereto, *Selected Characteristics of Occupations* published by the Department of Labor, reflects that individuals with basic competences in speaking, reading, writing, and making simple calculations do have the educational capabilities for performing unskilled work. The *Occupational Outlook Handbook*, published by the Bureau of Labor Statistics (page 778, 1970–1971 edition and page 764, 1974–1975 edition), also reflects that people who have less than a high school education and no previous experience often can qualify for unskilled jobs. Other materials indicate similar correlations and reflect that employability tends to increase with education. See, for example, in the *Occupational Outlook Handbook*, published by the Bureau of Labor Statistics (1974–1975 edition), the section within each occupational listing entitled "Training, Other Qualifications, and Advancement," for example, see page 764; *The Long Term Unemployed, Educational Attainment* (October 1964) published by the Manpower Administration of the Department of Labor in cooperation with the Oklahoma Employment Security Commissioner (pages vi, and 18); *Monthly Labor Review* of January 1974, an article entitled "Educational Attainment of Workers, March 1973" (pages 58–61); Automation Manpower Services Program Report by the New Jersey State Employment Service entitled *"The 'Mack' Worker, The Impact of His Job Loss 2½ Years Later* (December 1965) (pages 14 and 15); *A Survey of the Employment of Older Workers* (1965) by the State of California Department of Employment and Citizens' Advisory Committee on Aging; *The Impact of Technological Change in the Meatpacking Industry*, published by the Division of Employment, Department of Labor in March 1966 (page 16). Illiteracy as an adverse factor has also been discussed in certain sources (e.g., *Rehabilitation of the Aging* prepared by Portland State College under auspices of Vocational Rehabilitation; *Monthly Labor Review*, September 1972, an article titled "How Employers Screen Disadvantaged Job Applicants").

An education of high school level or above may serve as a partial substitute for loss of physical capacity, i.e., better educated individuals are more likely to be engaged in sedentary and professional jobs. Thus, they are not as likely to apply for benefits or to be classified as disabled. In support of this, the data do not show the better educated to be heavily represented among the disabled; see, for example, Social Security Disability Applicant Statistics/1970, DHEW Pub. No. (SSA) 75–11911, pages 45, 46, 47, tables 18, 19, and 20.

In viewing the overall implications of the data in the sources cited, it must be recognized that there is a direct relationship between the level of education attained and the likelihood of employment. These sources indicate that young people who have less than a high school education and no previous work experience often can only qualify for employment in unskilled jobs such as kitchen workers, dishwashers, or construction laborers. Also, it is noted that individuals with the least schooling tend to have the most unemployment. In the blue collar classification, skilled workers tend to have a higher educational attainment than semi-skilled workers. In the white collar classification, most employees are high school graduates. Additionally, upon becoming unemployed or laid off, individuals with at least a high school education have better success in finding new employment. As a corollary, the chronically unemployed tend to be functional illiterates since most employers require that prospective employees at least be able to read and write. This is true even in the case of some unskilled work.

Thus, it can be seen that employability tends to increase and unemployment tends to decrease as the level of education increases. Increasing adaptability to changing working conditions and acquisition of more readily transferable skills occurs with increased education. Further, individuals who lack an adequate education, especially if they are illiterate, may be excluded from consideration for jobs which require a specified minimal educational background, even though these individuals might meet all other job quali-

fications. In considering the impact of education in social security disability adjudication, judgments must be made beyond the mere use of the number of grades of formal schooling an individual has achieved. In applying the Rules in Appendix 2, the factor of education must represent the individual's demonstrated competences in addition to or instead of a particular number of years of formal schooling or a lack of formal schooling.

WORK EXPERIENCE

An individual's past work experience is considered as demonstrating most persuasively the kinds of work and skill level at which an individual is qualified to perform. In the regulations, previous experience, particularly if it resulted in work skills that are transferable to other jobs, is treated as a substantial vocational asset in accordance with sources which reflect that workers with skills tend to have fewer and shorter periods of unemployment, and that skilled workers are often in demand even at age levels when some workers without acquired skills are experiencing difficulty in the labor market. Some of these sources are: *Counseling and Placement Services for Older Workers* (September 1956) published by the Department of Labor, Page 4, Section C.2.c; page 12, No. 14; page 15, No. 8, page 77, Section H.1; *A Survey of the Employment of Older Workers 1964,* published by the State of California, Department of Employment and Citizens' Committee on Aging, Page 9, Section B.1; Page 10, under the heading "Experience"; Page 49, Section A.; Page 70, Section 2.a.; and *Services to Older Workers* by the Public Employment Service (May 1957), published by the U.S. Department of Labor; Page 7, Section C. However, to be under a disability an individual must not only be unable to do his or her customary work but also must be unable to do any other kind of work that exists in significant numbers in the national economy. Although past work experience provides an individual with familiarity with certain work environments, as previously noted the third edition of the *Dictionary of Occupational Titles,* and other sources identify many unskilled jobs in the national economy at all levels of exertion which do not require skills or previous work experience, and even individuals without past work experience may vocationally qualify for such jobs. Notwithstanding this fact, the expanded regulations do recognize that where the applicant has had no prior work experience (a significant number of applicants for Supplemental Security Income benefits fall in this category) this is an adverse vocational factor which must be taken into consideration, particularly for individuals of advanced age.

PUBLIC COMMENTS

Over 2,800 comments have been received on these amendments following their publication as a notice of proposed rulemaking (NPRM) in the FEDERAL REGISTER, Volume 43, No. 45 on March 7, 1978, beginning at page 9284. Some of those who had comments were supportive of the regulations. Others feared that the substance of the amendments is new and intended primarily to deny benefits to disabled individuals in order to save trust fund moneys. The majority of commenters were concerned that the amendments represented new policies which were intended to pay many persons who would not now qualify for disability benefits, thereby adversely affecting program financing.

The policies, definitions and rules set out in the regulations reflect existing policies. We believe that the regulations will not have any significant effect on the current allowance-denial rates. Rather than abridge claimants' rights, the regulations will provide information about the applicable rules, and will promote more equitable, consistent and understandable decisions.

Many of the comments raised issues which were answered in the preamble to the NPRM published on March 7 (43 FR 9284). Since the issues in these comments were addressed in the NPRM and changes were made in response to the ones that were accepted, the repetitive comments are included in this preamble only where helpful in responding to new comments, or where there are significant variations. We regret, however, that some of the repeated comments reflect some misconceptions that have persisted despite frank discussions. Some additional changes have been made in the amendments as a result of the comments currently received. However, these are mostly of a clarifying nature and do not change the substance of the regulations. For example, several cross references to related disability regulations (including those concerning "substantial gainful activity") have been added and certain complex sections subdivided to make them more readily understood.

Because of the volume of comments, we have not provided individual responses. The following discussion sorts the comments into broad categories and responds to the issues raised.

I. *Public Perceptions of the Nature and Effect of the Regulations*

Issues

Several commenters requested that the regulations be withdrawn or extensively modified on the basis that "everyone has expressed opposition to their publication." Some continued to suggest that the Social Security Administration (SSA) was introducing at least a "limited" average man concept. Fears were also expressed that the regulations will cause a crisis in hearings, appeals and judicial review, leading to delays of decisions for claimants, and that administrative law judges (ALJ's) and other decisionmakers will make preconceived decisions. It was further suggested that additional instructional material will be needed for Federal and State adjudicators, new pamphlets for the public and more detailed notices of findings of not disabled at the initial and reconsideration levels.

Several said that it will become necessary for claimants to be represented by attorneys, while others believed that the regulations will encourage fraud, discourage people from self-improvement, and result in more findings of disabled for minority groups. Another writer asked what part of SSA's disability caseload will be affected by the regulations.

Response

The bulk of the public comments on the regulations have been from two distinct sources: (1) A coordinated response form claimant advocacy groups who fear that the regulations are intended to "deliberalize" the disability program at the expense of disabled persons in order to save trust fund moneys; and (2) a large response (over 2,500) generated by a syndicated newspaper column and related articles which pictured the regulations as a "liberalization" intended to pay benefits to nondisabled persons and thus cause the trust funds to go broke.

The two main groups of commenters, while both objecting to the proposed regulations, are on opposite sides regarding the direction they believe the disability program will and should take. Actually, the regulations as reflective of longstanding policies are neither intended nor expected to make the disability program more or less liberal. They are in accordance with the Social Security Act and legislative history, and intended only for the purposes set out in the NPRM.

Contrary to many of the commenters' concerns about "liberalization" of the program, the requirement of the law that a severe medically determinable impairment must be present for any finding of disability has not been changed. In fact, the regulations reemphasize the primary importance of the individual's impairment. These concerns arose mainly from newspaper articles which indicated that an inability to add and subtract, advanced age, inability to adjust to new work or inability to communicate

in English would replace consideration of a severe impairment to qualify persons for disability benefits. Since this information (upon which over 2,500 commenters relied) was faulty, this preamble does not include discussion of each of the items erroneously described as replacing a severe impairment as the basic requirement for disability benefits. However, these comments were not ignored. We individually considered and acknowledged all of the comments received, sent copies of the NPRM to those who requested them, and provided additional information in response to mail and telephone inquiries. It is hoped that these efforts have helped achieve a better understanding of the regulations.

Regarding "deliberalization" of the program, some of the continued fears about an "average man" approach in place of individualized adjudication appear to result from an emphasis on the tables in Appendix 2 to the exclusion of the rest of the regulations. These tables cannot be applied, and should not be read, out of context. The explanatory material, definitions and guides in the regulations must also be considered, and adjudication must proceed in a sequential manner as set out in the regulations. In following this sequence and considering all appropriate factors, individualized adjudication is assured as in the past.

ALJ's and other decision makers are aware that a person's impairments can worsen or improve with the passage of time and that thorough individual consideration of all applicable factors is necessary in each claim. Decision makers are expected to use the regulations as they are published, which will improve decision making rather than lead to pre-conceived decisions, or the disregarding of evidence or other misuse of the tables in Appendix 2.

As in the past when such major regulations as those on medical criteria and substantial gainful activity were issued, SSA will hold training sessions and publish instructions for personnel in the disability program, as well as issue any appropriate pamphlets or other materials for the general public and revise notices as appropriate.

These regulations do not address the basic medical aspects of disability evaluation, the nature and sufficiency of signs, symptoms and laboratory findings reported; these are at least as complex as vocational factors and are the basis of the assessment of the claimant's residual functional capacity which, in turn, provides the setting for evaluation of age, education and work experience. This is the same as before. However, the regulation set out and defined in a single source the longstanding guides for evaluating the vocational factors in context with the individual's residual functional capacity, making this material more readily available in detail to everyone.

Therefore, we do not agree that a person could not prosecute his or her own disability claim or would be likely, because of these regulations, to need attorney representation more than in the past. Further, the denial notice at each adjudicative level clearly informs the claimant of appeal rights and, if a claimant expresses interest in having representation, he or she is told about the right to be represented; how to appoint a representative; what a representative may do; and fee regulations.

While in the short run delays in claim processing could result if the courts decide to make wholesale remands, this would have to be dealt with at the appropriate time and the inconvenience to claimants minimized. Such possibilities are not unique to these regulations and do not obviate their need. Further, the regulations have a 90-day delayed effective date to help prepare for their implementation.

Previous publications of regulations setting out disability criteria, such as the medical listings and the substantial gainful activity (SGA) criteria, did not result in an increase in fraudulent statements by claimants or their representatives, and it is not anticipated that these regulations will either. Any significant increase in misstatements would result in a review of documentation policies. With respect to the possibility that the regulations will nurture of lack of motivation for a person to become better educated or skilled, it is emphasized that the presence of adverse vocational factors without a severe physical or mental impairment does not warrant a finding of disabled.

The longstanding policies for the adjudicative consideration of age, education and work experience apply equally in consideration of all individuals who are severely impaired. These policies, which reflect an individualized adjudicative approach, apply regardless of where a severely impaired person may live. Otherwise the disability program, which is national in scope, would not treat impaired persons living in different areas, or persons who might move to other areas, in the same manner. Each claimant will receive a determination that reflects the facts in his or her case. However, the regulation will help to assure consistent results for claimants with similiar factual situations.

We are aware that there have often been greater concentrations of individuals in particular areas or groups who may be more poorly educated, unable to communicate in English or less skilled, and that such individuals who are severely impaired may be more likely to be found disabled. However, they will not be paid disability benefits on the basis of their residence or cultural background, but on the basis of a severe impairment and the existence of adverse vocational factors. As stated in existing policies and as reflected in these regulations, *disabled individuals* are paid benefits regardless of where they live, from where they may have come, or how many other disabled individuals may have a similar background or residence. Examples of some areas in which greater numbers of persons with adverse nonmedical factors have been found in the past include Puerto Rico, some Indian reservations, parts of Alaska, Appalachia, cities where disadvantaged or newly arrived groups have congregated, and other urban and rural areas. The fact that SSA's policies have recognized these realities in the past would indicate no expected overall change in allowance/denial rates.

Figures were distributed at the public meetings which SSA held in Baltimore (41 FR 51471), Dallas, and San Francisco (42 FR 8223), about title II cases processed in Fiscal Year 1976 which show that, on the initial level, of 948,180 worker claims processed that year 91,969 individuals were found not disabled because they could do other work; while 116,088 were found disabled because they could not do other work. This is the type of case covered in these regulations. The remainder of the cases were decided on purely medical and other bases. Approximately the same distribution exists for other years.

II. *Procedures Used in Promulgating the Regulations*

Issues

Two writers stated that additional public meetings should be held to discuss the NPRM responses to the issues raised in public comments. Others asked for an additional extension of the public comment period. One commenter suggested that lower-ranking officials have been remiss in not presenting the views opposed to the regulations to the Commissioner of Social Security and the Under Secretary of HEW, and requested a meeting with them. Another writer noted that all questions and comments resulting from the public meetings and responded to in the NPRM were from individuals and groups who feared the regulations were more restrictive than past policies, and inquired if any attempt had been made to obtain comments from persons with the opposite view—that the regulations are more liberal and will, therefore, result in benefits being paid to more people than before.

Response

We have tried to obtain as much public imput over as broad a spectrum

as possible through publicizing the regulations and inviting comments. To this purpose, the public meetings held in Baltimore, Dallas, and San Francisco were announced in the FEDERAL REGISTER and in press releases, inviting everyone to attend and to provide comments. In addition, public comment periods were provided following the meetings. Since most of the persons who attended the meetings represented claimant advocacy groups, the comments addressed in the NPRM were largely in response to their concerns.

Publication of the NPRM with attendant publicity represented an additional effort to expose the proposed regulations to as much public scrutiny as possible, and to encourage everyone to submit any comments they might wish to make. The extension of the NPRM comment period for an additional 30 days to allow more time for public comments was also announced in the FEDERAL REGISTER (43 FR 19238) and in press releases. Further, representatives of groups opposed to the regulations have had access to SSA documents, and have met with the immediate staffs of both the Commissioner and Under Secretary. All views expressed during these meetings have been presented fully and accurately to top SSA and HEW staff.

Several changes were made in the NPRM as a result of views expressed in the public meeting and the written comments which were received thereafter. In light of more than ordinary efforts to seek and accommodate public participation, and since there have been no significant changes in the regulations on SSA's own motion after the public meetings, there is no present need for additional publicity, meetings or extensions of public comment period. We believe that full opportunity to comment has been offered, and that the full range of comments on these regulations has now been received and carefully considered.

III. *SAA's Experience, Data and Studies Used to Support the Regulations*

Issues

One commenter stated that SSA has misled the public about the regulations being merely an elaboration of longstanding policy, and that a new NPRM should be issued with deletions of any such references. Another commenter stated that the regulations have not been used in the past in any form which is entitled to any weight in rulemaking. Some writers suggested that SSA used references to experience as a substitute for data, evidence and careful study; and one requested an opportunity to cross-examine social security employees having knowledge of SSA's adjudicative experience and data relied upon in the proposed regulations.

In related questions, writers asked how quality control results were used in testing the regulations, and what data support the use of the 15 year period for consideration of an individual's past work. Also, some commenters repeated statements that scientific pretesting of the regulations should have been done.

Response

In promulgating these regulations, the Secretary is exercising statutory rulemaking authority to put into the regulations a construction that has existed for many years. While extensive background and experience is not required for such publications, SSA does, in fact, have considerable agency expertise developed over many years. Organizations and professions commonly recognize the value of experience even though it may not always be presented in statistical form.

Experience with the adjudicative policies set out and elaborated upon in the regulations is commonly held knowledge by thousands of past and present State and Federal employees who have worked in the social security disability program. Further, inspection of SSA files under the Freedom of Information Act showed the policy system reflected in the regulations to not be of recent origin. Accordingly, we do not believe that cross-examination of present SSA personnel as to experience or other subjects is either necessary or appropriate.

The data used in the evolution of the policies over the years are largely in the public domain. While data and reference materials have been used as appropriate, it must be borne in mind that SSA has had to create policy in several areas of the disability program that is different, by law, from other Governmental and private disability programs.

As stated in the NPRM, the 15-year period established as a limitation for considering past work is designated essentially as a safeguard in the interest of the disability claimant. While the law speaks only of "previous work," there is obviously some doubt that a claimant should be denied disability benefits on the basis that he or she could still functionally engage in some particular job held many years in the past, or because of skills he or she acquired at that time which have not been used since. The 15-year guide is a longstanding policy which was adopted many years ago during the evolution of the disability policy system, and has been followed since.

Continued suggestions that the regulations be pretested apparently resulted from beliefs that the regulations reflect new policies. While, as noted in the NPRM, we do not consider pretesting necessary because of expectations based on long experience, we plan to monitor the disability program to make sure there are no unforeseen effects. Quality control findings, which were noted during the evolution of the policy system will be a part of the monitoring effort.

One organization commissioned a study of the proposed regulations and submitted the study report as supporting their comments, including the major criticisms of the regulations which they and others have advanced. A thorough study by qualified SSA professionals revealed that the organization relied to some extent on faulty premises in making their comments. Thus most of the commissioned study conclusions were not applicable. The commissioning organization was provided directly with SSA's detailed analysis and discussion of the conclusions of the study. While the lengthy professional evaluation could not be readily included in this preamble, it is available upon request.

IV. *Definition of Impairments as "Not Severe"*

Issues

Several commenters questioned the use of the term "not severe." One suggested that the term indicates a change in the definition of disability, while another believed it could be seen as a device to limit entitlement. A writer stated that, instead of the negative wording, "A medically determinable impairment is not severe if it does not significantly limit an individual's physical or mental capacity to perform basic work-related functions," the definition should be given in the positive terms, "A severe impairment is one that significantly limits an individual's physical or mental capacity to perform basic work-related functions." Another commenter believed that it would be simpler to say that an individual can be found not disabled on medical considerations alone when the impairment does not prevent heavy work.

Still another writer, not questioning the concept itself, pointed out that in regulations sections 404.1502(a)/416.902(a), the phrase "absent evidence to the contrary" at the end of the sentence is misplaced and implies that, where medical considerations alone justify a finding of no disability, something other than medical evidence can justify a finding that an individual is under a disability.

Response

The definition, "A medically determinable impairment is not severe if it does not significantly limit an individual's physical or mental capacity to

perform basic work-related functions" is a clarification of the previous regulations terms "a slight neurosis, slight impairment of sight or hearing, or other slight abnormality or a combination of slight abnormalities." Both have a negative sense and are related to the requirement of the law that, for impairments to be disabling, they must be "of such severity" as to prevent the claimant from doing previous work and, considering age, education and work experience, prevent the individual from engaging in *any* kind of substantial gainful work which exists in the national economy. The discussion on pages 9296 and 9297 of the NPRM shows that there is no intention to alter the levels of severity for a finding of disabled or not disabled on the basis of medical considerations alone, or on the basis of medical and vocational considerations. Negative phrasing of this concept is more useful in evaluating disability than affirmative terms would be. With respect to the suggestion that a "not severe" impairment be defined as one that does not prevent heavy work, it cannot be adopted because such a definition would not pertain to loss of mental function and all other nonexertional impairments.

We are appreciative of the writer's calling our attention to the possible misconstruction that could occur of the wording in §§ 404.1502(a)/416.902(a), which has been changed to, "Medical evidence (i.e., signs, symptoms, and laboratory findings) alone can justify a finding that an individual is not under a disability, or absent evidence to the contrary, that an individual is under a disability."

V. *Consideration of Medical Factors before Consideration Is Given to Vocational Factors*

Issues

Several commenters stated that there should be no "gray areas" of disability decisions, that people are either disabled or not disabled, and that this can be determined on a medical basis alone, without considering age, education, and work experience. One commenter wished to have a definition of "erratic or irregular" as used in the preamble response on page 9299 of the NPRM. Another writer stated that pain should be considered a nonexertional impairment along with mental, sensory and skin impairments. Somewhat in the same vein, one commenter observed that, under case law, SSA must consider the claimant's subjective evidence not only of pain but also of his or her exertional abilities.

One writer was concerned that "evidence of record" as used in regulations sections 404.1505(a)/416.905(a) not be construed as preventing the testimony of witnessess at a hearing. Several commenters stated that the regulations are vague about the extent, if any, of their application to nonexertional impairments. One questioned whether the definitions of functional levels take any notice of particular functions that may be critical to one range of work but not another. Others questioned whether Appendix 2 rules are intended to apply if there are additional limitations such as in pushing, pulling, gripping, bending, stooping, etc.

Some commenters suggested that the regulations result in shifting the burden of proof from the Secretary to the claimant where the claimant has nonexertional impairments. Two writers believed that since, under title XVI, the Government will pay for medical evidence of record as well as for tests and consultative examinations, regulations sections 416.902 and 416.905 should be cross-referenced and expanded to include a detailed discussion of medical evidence.

Response

Under provisions of the law, medical considerations alone are the bases for determining whether disability exists for the statutorily blind; widows; widowers; surviving divorced wives; and children below age 18 under the supplemental security income program. For other disability applicants and beneficiaries, the law provides that age, education and work experience be considered. Thus, where a decision cannot be made on medical factors alone these regulations set forth the guides and rules to be used to arrive at a finding of disabled or not disabled considering age, education and work experience in conjuction with the person's residual physical and mental capacities.

The phrase "the capacity for such functions only on an erratic or irregular basis," on page 9299 of the NPRM, relates to the heading, "Residual functional capacity, maximum sustained work capability," of Tables No. 1, 2, and 3 in Appendix 2. An erratic or irregular basis refers to a person's *inability to sustain* work-related activities in terms of an ordinary work day on a continuous day-to-day basis.

In regulations §§ 404.1501(c)/416.901(c) which are not being amended at this time a physical or mental impairment is defined as "an impairment that results from anatomical, physiological or psychological abnormalities which are demonstrable by medically acceptable clinical and laboratory diagnostic techniques. Statements of the applicant, including his own description of his impairment (symptoms) are, alone, insufficient to establish the presence of a physical or mental impairment." Signs and laboratory findings must be considered together with symptoms in determining the nature and extent of an impairment, as explained in previous regulations §§ 404.1506/416.906, now renumbered §§ 404.1517/416.917. Symptoms such as pain, fatigue and shortness of breath enter into evaluation under the Listing of Impairments in Appendix 1 and are also considered when determining a claimant's residual functional capacity for use in a medical-vocational decision. Thus, pain and other symptoms are constituents of an impairment, not impairments by themselves, and are given recognition in Tables No. 1, 2 and 3 in Appendix 2, as elements of residual functional capacity when the impairment with which they are associated is one that limits exertional capability to sedentary, light or medium work. Guidelines are also provided for considering limitations within ranges of work, including any additional limitations imposed by nonexertional impairments.

"Evidence of record" as used in regulations §§ 404.1505(a)/416.905(a) is not meant to prevent the testimony of witnesses at a hearing, whether the subject is the claimant's symptoms or any other matter. Such a construction of intent is precluded by the regulations on hearings, particularly §§ 404.927/416.1441, 404.928/416.1442, 404.929/416.1443 and 404.934/416.1446.

Many commenters did not appear to have a clear understanding of SSA's use of the term "nonexertional impairment." Nonexertional limitations involve mental, sensory or skin impairments. Emvironmental restrictions such as the need to avoid moving machinery and unprotected elevations, avoid breathing certain fumes or dust, avoid contact with certain substances, or avoid extremes of heat or cold, significant temperature changes, high humidity, noise or vibration are also considered, as well as restrictions in postural or manipulative abilities. All limitations which result from medically determinable impairments are considered in assessing residual functional capacity as illustrated by the examples in § 201.00(h) of Appendix 2.

Where a person has nonexertional (or additional exertional) limitations, the ranges of work he or she can perform (sedentary to very heavy) are diminished by exclusion of the particular occupations or kinds of work within those ranges that entail use of the abilities which the person has lost. In some cases, the exclusion will have a negligible effect, still leaving a wide range of work capability within the functional level; while in others the range of possible work may become so narrowed that the claimant does not have a meaningful employment opportunity. Different types of functional loss may be more critical to some exertional levels than to others; e.g., loss

of fine dexterity would narrow the range of sedentary work much more than it would for light, medium or heavy work. In the absence of such other limiting factors, it is presumed that an individual can also do all lesser ranges of work.

Nonexertional limitations are discussed in §§ 404.1505(c),(d)/416.905(c), (d) and 404.1511(b)/416.911(b) of the regulations as well as §§ 200.00(d), (e), (1), (2) and 201.00(h) of Appendix 2. This particular area does not lend itself to a great degree of specificity, and judgments are required as in the past. For example, a claimant who would otherwise fully meet Rule 201.29 in Table No. 1 is also allergic to petroleum derivatives. He or she would be found not disabled on the basis of being able to do sedentary occupations except for those relatively few ones which require contact with or other hazardous exposure to petroleum derivatives. However, assuming the existence of several medically determinable nonexertional and environmental impairments, or even one critical to the performance of unskilled sedentary occupations in general, or a large number of specific occupations of that type, the same claimant may be found disabled.

A person with nonexertional impairments has no different burden of proving his or her claim than does another person with only exertional impairments. The burden of proof remains as established in case law and observed by SSA. Where the medical evidence establishes the claimant's inability to do vocationally relevant past work, the Secretary will continue to consider all the claimant's work-related physical and mental limitations, including those of a nonexertional nature, in determining what the claimant can do functionally and what occupational opportunities in the national economy—if any—there are for a person who can do only what the claimant can do.

We agree with the writers who suggested that regulations §§ 416.902 and 416.905 should be cross-referred to each other, as both relate to medical evidence and the Secretary's assistance in securing and paying for it. We have done this, as well as referencing them to §§ 416.924 and 416.927, which also relate to medical evidence under title XVI. However, expansion and elaboration upon medical evidentiary standards is not within the scope of these regulations.

VI. *Age as an Adjudicative Consideration*

Issues

Several commenters expressed the belief that the age criteria of 45, 50, 55, and 60 are arbitrary and rigid break-off points which will cause dramatic shifts in adjudicative results due to the passage of a few days or months. Having the same view, a writer stated that, when age has been critical to the decision of denial, the applicant should be notified to reapply for benefits upon reaching the critical age. Another commenter wrote that the use of these age criteria is unjust to some minority groups because the life spans of members of some minorities are shorter than the national average and, thus, these persons would not have an opportunity to qualify for disability benefits. In contrast, several writers believe that age 55 is too young to be defined as "advanced age," since most persons continue to work after age 55, and there is recent legislation raising the mandatory retirement age to 70.

Response

The discussion of age on page 9289 of the NPRM refers to the publications relied upon when policy was being formulated. As stated there, the "older worker" is usually considered as an individual 45 years of age and older, while age 55 represents a critical point in the attempts of "older workers" to obtain employment. At age 65, of course, the "older worker" can qualify for unreduced social security retirement benefits. Between these 10-year increments, the regulations include ages 50 and 60 resulting in a 5-year gradation of age distinctions which better recognizes progressive difficulties.

We acknowledge that there are no conclusive data which relate varying specific chronologial ages to specific physiologially-based vocational limitations for performing jobs; this was a pioneering effort by SSA due to the unique nature of its disability program. Although ages 45, 50, 55 and 60 may be considered by some as too sharply defined as points in a progression of increasing difficulties, the concept of adversity of the aging process for severely impaired persons approaching advanced or retirement age is not arbitrary. On the one hand, age may not be crucial in a particular case; on the other hand, where age is critical to a decision, recognition is taken of increasing physiological deterioration in the senses, joints, eye-hand coordination, reflexes, thinking processes, etc., which diminish a severely impaired person's aptitude for new learning and adaptation to new jobs.

With respect to the possibility of rigidity and dramatic shifts in adjudicative results due to the passage of a few days or months, we state on page 9289 of the NPRM that ages 45, 50, 55 and 60 are intended as specific indicators but are not intended to be applied mechanically in borderline situations; this was repeated on page 9300. SSA practice over the years, in fact, has been in agreement with the commenter that the passage of a few days or months before the attainment of a certain age should not preclude a favorable disability decision. In response to comments that the caution in the preamble should be included in the regulations, we have modified sections 404.1506/416.906 accordingly.

False expectations of entitlement to disability benefits could be raised if SSA were to notify denied applicants that they should routinely reapply upon nearing or attaining ages 45, 50, 55 and 60. It must be considered that future circumstances cannot be exactly forecast. While someone will now have a severe impairment and a vocational background that, combined with future attainment of a certain age would qualify him or her as disabled, the person may recover medically, may acquire new education or work skills, or may actually be engaging in substantial gainful activity by the time of attainment of the specified age. Notices sent to denied applicants would have to take these factors into account and, as in the past, advise the persons that they *may* be found disabled if they reapply.

We realize that life spans of some individuals—including members of some minority groups—are shorter than the national average. However, unlike retirement programs where benefits depend upon an individual's living to a particular age, the social security disability program is based on the severity of an individual's impairment—at any age. In fact, age is not considered at all in the bulk of initial allowances of disability benefits. These cases are decided on the severity of the impairment alone. Where it is necessary to consider age, it is one of three additional factors for consideration and is never, in itself, determinative of disability. The severity of an individual's impairment remains as the primary consideration, and must be the primary reason for the applicant to be unable to work.

While most persons continue to work after age 55 and some work until age 70 or beyond, these persons are usually unimpaired or not severely impaired. Contrary to some writers' fears, the regulations do not indicate that persons "fall apart" or are unable to work at age 55; neither do they suggest age 55 as a retirement age in conflict with the recent legislation on mandatory retirement. As discussed in the NPRM the use of age 55 relates only to the social security disability program and is not intended for use by other programs or for retirement plans.

VII. *Education as an Adjudicative Consideration*

Issues

Some commenters wrote that the regulations on education are defective in that they do not more clearly articulate the need for the adjudicator to closely examine asserted grade levels, and because they believe that persons with a high school diploma are treated as the equivalent of persons with university degrees. They are particularly concerned that an education received in a school with high academic standards and excellent resources will not be the equivalent of one obtained in a marginal school with inadequate resources; and that grade placement may not be a true indicator of grade-level achievement. The same commenters believe that data show only a straight-line progression between education and an ability to obtain and perform work; therefore, they suggest that the educational categories in the regulations are arbitrary, unreasonable, and dramatic critical demarcations.

Another writer was concerned that an overstated educational background, possibly due to a claimant's embarrassment at his or her actual educational level, could result in that person's being erroneously denied disability benefits. Two other commenters asked how many months or years could elapse between completion of a claimant's education and the date of adjudication for the education to be considered as "recently acquired."

Response

We do not believe that the educational categories are arbitrary or unreasonable. As previously explained on page 9290 of the NPRM, the cited published materials show that increasing adaptability to changing work conditions and acquisition or more readily transferable skills occur with increased education. It is important to observe that Tables No. 1, 2, and 3 in Appendix 2 do not contain specific grade levels but have terms ranging upward from illiterate to high school graduate or more. Explanatory material in §§ 404.1507/416.907 states that what is meant by a sixth grade level or less ("marginal education") is an education qualifying a person for no more than simple, unskilled types of jobs. A seventh through eleventh grade level ("limited education") is qualifying for some semi-skilled and skilled jobs; while high school education and above refers to such a level of competence in reasoning, arithmetic and language skills that the person can generally be expected to work at a semi-skilled through skilled level of job complexity. There is a correlation between these levels and the general educational development level figures used in the Dictionary of Occupational Titles (DOT) as one of the criteria in classifying occupational complexity.

SSA policy is and has been that asserted grade level is determinative only in the absence of evidence to the contrary. Demonstrated competences in work and daily living rather than a particular number of years of formal schooling (or no schooling) are the better adjudicative measure. Accordingly, where a claimant's file shows that he or she did not work or function at the asserted educational level, the adjudicator continues to be directed to determine the effective level of education, which may actually be higher or lower than stated. While regulations §§ 404.1507(a)/416.907(a) did refer to the kinds of responsibilities assumed when working, daily activities, hobbies, the results of testing and what the individual has done with his or education in a work context, we have acted on the commenter's suggestion to expand the regulations explanation of how to evaluate educational levels.

It was previously explained on page 9290 of the NPRM that, on the one hand, the chronically unemployed tend to be functional illiterates; and, on the other hand, upon becoming unemployed or laid off, individuals with at least a high school education have better success in finding new employment. We also observed that better-educated persons are more likely to be engaged in sedentary and professional jobs, are not as likely to apply for benefits or to be classified as disabled and, in fact, are not heavily represented among the disabled. A corollary is that, while functional illiterates are unlikely to have transferable work skills, better-educated persons would tend to have such skills, and decisions on their disability claims would often depend more on past work and acquired skills than on the level of education. In these respects, therefore, a high school graduate and a university graduate ordinarily have a similar advantage in being able to learn and do a new unskilled job, although the university graduate may have more transferable skills to assist in his or her change to a job which is compatible with lessened functional capacity.

Judgments must be made in some areas of disability evaluation, medical as well as vocational, as they always have. Because assessments are made of each appropriate factor for each claimant, the individual circumstances cannot always be anticipated with precision, and specific guides set. "Recently completed education," as discussed in § 201.00(d) of Appendix 2, refers to the *rare* situation where a claimant of advanced age has recently completed education which provides a basis for direct entry into skilled sedentary work (this circumstance is taken into account in Tables No. 2 and 3, as well as in Table No. 1). Here, there is a requirement of skilled educational content qualifying a person immediately to begin a specific skilled job, as opposed to the competences in reasoning, communicating and calculating referred to in regulations §§ 404.1507/416.907. The immediacy of the person's ability to enter a job establishes that his or her education has current application. Where such education is footnoted in the tables, and a decision depends on the factor, there should be very little time lapse.

VIII. *Work Experience and Job Existence as Adjudicative Considerations*

Issues

Many commenters expressed their beliefs that only persons with work experience who have contributed tax payments for social security should receive benefits from the trust funds. One writer cited the financial and physical inability of many persons to move and secure jobs in the continental United States, and suggested that the "national economy test" should not apply to such noncontiguous areas as Alaska, Hawaii, Puerto Rico, Guam, American Samoa, the Trust Territory of the Pacific, and the Virgin Islands.

Two commenters were concerned about the intention of the words "majority of jobs within a particular range of work" on page 9300 of the NPRM. They observed that Rule 203.00 in Appendix 2 states that approximately 2,500 separate unskilled sedentary, light and medium occupations can be identified as existing in the national economy. They suggested that this could mean that the Secretary would need to show that a not disabled claimant with the exertional capacity for medium work could do 1,251 occupations, the majority of 2,500. Another person wrote that by not identifying the 2,5000 occupations of which administrative notice is taken, and other occupations, SSA prevents a necessary assessment of transferability of skills from taking place.

Some commenters stated that the regulations are already dated in that they rely to a large extent on the 1966 (third) edition of the Dictionary of Occupational Titles rather than the recently published fourth edition. They requested a detailed analysis of the new DOT before issuance of the regulations and notice to interested parties of the results of the evaluation, particularly if changes in the DOT warrant restructuring of the regulations. Another individual wrote that the regulations should consider the realities of the changing economy which provide an increasingly better chance for imparied persons to earn a livelihood as opportunities in the service indus-

try increase and work is made physically easier through automation.

One writer questioned whether administrative notice of job existence in the national economy precludes rebuttal of decisions based on specific rules in Appendix 2. Several commenters questioned the basis for and use of the guides for determining transferability of work skills. They requested the meaning of the term "occupationally significant work functions," asked what other factors are involved, and wanted to know how an adjudicator would decide whether there is a transferability of skills from a dishwasher to a chemist in view of the fact that both handle glassware in their work. Other writers stated that the regulations do not clarify the degree to which Administrative Law Judges (ALJs) are to determine whether a claimant's past work was unskilled, semiskilled, or skilled, whether skills can be transferred, and to which occupations the skills can be transferred.

Response

Benefit payments from the disability trust fund are made only where workers have had sufficient work credits to insure them for disability protection. In the event that a person has insufficient or no work credits, and he or she applies for and receives disability benefits under the supplemental security income program (title XVI), payments are made from general revenues.

One of the considerations in the definition of disability in sections 223(d)(2)(A) and 1614(a)(3)(B) of the Social Security Act is a claimant's ability (or inability) to do work "which exists in the national economy." Congress intended to have a definition of disability which could be uniformly and consistently applied throughout the Nation without regard to the place of an individual's residence. Legislative intent has also been to have a clear distinction between inability to *do* a job—the disability programs—and inability to *get* a job—the unemployment programs. The law does not permit exemptions from the "national economy test" for areas within the continental United States or for noncontiguous areas. Where occupations are named that a claimant can do, the citations are meant to show that the individual has a meaningful vocational opportunity despite the limiting effects of his or her impairment(s), not that job vacancies exist or that the claimant would be hired if he or she applied for those jobs.

On page 9300 of the preamble to the NPRM, perhaps the better word would have been *most* or *bulk* since no mathematical distinction was intended by the use of the word "majority." The point being made was that *within* a range of work (sedentary, light, medium, heavy or very heavy) unless the individual possesses physical capacities equal to the strength requirements for *most* of the jobs in that range, he or she cannot be classified as able to do the pertinent range of work. This has no relationship to the discussion in § 203.00 of Appendix 2, or to the numbers of citations of potential occupations necessary to sustain a denial of disability benefits.

It is not necessary and would be far too cumbersome to provide in these regulations lists of the thousands of different occupations at all skill levels which exist in the national economy. This information is available in public libraries, local employment agencies, etc. The 2,500 sedentary, light and medium occupations whose existence is being administratively noticed (identifiable in "Selected Characteristics of Occupations (Physical Demands, Working Conditions, Training Time), A Supplement to the Dictionary of Occupational Titles, Third Edition") are all *unskilled* occupations; since no work skills are attributable to unskilled occupations, no skills can be transferred to or from these occupations. Where transferability of skills is an issue, past and potential occupations other than these relatively simple ones will be involved. While understanding of skills and the basis of transferability can be obtained from Volume II of the DOT and the lists of occupations in "Selected Characteristics of Occupations By Worker Traits and Physical Strength, Supplement 2 to the Dictionary of Occupation Titles, Third Edition", this remains a judgmental area.

The third edition of the Dictionary of Occupational Titles will remain the only one which bears directly on the SSA disability program until the time that the fourth edition becomes available in its entirety. At present, only the first volume of the fourth edition has been issued, with a second volume and a supplement to be published, as in the past, with the cooperation of SSA. Because the latest first volume is different in content and substance, we cannot do a detailed analysis of the fourth edition in the immediate future, and we have not delayed publication of the vocational factors regulations on that account. While we do not anticipate any major changes of job incidence or other occupational data, if later analyses indicate that any rules should be restructured, the public will be notified. If, as the commenter suggested, impaired persons may benefit because of increased opportunities in the service industry and physically easier jobs through automation, we would need firm evidence of this. Further, only a significantly increased number of unskilled jobs could affect the tables in Appendix 2 in the manner suggested by the commenter.

As to whether administrative notice of job existence in the national economy precludes rebuttal of decisions based on specific rules in Appendix 2, it must be noted that the regulations do not take administrative notice of jobs above the unskilled level. Hence, the rules pertaining to denial on the basis of transferable skills would be subject to rebuttal on that issue. Also rebuttable, of course, is the accuracy of the assessment of the claimant's residual functional capacity, age education, and work experience. As indicated on page 9301 of the NPRM, the distinction should be made between adjudicative facts, which can be rebutted, and the adjudicatory rule to be applied to these facts, which is conclusive. Where any one of the findings of adjudicative fact does not coincide with the corresponding criterion of a rule, the rule does not apply in that paticular case and, accordingly, does not direct a conclusion of disabled or not disabled.

The use of the word "largely" in regulations §§ 404.1511(e)/416.911(e) caused several commenters to ask what factors other than occupationally significant work functions are involved in the transferability of skills, and why they cannot be articulated. The work *functions* are those involving action or activity: (1) the same or lesser degree of skills; (2) the same or similar tools and machines; and (3) the same or similar raw materials, products, processes or services. In addition to work functions, the *industry* and *work environment* may sometimes be of importance, since if a person's skill is so specialized or acquired in such an isolated vocational setting that it is not readily usable in other industries, jobs and work environments, the person's vocational outlook may be as limited as if he or she had no skill. The regulations have been expanded to include an additional sentence to cover this. An adjudicator should immediately be aware that there is no transferable skill connection between such entirely different types of workers as professional persons engaged in scientific analysis or research and hotel or restaurant employees primarily using their hands or machines to clean kitchen and dining room utensils. A dishwasher is unskilled, a chemist is highly skilled, and by those facts alone the jobs cannot be compared to each other in terms of transferable skills.

Where called for in individual cases, Administrative Law Judges will be expected to make the ultimate determinations as to the skill levels of a claimant's vocationally relevant past jobs and the relationship of those skills to potential occupations. However, these

regulations do not pertain to the conduct of title II or title XVI hearings, which is covered in 20 CFR 404.917 through 404.940, particularly 404.927; and 20 CFR 416.1425 through 416.1458, particularly 416.1441. The use of a vocational expert is at the discretion of the Administrative Law Judge, and it is anticipated that some issues on hearing may continue to require the services of vocational experts.

Summation

In essence, the regulations and Appendix 2 identify and define the individual medical-vocational factors which Congress intended to be considered in appropriate cases and illustrate the relative weights to be ascribed to each factor in conjunction with all of the other variables in determining an individual's ability or inability to perform substantial gainful activity. Appendix 2 sets forth these interactions in the form of individual profiles demonstrating the changing adjudicative weights to be accorded each factor in relation to the others. The conclusion of disabled or not disabled shown in a rule reflects whether or not a severely impaired individual with that particular combination of individual characteristics is able to engage in substantial gainful activity. The conclusion in the individual case is based on a medical-vocational determination of capacity for the performance of ranges of work, rather than singular or isolated occupations and, therefore, inherently considers the performance of a significant number of jobs that exist in the national economy.

The publication of Appendix 2 is not intended to direct the adjudication of social security disability claims on the basis of an "average man" approach. Rather, the rules make the process of determining the ability to engage in subtantial gainful activity (work) more uniform and definitive while preserving the individuality of the determination. The standards for evaluation included in Appendix 2 are rules whereby each case is evaluated. They do not detract from the requirement that the determination of facts in every case be on an individual basis. To the contrary, the rules require that individualized findings of fact be made with respect to each individual's age, education, work experience, and physical and mental limitations, and that all factors resulting from those findings of fact coincide with the criteria of a particular rule in order for that rule to direct a conclusion of disabled or not disabled in the individual case. Thus, the rules require that each individual's age, education, work experience, and physical and mental limitations personal to him or her, be taken thorough account of before the rules are applied to the facts in the case. The rules need to be as definitive as possible so that the claims of all individuals similarly situated are handled in a fair and consistent manner and to assure that determinations made by one set of adjudicators on the basis of the same facts will be handled the same way by another group of adjudicators, wherever in the country they are located. The necessity for each determination to be an individual one does not eliminate the need for consistency and uniformity in determinations. The way that is achieved administratively is by the regulations and the Appendices (1 and 2).

With respect to those claims not covered within the specific parameters of a rule in Appendix 1 or 2, a determination will have to be made on the basis of the discussions and definitions in the main body of the regulations, taking appropriate account of the rules in Appendix 2.

The rules stated herein represent a consolidation and elaboration of longstanding medical-vocational evaluation policies, which heretofore have been reflected in fragmented guides not readily available in the same format at all levels of adjudication. The regulations and Appendix 2 take appropriate account of the Social Security Administration's extensive experience to date in administering disability programs. Appendix 2 will help insure individual consideration of all appropriate factors in each case, while providing meaningful rules for soundness, consistency and equity of disability adjudications.

The amendments will become effective February 26, 1979.

(Secs. 205, 223, 1102, 1614, and 1631, of the Social Security Act, as amended; 53 Stat. 1368, as amended; 70 stat. 815, as amended; 49 Stat. 647, as amended, 86 Stat. 1471, 86 Stat. 1475; 42 U.S.C. 405, 423, 1302, 1382c, 1383.)

(Catalog of Federal Domestic Assistance Program No. 13.802, Disability Insurance; No. 13.807, Supplemental Security Income Program.)

Dated: September 25, 1978.

DON WORTMAN,
Acting Commissioner of Social Security.

Approved: November 11, 1978.

HALE CHAMPION,
Acting Secretary of Health, Education, and Welfare.

Part 404 and Part 416 of Chapter III of Title 20 of the Code of Federal Regulations are amended as follows:

1. Section 404.1502 is revised to read as follows:

§ 404.1502 Evaluation of disability in general.

The provisions of §§ 404.1502 through 404.1513 apply to cases involving disability insurance benefits (except statutory blindness) under section 223 of the Act, child's insurance benefits based on disability under section 202(d) of the Act, and a period of disability under section 216(i)(1)(A) of the Act. In general, the individual has the burden of proving that he or she is disabled and of raising every issue with respect to his or her alleged disability. Whether an impairment in a particular case constitutes a disability is determined from all the pertinent facts of that case. The determination of disability may be based on medical considerations alone, or on medical considerations and vocational factors as follows:

(a) *Disability determinations on the basis of medical considerations alone.* Medical evidence (i.e., signs, symptoms and laboratory findings) alone can justify a finding that an individual is not under a disability, or absent evidence to the contrary that an individual is under a disability.

(b) *Disability determinations in which vocational factors must be considered along with the medical evidence.* In those cases where a finding of disabled or not disabled cannot be made based on medical evidence alone, other evidence is required. This other evidence may include information about:

(1) The individual's residual functional capacity;

(2) The individual's age, education, and work experience; and

(3) The kinds of substantial gainful activity (work) which exist in significant numbers in the national economy for someone who can do only what the individual can do.

(c) *Disability determinations in which vocational factors are extremely adverse.* Where an individual with a marginal education and long work experience (e.g., 35 to 40 years or more) limited to the performance of arduous unskilled physical labor is not working and is no longer able to perform such labor because of a significant impairment or impairments, such an individual may be found to be under a disability.

§§ 404.1503 through 404.1507 [Redesignated as § 404.1514 through 404.1518]

2. Sections 404.1503 through 404.1507 are redesignated as §§ 404.1514 through 404.1518 respectively.

3. New §§ 404.1503 through 404.1513 are added to read as follows:

§ 404.1503 Considerations in the sequential evaluation of disability.

(a) *General.* In the determination of whether or not an impairment in a particular case constitutes a disability as defined in § 404.1501, consideration is given to all the pertinent facts of that case. If the individual is engaging in substantial gainful activity, a determination that he or she is not disabled shall be made. In all other cases, primary consideration is given to the physical or mental impairment(s), which must be severe. The impairment(s) must also meet the duration requirement before disability can be found to exist. However, in determining whether an individual is disabled, a sequential evaluation process shall be followed, whereby current work activity, severity of the impairment(s), and vocational factors are assessed in that order. The following evaluation steps shall be followed in the sequence shown, but when a determination that an individual is or is not disabled can be made at any step, evaluation under a subsequent step shall be unnecessary.

(b) *Is the individual currently engaging in substantial gainful activity?* Where an individual is actually engaging in substantial gainful activity, a finding shall be made that the individual is not under a disability without consideration of either medical or vocational factors. (See §§ 404.1532, 404.1533, 404.1534)

(c) *Does the individual have any severe impairment?* Where an individual does not have any impairment(s) which significantly limits his or her physical or mental capacity to perform basic work-related functions, a finding shall be made that he or she does not have a severe impairment and therefore is not under a disability without consideration of the vocational factors.

(d) *Does the individual have any impairment(s) which meets or equals those listed in Appendix 1?* Where an individual's impairment(s) meets the duration requirement and is either listed in Appendix 1 or is determined to be medically the equivalent of a listed impairment, a finding of disability shall be made without consideration of the vocational factors.

(e) *Does the individual have any impairment(s) which prevents past relevant work?* Where a finding of disability or no disability cannot be made based on current work activity or on medical considerations alone, and the individual has a severe impairment(s), his or her residual functional capacity and the physical and mental demands of his or her past relevant work shall be evaluated. If the impairment(s) does not prevent the individual from meeting the physical and mental demands of past relevant work, including arduous unskilled physical labor, disability shall be found not to exist.

(f) *Does the individual's impairment(s) prevent other work?* If an individual cannot perform any past relevant work because of a severe impairment(s), but the individual's remaining physical and mental capacities are consistent with his or her meeting the physical and mental demands of a significant number of jobs (in one or more occupations) in the national economy, and the individual has the vocational capabilities (considering age, education, and past work experience) to make an adjustment to work different from that which he or she has performed in the past, it shall be determined that the individual is not under a disability. However, if an individual's physical and mental capacities in conjunction with his or her vocational capabilities (considering age, education, and past work experience) do not permit the individual to adjust to work different from that which he or she has performed in the past, it shall be determined that the individual is under a disability.

§ 404.1504 Determining whether disability exists—medical and other considerations.

(a) *Medical considerations*—(1) *Finding individual not disabled.* Medical considerations alone can justify a finding that an individual is not under a disability where the medically determinable impairment is not severe. A medically determinable impairment is not severe if it does not significantly limit an individual's physical or mental capacity to perform basic work-related functions.

(2) *Finding individual disabled.* Medical considerations alone (including the physiological and psychological manifestations of aging) can justify a finding that an individual is under a disability, absent evidence to the contrary. Medical considerations which justify a finding that an individual is under a disability are those that bring an individual's impairment(s) under the listing in Appendix 1 of this subpart or which justify a determination by the Secretary that the impairment(s) is the medical equivalent of an impairment listed in Appendix 1 of this subpart.

(b) *Relevant work.* Any medically determinable impairment(s) may justify a finding that an individual is under a disability if the impairment(s) is severe and prevents an individual from engaging in substantial gainful activity. In determining whether impairment(s) not listed in Appendix 1 of this subpart (nor found to be the equivalent of an impairment listed in Appendix 1) meet this test, additional considerations are evaluated. These include determining whether an individual can qualify because he or she has only performed arduous unskilled work for a long period of time or, if not, whether he or she can perform vocationally relevant past work.

(c) *Vocational Factors.* In those cases in which an individual is found unable to perform vocationally relevant past work, age, education, and work experience must then be considered in addition to the functional limitations imposed by the individual's physical or mental impairment(s).

§ 404.1505 Residual functional capacity.

(a) *General.* Physical or mental impairment(s) may impose functional limitations on an individual's ability to engage in substantial gainful activity. The kind and severity of the impairment(s) determine the individual's work limitations and residual functional capacity. The manner in which the impairment(s) affects the individual's ability to perform work-related physical and mental activities, and the kind and extent of function the individual retains, are assessed in determining the individual's residual functional capacity. Where multiple impairments are involved, the assessment of residual functional capacity reflects the totality of restrictions resulting from all impairments. Assessments of residual functional capacity may be based solely on medical evidence where such evidence includes sufficient findings (e.g. signs, symptoms and laboratory findings) to permit and support the necessary judgments where relevant, with respect to the individual's physical, mental, and sensory capabilities. Where all reasonably obtainable relevant medical findings alone are not sufficient for an adequate assessment of residual functional capacity, additional factors may be considered. Such additional factors as the individual's description of the impairment, recorded observations of the individual, and any other evidence of record may be considered in conjunction with the medical findings.

(b) *Physical capacities.* Assessment of physical capacities (e.g., strength and exertional capabilities) includes an evaluation of the individual and indicates the individual's maximal residual functional capacity for sustained activity on a regular basis. The assessment also includes the evaluation of the individual's ability to perform significant physical functions such as walking, standing, lifting, carrying, pushing or pulling. The assessment includes the evaluation of other physical traits and sensory characteristics such as reaching, handling, seeing, hearing, and speaking, insofar as limited capacity to perform these functions may also affect the individual's capacity for

work for which the individual would otherwise be qualified.

(c) *Mental impairments.* The assessment of impairments because of mental disorders includes a consideration of such factors as the capacity to understand, to carry out and remember instructions, and to respond appropriately to supervision, co-workers and customary work pressures in a routine work setting.

(d) *Non-exertional limitations.* Any medically determinable impairment(s) resulting in non-exertional limitations (such as certain mental, sensory, or skin impairments) must be considered in terms of the limitations resulting from the impairment. When an individual has a non-exertional impairment in addition to an exertional impairment(s), the residual functional capacity must be assessed in terms of the degree of any additional narrowing of the individual's work-related capabilities.

(e) *When assessment is required.* An assessment of residual functional capacity is required only with respect to those specific physical or mental capacities that are in doubt by reason of the individual's allegations or the evidence adduced. Where such doubt does not exist with respect to particular physical or mental capacities, the individual is considered to have no restrictions with respect to those capacities.

(f) *Relationship of residual functional capacity to ability to do work.* Where the residual functional capacity so determined is sufficient to enable the individual to do his or her previous work (i.e., usual work or other vocationally relevant past work), a determination is made that the individual is not under a disability. Where the residual functional capacity so determined is not sufficient to enable the individual to do his or her previous work, it must be determined what work, if any, the individual can do, taking into consideration the individual's residual functional capacity, age, education, and work experience and whether work that the individual can do exists in significant numbers in the national economy.

§ 404.1506 Age as a vocational factor.

(a) *General.* The term "age" refers to chronological age and the extent to which it affects the individual's capability to engage in work in competition with others. However, the factor of age in itself is not determinative of disability; the residual functional capacity and the education and work experience of the individual must also be considered. An individual who is unemployed because of age cannot be found incapable of engaging in substantial gainful activity when the individual's impairment and other vocational considerations, e.g., education and work experience, would enable the individual to perform a significant number of jobs which exist in the national economy. The considerations given to age are appropriately reflected in Appendix 2, but are not to be applied mechanically in borderline situations.

(b) *Younger individual.* In the case of a younger individual (under age 50), age in itself is ordinarily not considered to affect significantly the individual's ability to adapt to a new work situation.

(c) *Individual approaching advanced age.* For the individual not of advanced age but who is closely approaching advanced age (age 50–54), the factor of age, in combination with a severe impairment and limited vocational background may substantially affect the individual's adaptability to a significant number of jobs in a competitive work environment.

(d) *Individual of advanced age.* "Advanced" age (age 55 or over) represents the point where age significantly affects the ability to engage in substantial work. Where a severely impaired individual is of advanced age, such ability may be adversely affected except where the individual has skills that are readily transferable to jobs which exist in significant numbers in the national economy. Those individuals of advanced age who are aged 60–64 are further described as closely approaching retirement age.

§ 404.1507 Education as a vocational factor.

(a) *General.* The term "education" is primarily used in the sense of formal schooling or other training which contributes to the individual's ability to meet vocational requirements, e.g., reasoning ability, communication skills, and arithmetical ability. Lack of formal schooling is not necessarily proof that the individual is uneducated or lacks such capacities. For individuals with past work experience, the kinds of responsibilities assumed when working may indicate the existence of such intellectual capacities although their formal education is limited. Other evidence of such capacities, for individuals with or without past work experience, may consist of daily activities, hobbies, or the results of testing. The significance of an individual's educational background may be materially affected by the time lapse between the completion of the individual's formal education and the onset of physical or mental impairment(s) and by what the individual has done with his or her education in a work context. Formal education that was completed many years prior to onset of impairment or unused skills and knowledge that were a part of such formal education may no longer be useful or meaningful in terms of the individual's ability to work. Thus, the numerical grade level of educational attainment may not be representative of an individual's present educational competences which could be higher or lower. However, in the absence of evidence to the contrary, the numerical grade level will be used. The term "education" also indicates whether an individual has the ability to communicate in English, since that ability is often acquired or enhanced through educational exposure. In evaluating the educational level of an individual, the following classifications are used:

(b) *Illiteracy.* Illiteracy refers to the inability to read or write. An individual who is able to sign his or her name, but cannot read or write a simple communication (e.g., instructions, inventory lists), is considered illiterate. Generally, an illiterate individual has had little or no formal schooling.

(c) *Marginal education.* Marginal education refers to competence in reasoning, arithmetic, and language skills which are required for the performance of simple, unskilled types of jobs. Absent evidence to the contrary, formal schooling at a grade level of sixth grade or less is considered a marginal education.

(d) *Limited education.* Limited education refers to competence in reasoning, arithmetic, and language skills which, although more than that which is generally required to carry out the duties of unskilled work, does not provide the individual with the educational qualifications necessary to perform the majority of more complex job duties involved in semi-skilled or skilled jobs. Absent evidence to the contrary, a seventh grade through the eleventh grade level of formal education is considered a limited education.

(e) *High school education and above.* High school education and above refers to competence in reasoning, arithmetic, and language skills acquired through formal schooling at a level of grade twelve or above. Absent evidence to the contrary, these educational capacities qualify an individual for work at a semi-skilled through a skilled level of job complexity.

(f) *Inability to communicate in English.* Ability to communicate in English is often acquired or enhanced through educational exposure, and this may be considered an educational factor. Where there is inability to communicate in English, the dominant language of the national economy, this may be considered a vocational handicap because it often narrows an individual's vocational scope. For example, the inability to communicate in English may preclude an individual from performing jobs which require conversing with peers and supervisors

in English, or reading instructions, signs, forms, etc., which are printed in English. However, the inability to communicate in English in no sense implies that an individual lacks formal schooling or intelligence. A person unable to communicate in English may have a vocational handicap which must be considered in assessing what work, if any, the individual can do. The particular non-English language in which an individual may be fluent is generally immaterial.

§ 404.1508 Work experience as a vocational factor.

The term "work experience" means skills and abilities acquired through work previously performed by the individual which indicates the type of work the individual may be expected to perform. Work for which the individual has demonstrated a capability is the best indicator of the kind of work that the individual can be expected to do. Such work experience has current vocational relevance where the recency of the work and the skills acquired demonstrate the individual's ability to perform work which exists in the national economy. Work performed 15 years or more prior to the point at which the claim is being considered for adjudication (or when the earnings requirement was last met) is ordinarily not considered vocationally relevant. In our economic system, a gradual transition occurs in the job functions of most jobs so that by the time 15 years have elapsed, it is no longer realistic to assume that skills and abilities acquired in a job performed more than 15 years ago continue to be relevant. The 15-year guide is essentially intended to insure that current vocational relevance is not imputed to remote work experience which could not reasonably be expected to enhance an individual's vocational prospect as of the point of adjudication. An individual who has no prior work experience or has worked only sporadically or for brief periods of time during the 15-year period may be considered to have no relevant work experience. Any skills acquired through work experience are vocational assets unless they are not transferable to other skilled or semi-skilled work within the individual's current capacities. When acquired skills are not transferable, the individual is considered capable of only unskilled work. However, an individual need not have work experience to qualify for unskilled work which requires little or no judgment in the performance of simple duties which can be learned in a short period of time.

§ 404.1509 Work which exists in the national economy.

(a) *General.* Work is considered to exist in the national economy when it exists in significant numbers either in the region where the individual lives or in several other regions of the country, regardless of whether such work exists in the immediate area in which the individual lives, or whether a specific job vacancy exists for the individual, or whether the individual would be hired if the individual applied for work. A finding that work exists in the national economy is made when there is a significant number of jobs (in one or more occupations) having typical requirements which do not exceed the individual's physical or mental capacities and vocational qualifications. Isolated jobs of a type that exist only in very limited number or in relatively few geographic locations outside of the region where the individual resides are not considered to be "work which exists in the national economy" for purposes of determining whether an individual is under a disability; an individual is not denied benefits on the basis of the existence of such jobs. If work that the individual can do does not exist in the national economy, disability shall be determined to exist. If such work does exist in the national economy, disability shall be determined not to exist.

(b) *Inability of individual to obtain work.* If an individual's residual functional capacity and vocational capabilities are consistent with the performance of work which exists in the national economy but the individual remains unemployed because the individual is unsuccessful in obtaining such work or because such work does not exist in the individual's local area; or because of the hiring practices of employers, technological changes in the industry in which the individual has worked, or cyclical economic conditions; or because there are no job openings for the individual or the individual would not actually be hired to do work the individual could otherwise perform, the individual is considered not to be under a disability as defined in § 404.1501.

(c) *Administrative notice of job data.* In the determination of whether jobs, as classified by their exertional and skill requirements, exist in significant numbers either in the region or the national economy, administrative notice shall be taken of reliable job information available from various governmental and other publications; e.g., "Dictionary of Occupational Titles," published by the Department of Labor; "County Business Patterns", published by the Bureau of the Census; "Census Reports", also published by the Bureau of the Census; occupational analyses prepared for the Social Security Administration by various State employment agencies; and the "Occupational Outlook Handbook", published by the Bureau of Labor Statistics.

§ 404.1510 Exertional requirements.

(a) *General.* For the purpose of determining exertional requirements of work in the national economy, jobs are classified as "sedentary," "light," "medium," "heavy," and "very heavy." Such terms have the same meaning as they have in the "Dictionary of Occupational Titles", published by the Department of Labor, and when used in making disability determinations under this subpart are defined as follows:

(b) *Sedentary work.* Sedentary work entails lifting 10 pounds maximum and occasionally lifting or carrying such articles as dockets (e.g., files), ledgers, and small tools. Although a sedentary job is defined as one which involves sitting, a certain amount of walking and standing is often necessary in carrying out job duties. Jobs are sedentary if walking and standing are required occasionally and other sedentary criteria are met.

(c) *Light work.* Light work entails lifting 20 pounds maximum with frequent lifting or carrying of objects weighing up to 10 pounds. Even though the weight lifted may be only a negligible amount, a job is in this category when it requires walking or standing to a significant degree, or when it involves sitting most of the time with a degree of pushing and pulling of arm or leg controls. To be considered capable of performing a full or wide range of light work, an individual must be capable of performing substantially all of the foregoing activities. The functional capacity to perform light work includes the functional capacity to perform sedentary work.

(d) *Medium work.* Medium work entails lifting 50 pounds maximum with frequent lifting or carrying of objects weighing up to 25 pounds. The functional capacity to perform medium work includes the functional capacity to perform sedentary work and light work as well.

(e) *Heavy work.* Heavy work entails lifting 100 pounds maximum with frequent lifting or carrying of objects weighing up to 50 pounds. The functional capacity to perform heavy work includes the functional capacity to perform work at all of the lesser functional levels.

(f) *Very heavy work.* Very heavy work entails lifting objects in excess of 100 pounds with frequent lifting or carrying of objects weighing 50 pounds or more. The functional capacity to perform very heavy work includes the

functional capacity to perform work at all of the lesser functional levels.

§ 404.1511 Skill requirements.

(a) *General.* For purposes of assessing the skills reflected by an individual's work experience, and of determining the existence in the national economy of work the individual is competent to do, occupations are classified as unskilled, semi-skilled, and skilled. When used in making disability determinations under this subpart, these terms are used in the following sense:

(b) *Unskilled work.* Unskilled work denotes work which requires little or no judgment in the performance of simple duties that can be learned on the job in a short period of time. Considerable strength may or may not be required. As an example, where the primary work function of occupations consists of handling, feeding and offbearing (i.e., placing or removing materials from machines which are automatic or operated by others), or machine tending, and average successful job performance can ordinarily be achieved within 30 days, such occupations are considered unskilled. Other types of jobs requiring little specific vocational preparation and little judgment are likewise unskilled. No acquired work skills can be attributed to individuals who have performed only unskilled work.

(c) *Semi-skilled work.* Semi-skilled work denotes work in which some skills are involved but the more complex work functions are not required. Semi-skilled jobs may require alertness and close attention to watching machine processes; or inspecting, testing or otherwise detecting irregularities; or tending or guarding equipment, property, materials, or persons against loss, damage or injury; or other types of activities involving work functions of similar complexity. A job may be classified as semi-skilled where coordination and dexterity are necessary as in the use of the hands or feet for the rapid performance of repetitive tasks.

(d) *Skilled work.* Skilled work requires qualifications in which the independent judgment of the individual determines the machine and manual operations to be performed in obtaining the proper form, quality, or quantity of material to be produced. The individual may be required to lay out work, to estimate quality, suitability and needed quantities of materials, to make precise measurements, to read blueprints or other specifications, or to make necessary computations or mechanical adjustments to control or regulate processes. Other skilled jobs may require dealing with personnel, data, or abstract ideas at a high level of complexity.

(e) *Transferable work skills.* An individual is considered to have transferable skills when the skilled or semi-skilled work functions which he or she has demonstrated in his or her past work can be applied to meet the requirements of skilled or semi-skilled work functions of other jobs or kinds of work. Transferability depends largely on the similarity of occupationally significant work functions among jobs. Transferability is most probable and meaningful among jobs in which the same or a lesser degree of skill is required; and the same or similar tools and machines are used; and the same are similar raw materials, products, processes, or services are involved. There are degrees of transferability ranging from a close approximation of work functions involving all three factors to only remote and incidental similarities among jobs. A complete similarity of all three factors is not necessary to warrant the inference of transferability. Where an individual's work skills are so specialized or have been acquired in such a limited vocational setting that they are not readily usable in other industries, jobs and work environments, they are not transferable and the individual may be considered as if he or she is unskilled. (Also, see Appendix 2, § 201.00(e), (f), and § 202.00(e), (f).)

§ 404.1512 Effect of performance of arduous unskilled physical labor.

Where an individual with a marginal education and long work experience (e.g., 35 to 40 years or more) limited to the performance of arduous unskilled physical labor is not working and is no longer able to perform such labor because of a significant impairment or impairments and, considering his or her age, education, and vocational background is unable to engage in lighter work, such individual may be found to be under a disability. On the other hand, a different conclusion may be reached where it is found that such individual is working or has worked despite his or her impairment or impairments (except where such work is sporadic or is medically contraindicated) depending upon all the facts in the case. In addition, an individual who was doing heavy physical work at the time he or she suffered such impairment might not be considered unable to engage in any substantial gainful activity if the evidence shows that he or she has the training or past work experience which qualifies him or her for substantial gainful work in another occupation consistent with his or her impairment, either on a full-time or a reasonable regular part-time basis.

Example. B, a 60-year old miner, with a fourth grade education, after a life-long history of arduous physical labor alleged that he was under a disability because of arthritis of the spine, hips, and knees and other impairments. Medical evidence shows a combination of impairments and establishes that these impairments prevent B from performing his usual work or any other type of arduous physical labor. His vocational background does not disclose either through performance or by similarly persuasive evidence that he has skills or capabilities needed to do lighter work which would be readily transferrable to another work environment. Under these circumstances, B may be found to be under a disability.

§ 404.1513 Listing of medical-vocational guidelines in Appendix 2.

In light of information that is available about jobs (classified by their exertional and skill requirements) that exist in the national economy, Appendix 2 sets forth rules reflecting the major functional and vocational patterns which are encountered in cases which do not fall within the criteria of § 404.1504(a) and (b) or § 404.1512, where an individual is not engaging in substantial gainful activity and is prevented by a medically determinable impairment from performing his or her vocationally relevant past work. The Appendix 2 rules do not encompass all possible variations of factors and, as explained in § 200.00 of Appendix 2, are not applicable in any case where any one of the findings of fact made with respect to the individual's vocational factors and residual functional capacity does not coincide with the corresponding criterion of a rule. In such instances, full consideration must be given to all relevant facts in accordance with the definitions and discussions of each factor in §§ 404.1505–404.1511. However, when the findings of fact made as to all factors coincide with the criteria of a rule, that rule directs a factual conclusion of disabled or not disabled.

Appendix (Listing of Impairments) [Redesignated as Appendix 1]

4. Subpart P of part 404 is further amended by designating the Appendix (Listing of Impairments), appearing at the end, as Appendix 1, and by adding a new Appendix 2, to read as follows:

APPENDIX 2—MEDICAL—VOCATIONAL GUIDELINES

Sec.

200.00 Introduction.
201.00 Maximum sustained work capability limited to sedentary work as a result of severe medically determinable impairment(s).
202.00 Maximum sustained work capability limited to light work as a result of severe medically determinable impairment(s).
203.00 Maximum sustained work capability limited to medium work as a result of

severe medically determinable impairment(s).

204.00 Maximum sustained work capability limited to heavy work (or very heavy work) as a result of severe medically determinable impairment(s).

200.00 *Introduction.* (a) The following rules reflect the major functional and vocational patterns which are encountered in cases which do not fall within the criteria of § 404.1504 (a) and (b) or § 404.1512, where an individual with a severe medically determinable physical or mental impairment(s) is not engaging in substantial gainful activity and the individual's impairment(s) prevents the performance of his or her vocationally relevant past work. They also reflect the analysis of the various vocational factors (i.e., age, education, and work experience) in combination with the individual's residual functional capacity (used to determine his or her maximum sustained work capability for sedentary, light, medium, heavy, or very heavy work) in evaluating the individual's ability to engage in substantial gainful activity in other than his or her vocationally relevant past work. Where the findings of fact made with respect to a particular individual's vocational factors and residual functional capacity coincide with all of the criteria of a particular rule, the rule directs a conclusion as to whether the individual is or is not disabled. However, each of these findings of fact is subject to rebuttal and the individual may present evidence to refute such findings. Where any one of the findings of fact does not coincide with the corresponding criterion of a rule, the rule does not apply in that particular case and, accordingly, does not direct a conclusion of disabled or not disabled. In any instance where a rule does not apply, full consideration must be given to all of the relevant facts of the case in accordance with the definitions and discussions of each factor in §§ 404.1505–404.1511.

(b) The existence of jobs in the national economy is reflected in the "Decisions" shown in the rules; i.e., in promulgating the rules, administrative notice has been taken of the numbers of unskilled jobs that exist throughout the national economy at the various functional levels (sedentary, light, medium, heavy, and very heavy) as supported by the "Dictionary of Occupational Titles" and the "Occupational Outlook Handbook," published by the Department of Labor; the "County Business Patterns" and "Census Surveys" published by the Bureau of the Census; and occupational surveys of light and sedentary jobs prepared for the Social Security Administration by various State employment agencies. Thus, when all factors coincide with the criteria of a rule, the existence of such jobs is established. However, the existence of such jobs for individuals whose remaining functional capacity or other factors do not coincide with the criteria of a rule must be further considered in terms of what kinds of jobs or types of work may be either additionally indicated or precluded.

(c) In the application of the rules, the individual's residual functional capacity (i.e., the maximum degree to which the individual retains the capacity for sustained performance of the physical-mental requirements of jobs), age, education, and work experience must first be determined.

(d) The correct disability decision (i.e., on the issue of ability to engage in substantial gainful activity) is found by then locating the individual's specific vocational profile. If an individual's specific profile is not listed within this Appendix 2, a conclusion of disabled or not disabled is not directed. Thus, for example, an individual's ability to engage in substantial gainful work where his or her residual functional capacity falls between the ranges of work indicated in the rules (e.g., the individual who can perform more than light but less than medium work), is decided on the basis of the principles and definitions in the regulations, giving consideration to the rules for specific case situations in this Appendix 2. These rules represent various combinations of exertional capabilities, age, education and work experience and also provide an overall structure for evaluation of those cases in which the judgments as to each factor do not coincide with those of any specific rule. Thus, when the necessary judgments have been made as to each factor and it is found that no specific rule applies, the rules still provide guidance for decisionmaking, such as in cases involving combinations of impairments. For example, if strength limitations resulting from an individual's impairment(s) considered with the judgments made as to the individual's age, education and work experience correspond to (or closely approximate) the factors of a particular rule, the adjudicator then has a frame of reference for considering the jobs or types of work precluded by other, nonexertional impairments in terms of numbers of jobs remaining for a particular individual.

(e) Since the rules are predicated on an individual's having an impairment which manifests itself by limitations in meeting the strength requirements of jobs, they may not be fully applicable where the nature of an individual's impairment does not result in such limitations, e.g., certain mental, sensory, or skin impairments. In addition, some impairments may result solely in postural and manipulative limitations or environmental restrictions. Environmental restrictions are those restrictions which result in inability to tolerate some physical feature(s) of work settings that occur in certain industries or types of work, e.g., an inability to tolerate dust or fumes.

(1) In the evaluation of disability where the individual has solely a nonexertional type of impairment, determination as to whether disability exists shall be based on the principles of §§ 404.1505–404.1511, giving consideration to the rules for specific case situations in this Appendix 2. The rules do not direct factual conclusions of disabled or not disabled for individuals with solely nonexertional types of impairments.

(2) However, where an individual has an impairment or combination of impairments resulting in both strength limitations and nonexertional limitations, the rules in this subpart are considered in determining first whether a finding of disabled may be possible based on the strength limitations alone and, if not, the rule(s) reflecting the individual's maximum residual strength capabilities, age, education, and work experience provide a framework for consideration of how much the individual's work capability is further diminished in terms of any types of jobs that would be contraindicated by the nonexertional limitations. Also, in these combinations of nonexertional and exertional limitations which cannot be wholly determined under the rules in this Appendix 2, full consideration must be given to all of the relevant facts in the case in accordance with the definitions and discussions of each factor in §§ 404.1505–404.1511, which will provide insight into the adjudicative weight to be accorded each factor.

201.00 *Maximum sustained work capability limited to sedentary work as a result of severe medically determinable impairment(s).* (a) Most sedentary occupations fall within the skilled, semi-skilled, professional, administrative, technical, clerical, and benchwork classifications. Approximately 200 separate unskilled sedentary occupations can be identified, each representing numerous jobs in the national economy. Approximately 85 percent of these jobs are in the machine trades and benchwork occupational categories. These jobs (unskilled sedentary occupations) may be performed after a short demonstration or within 30 days.

(b) These unskilled sedentary occupations are standard within the industries in which they exist. While sedentary work represents a significantly restricted range of work, this range in itself is not so prohibitively restricted as to negate work capability for substantial gainful activity.

(c) Vocational adjustment to sedentary work as defined in § 404.1510(b) may be expected where the individual has special skills or experience relevant to sedentary work or where age and basic educational competences provide sufficient occupational mobility to adapt to the major segment of unskilled sedentary work. Inability to engage in substantial gainful activity would be indicated where an individual who is restricted to sedentary work because of a severe medically determinable impairment lacks special skills or experience relevant to sedentary work, lacks educational qualifications relevant to most sedentary work (e.g., has a limited education or less) and the individual's age, though not necessarily advanced, is a factor which significantly limits vocational adaptability.

(d) The adversity of functional restrictions to sedentary work at advanced age (55 and over) for individuals with no relevant past work or who can no longer perform vocationally relevant past work and have no transferable skills, warrants a finding of disabled in the the absence of the rare situation where the individual has recently completed education which provides a basis for direct entry into skilled sedentary work. Advanced age and a history of unskilled work or no work experience would ordinarily offset any vocational advantages that might accrue by reason of any remote past education, whether it is more or less than limited education.

(e) The presence of acquired skills that are readily transferable to a significant range of skilled work within an individual's residual functional capacity would ordinarily warrant a finding of ability to engage in substantial gainful activity regardless of the adversity of age, or whether the individual's formal education is commensurate with his or her demonstrated skill level. The acquisition of work skills demonstrates the ability to perform work at the level of complexity demonstrated by the skill level attained regardless of the individual's formal educational attainments.

(f) In order to find transferability of skills to skilled sedentary work for individuals who are of advanced age (55 and over), there must be very little, if any, vocational adjustment required in terms of tools, work processes, work settings, or the industry.

(g) Individuals approaching advanced age (age 50–54) may be significantly limited in vocational adaptability if they are restricted to sedentary work. When such individuals have no past work experience or can no longer perform vocationally relevant past work and have no transferable skills, a finding of disabled ordinarily obtains. However, recently completed education which provides for direct entry into sedentary work will preclude such a finding. For this age group, even a high school education or more (ordinarily completed in the remote past) would have little impact for effecting a vocational adjustment unless relevant work experience reflects use of such education.

(h) The term "younger individual" is used to denote an individual age 18 through 49. For those within this group who are age 45–49, age is a less positive factor than for those who are age 18–44. Accordingly, for such individuals; (1) who are restricted to sedentary work, (2) who are unskilled or have no transferable skills, (3) who have no relevant past work or who can no longer perform vocationally relevant past work, and (4) who are either illiterate or unable to communicate in the English language, a finding of disabled is warranted. On the other hand, age is a more positive factor for those who are under age 45 and is usually not a significant factor in limiting such an individual's ability to make a vocational adjustment, even an adjustment to unskilled sedentary work, and even where the individual is illiterate or unable to communicate in English. However, a finding of disabled is not precluded for those individuals under age 45 who do not meet all of the criteria of a specific rule and who do not have the ability to perform a full range of sedentary work. The following examples are illustrative: Example 1: An individual under age 45 with a high school education can no longer do past work and is restricted to unskilled sedentary jobs because of a severe medically determinable cardiovascular impairment (which does not meet or equal the listings in Appendix 1). A permanent injury of the right hand limits the individual to sedentary jobs which do not require bilateral manual dexterity. None of the rules in Appendix 2 are applicable to this particular set of facts, because this individual cannot perform the full range of work defined as sedentary. Since the inability to perform jobs requiring bilateral manual dexterity significantly compromises the only range of work for which the individual is otherwise qualified (i.e., sedentary), a finding of disabled would be appropriate. Example 2: An illiterate 41 year old individual with mild mental retardation (IQ of 78) is restricted to unskilled sedentary work and cannot perform vocationally relevant past work, which had consisted of unskilled agricultural field work; his or her particular characteristics do not specifically meet any of the rules in Appendix 2, because this individual cannot perform the full range of work defined as sedentary. In light of the adverse factors which further narrow the range of sedentary work for which this individual is qualified, a finding of disabled is appropriate.

(i) While illiteracy or the inability to communicate in English may significantly limit an individual's vocational scope, the primary work functions in the bulk of unskilled work relate to working with things (rather than with data or people) and in these work functions at the unskilled level, literacy or ability to communicate in English has the least significance. Similarly the lack of relevant work experience would have little significance since the bulk of unskilled jobs require no qualifying work experience. Thus, the functional capability for a full range of sedentary work represents sufficient numbers of jobs to indicate substantial vocational scope for those individuals age 18–44 even if they are illiterate or unable to communicate in English.

TABLE NO. 1.—*Residual functional capacity: Maximum sustained work capability limited to sedentary work as a result of severe medically determinable impairment(s)*

Rule	Age	Education	Previous work experience	Decision
201.01	Advanced age	Limited or less	Unskilled or none	Disabled.
201.02	do	do	Skilled or semiskilled—skills not transferable [1].	Do.
201.03	do	do	Skilled or semiskilled—skills transferable [1].	Not disabled.
201.04	do	High school graduate or more—does not provide for direct entry into skilled work [2].	Unskilled or none	Disabled.
201.05	do	High school graduate or more—provides for direct entry into skilled work [2].	Unskilled or none	Not disabled.
201.06	do	High school graduate or more—does not provide for direct entry into skilled work [2].	Skilled or semiskilled—skills not transferable [1].	Disabled.
201.07	do	High school graduate or more—does not provide for direct entry into skilled work [2].	Skilled or semiskilled—skills transferable [1].	Not disabled.
201.08	do	High school graduate or more—provides for direct entry into skilled work [2].	Skilled or semiskilled—skills not transferable [1].	Do.
201.09	Closely approaching advanced age.	Limited or less	Unskilled or none	Disabled.
201.10	do	do	Skilled or semiskilled—skills not transferable.	Do.
201.11	do	do	Skilled or semiskilled—skills transferable.	Not disabled.
201.12	do	High school graduate or more—does not provide for direct entry into skilled work [3].	Unskilled or none	Disabled.
201.13	do	High school graduate or more—provides for direct entry into skilled work [3].	do	Not disabled.
201.14	do	High school graduate or more—does not provide for direct entry into skilled work [3].	Skilled or semiskilled—skills not transferable.	Disabled.
201.15	do	do	Skilled or semiskilled—skills transferable.	Not disabled.
201.16	do	High school graduate or more—provides for direct entry into skilled work [3].	Skilled or semiskilled—skills not transferable.	Do.
201.17	Younger individual age 45–49.	Illiterate or unable to communicate in English.	Unskilled or none	Disabled.
201.18	do	Limited or less—at least literate and able to communicate in English.	do	Not disabled.
201.19	do	Limited or less	Skilled or semiskilled—skills not transferable.	Do.
201.20	do	do	Skilled or semiskilled—skills transferable.	Do.
201.21	do	High school graduate or more.	Skilled or semiskilled—skills not transferable.	Do.
201.22	do	do	Skilled or semiskilled—skills transferable.	Do.
201.23	Younger individual age 18–44.	Illiterate or unable to communicate in English.	Unskilled or none	Do. [4]
201.24	do	Limited or less—at least literate and able to communicate in English.	do	Do. [4]
201.25	do	Limited or less	Skilled or semiskilled—skills not transferable.	Do. [4]
201.26	do	do	Skilled or semiskilled—skills transferable.	Do. [4]
201.27	do	High school graduate or more.	Unskilled or none	Do. [4]
201.28	do	do	Skilled or semiskilled—skills not transferable.	Do. [4]
201.29	do	do	Skilled or semiskilled—skills transferable.	Do. [4]

[1] See 201.00(f).
[2] See 201.00(d).
[3] See 201.00(g).
[4] See 201.00(h).

202.00 *Maximum sustained work capability limited to light work as a result of severe medically determinable impairment(s).* (a) The functional capacity to perform a full range of light work as defined in § 404.1510(c) includes the functional capacity to perform sedentary as well as light work. Approximately 1,600 separate sedentary and light unskilled occupations can be identified in eight broad occupational categories, each occupation representing numerous jobs in the national economy. These jobs can be performed after a short demonstration or within 30 days, and do not require special skills or experience.

(b) The functional capacity to perform a wide or full range of light work represents substantial work capability compatible with making a work adjustment to substantial numbers of unskilled jobs and, thus, generally provides sufficient occupational mobility even for severely impaired individuals who are not of advanced age and have sufficient educational competences for unskilled work.

(c) However, for individuals of advanced age who can no longer perform vocationally relevant past work and who have a history of unskilled work experience, or who have only skills that are not readily transferable to a significant range of semi-skilled or skilled work that is within the individual's functional capacity, or who have no work experience, the limitations in vocational adaptability represented by functional restriction to light work warrant a finding of disabled. Ordinarily, even a high school education or more which was completed in the remote past will have little positive impact on effecting a vocational adjustment unless relevant work experience reflects use of such education.

(d) Where the same factors in paragraph (c) of this section regarding education and work experience are present, but where age, though not advanced, is a factor which significantly limits vocational adaptability (i.e., closely approaching advanced age, 50–54) and an individual's vocational scope is further significantly limited by illiteracy or inability to communicate in English, a finding of disabled is warranted.

(e) The presence of acquired skills that are readily transferable to a significant range of semi-skilled or skilled work within an individual's residual functional capacity would ordinarily warrant a finding of not disabled regardless of the adversity of age, or whether the individual's formal education is commensurate with his or her demonstrated skill level. The acquisition of work skills demonstrates the ability to perform work at the level of complexity demonstrated by the skill level attained regardless of the individual's formal educational attainments.

(f) For a finding of transferability of skills to light work for individuals of advanced age who are closely approaching retirement age (age 60–64), there must be very little, if any, vocational adjustment required in terms of tools, work processes, work settings, or the industry.

(g) While illiteracy or the inability to communicate in English may significantly limit an individual's vocational scope, the primary work functions in the bulk of unskilled work relate to working with things (rather than with data or people) and in these work functions at the unskilled level, literacy or ability to communicate in English has the least significance. Similarly, the lack of relevant work experience would have little significance since the bulk of unskilled jobs require no qualifying work experience. The capability for light work, which includes the ability to do sedentary work, represents the capability for substantial numbers of such jobs. This, in turn, represents substantial vocational scope for younger individuals (age 18–49) even if illiterate or unable to communicate in English.

TABLE No. 2.—*Residual functional capacity: Maximum sustained work capability limited to light work as a result of severe medically determinable impairment(s)*

Rule	Age	Education	Previous work experience	Decision
202.01	Advanced age	Limited or less	Unskilled or none	Disabled.
202.02	do	do	Skilled or semiskilled—skills not transferable.	Do.
202.03	do	do	Skilled or semiskilled—skills transferable [1].	Not disabled.
202.04	do	High school graduate or more—does not provide for direct entry into skilled work [2].	Unskilled or none	Disabled.
202.05	do	High school graduate or more—provides for direct entry into skilled work [2].	do	Not disabled.
202.06	do	High school graduate or more—does not provide for direct entry into skilled work [2].	Skilled or semiskilled—skills not transferable.	Disabled.
202.07	do	do	Skilled or semiskilled—skills transferable [1].	Not disabled.
202.08	do	High school graduate or more—provides for direct entry into skilled work [2].	Skilled or semiskilled—skills not transferable.	Do.
202.09	Closely approaching advanced age.	Illiterate or unable to communicate in English.	Unskilled or none	Disabled.
202.10	do	Limited or less—At least literate and able to communicate in English.	do	Not disabled.
202.11	do	Limited or less	Skilled or semiskilled—skills not transferable.	Do.
202.12	do	do	Skilled or semiskilled—skills transferable.	Do.
202.13	do	High school graduate or more.	Unskilled or none	Do.
202.14	do	do	Skilled or semiskilled—skills not transferable.	Do.
202.15	do	do	Skilled or semiskilled—skills transferable.	Do.
202.16	Younger individual.	Illiterate or unable to communicate in English.	Unskilled or none	Do.
202.17	do	Limited or less—At least literate and able to communicate in English.	do	Do.
202.18	do	Limited or less	Skilled or semiskilled—skills not transferable.	Do.
202.19	do	do	Skilled or semiskilled—skills transferable.	Do.
202.20	do	High school graduate or more.	Unskilled or none	Do.
202.21	do	do	Skilled or semiskilled—skills not transferable.	Do.
202.22	do	do	Skilled or semiskilled—skills transferable.	Do.

[1] See 202.00(f).
[2] See 202.00(c).

203.00 *Maximum sustained work capability limited to medium work as a result of severe medically determinable impairment(s).* (a) The functional capacity to perform medium work as defined in § 404.1510(d) includes the functional capacity to perform sedentary, light, and medium work. Approximately 2,500 separate sedentary, light, and medium occupations can be identified, each occupation representing numerous jobs in the national economy which do not require skills or previous experience and which can be performed after a short demonstration or within 30 days.

(b) The functional capacity to perform medium work represents such substantial work capability at even the unskilled level that a finding of disabled is ordinarily not warranted in cases where a severely impaired individual retains the functional capacity to perform medium work. Even the adversity of advanced age (55 or over) and a work history of unskilled work may be offset by the substantial work capability represented by the functional capacity to perform medium work. (Note that the provisions of § 404.1512 must have been given prior consideration.)

(c) However, the absence of any relevant work experience becomes a more significant adversity for individuals of advanced age (55 and over). Accordingly, this factor, in combination with a limited education or less, militates against making a vocational adjustment to even this substantial range of work and a finding of disabled is appropriate. Further, for individuals closely approaching retirement age (60–64) with a work history of unskilled work and with marginal education or less, a finding of disabled is appropriate.

TABLE NO. 3.—*Residual functional capacity: Maximum sustained work capability limited to medium work as a result of severe medically determinable impairment(s)*

Rule	Age	Education	Previous work experience	Decision
203.01	Closely approaching retirement age.	Marginal or none	Unskilled or none	Disabled.
203.02	...do	Limited or less	None	Do.
203.03	...do	Limited	Unskilled	Not disabled.
203.04	...do	Limited or less	Skilled or semiskilled—skills not transferable.	Do.
203.05	...do	...do	Skilled or semiskilled—skills transferable.	Do.
203.06	...do	High school graduate or more.	Unskilled or none	Do.
203.07	...do	High school graduate or more—does not provide for direct entry into skilled work.	Skilled or semiskilled—skills not transferable.	Do.
203.08	...do	...do	Skilled or semiskilled—skills transferable.	Do.
203.09	...do	High school graduate or more—provides for direct entry into skilled work.	Skilled or semiskilled—skills not transferable.	Do.
203.10	Advanced age	Limited or less	None	Disabled.
203.11	...do	...do	Unskilled	Not disabled.
203.12	...do	...do	Skilled or semiskilled—skills not transferable.	Do.
203.13	...do	...do	Skilled or semiskilled—skills transferable.	Do.
203.14	...do	High school graduate or more.	Unskilled or none	Do.
203.15	...do	High school graduate or more—does not provide for direct entry into skilled work.	Skilled or semiskilled—skills not transferable.	Do.
203.16	...do	...do	Skilled or semiskilled—skills transferable.	Do.
203.17	...do	High school graduate or more—provides for direct entry into skilled work.	Skilled or semiskilled—skills not transferable.	Do.
203.18	Closely approaching advanced age.	Limited or less	Unskilled or none	Do.
203.19	...do	...do	Skilled or semiskilled—skills not transferable.	Do.
203.20	...do	...do	Skilled or semiskilled—skills transferable.	Do.
203.21	...do	High school graduate or more.	Unskilled or none	Do.
203.22	...do	High school graduate or more—does not provide for direct entry into skilled work.	Skilled or semiskilled—skills not transferable.	Do.
203.23	...do	...do	Skilled or semiskilled—skills transferable.	Do.
203.24	...do	High school graduate or more—provides for direct entry into skilled work.	Skilled or semiskilled—skills not transferable.	Do.
203.25	Younger individual.	Limited or less	Unskilled or none	Do.
203.26	...do	...do	Skilled or semiskilled—skills not transferable.	Do.
203.27	...do	...do	Skilled or semiskilled—skills transferable.	Do.
203.28	...do	High school graduate or more.	Unskilled or none	Do.
203.29	...do	High school graduate or more—does not provide for direct entry into skilled work.	Skilled or semiskilled—skills not transferable.	Do.
203.30	...do	...do	Skilled or semiskilled—skills transferable.	Do.
203.31	...do	High school graduate or more—provides for direct entry into skilled work.	Skilled or semiskilled—skills not transferable.	Do.

204.00 *Maximum sustained work capability limited to heavy work (or very heavy work) as a result of severe medically determinable impairment(s).* The residual functional capacity to perform heavy work as defined in §404.1510(e), or very heavy work as defined in §404.1510(f), includes the functional capability for work at the lesser functional levels as well, and represents substantial work capability for jobs in the national economy at all skill and physical demand levels. Individuals who retain the functional capacity to perform heavy work (or very heavy work) ordinarily will not have a severe impairment or will be able to do their past work—either of which would have already provided a basis for a decision of "not disabled". Environmental restrictions ordinarily would not significantly affect the range of work existing in the national economy for individuals with the physical capability for heavy work (or very heavy work). Thus an impairment which does not preclude heavy work (or very heavy work) would not ordinarily be the primary reason for unemployment, and generally is sufficient for a finding of not disabled, even though age, education, and skill level of prior work experience may be considered adverse.

5. Section 416.902 is revised to read as follows:

§ 416.902 Evaluation of disability in general.

The provisions of §§ 416.902 through 416.913 apply to cases involving supplemental security income benefits based on disability under § 1614 of the Act (except for statutory blindness and children under age 18). In general, the individual has the burden of proving that he or she is disabled and of raising every issue with respect to his or her alleged disability. (See §§ 416.905, 416.924, 416.927.) Whether an impairment in a particular case constitutes a disability is determined from all the pertinent facts of that case. The determination of disability may be based on medical considerations alone, or on medical considerations and vocational factors as follows:

(a) *Disability determinations on the basis of medical considerations alone.* Medical evidence (i.e., signs, symptoms and laboratory findings) alone can justify a finding that an individual is not under a disability, or absent evidence to the contrary, that an individual is under a disability.

(b) *Disability determinations in which vocational factors must be considered along with the medical evidence.* In those cases where a finding of disabled or not disabled cannot be made based on medical evidence alone, other evidence is required. This other evidence may include information about:

(1) The individual's residual functional capacity;

(2) The individual's age, education, and work experience; and

(3) The kinds of substantial gainful activity (work) which exist in significant numbers in the national economy for someone who can do only what the individual can do.

(c) *Disability determinations in which vocational factors are extremely adverse.* Where an individual with a marginal education and long work experience (e.g., 35 to 40 years or more) limited to the performance of arduous unskilled physical labor is not working and is no longer able to perform such labor because of a significant impairment or impairments, such an individual may be found to be under a disability.

§ 416.903 through 416.907 [Redesignated §§ 416.914 through 416.918]

6. Sections 416.903 through 416.907 are redesignated as sections 416.914 through 416.918 respectively.

7. New §§416.903 through 416.913 are added to read as follows:

§ 416.903 Considerations in the sequential evaluation of disability.

(a) *General.* In the determination of whether or not an impairment in a particular case constitutes a disability as defined in § 416.901, consideration is given to all the pertinent facts of that case. If the individual is engaging in substantial gainful activity, a determination that he or she is not disabled shall be made. In all other cases, primary consideration is given to the physical or mental impairment(s), which must be severe. The impairment(s) must also meet the duration requirement before disability can be found to exist. However, in determining whether an individual is disabled, a sequential evaluation process shall be followed, whereby current work activity, severity of the impairment(s), and vocational factors are assessed in that order. The following evaluation steps shall be followed in the sequence shown, but when a determination that an individual is or is not disabled can be made at any step, evaluation under a subsequent step shall be unnecessary.

(b) *Is the individual currently engaging in substantial gainful activity?* Where an individual is actually engaging in substantial gainful activity, a finding shall be made that the individual is not under a disability without consideration of either medical or vocational factors. (See §§ 416.932, 416.933, 416.934.)

(c) *Does the individual have any severe impairments?* Where an individual does not have any impairment(s) which significantly limits his or her physical or mental capacity to perform basic work-related functions, a finding shall be made that he or she does not have a severe impairment and therefore is not under a disability without consideration of the vocational factors.

(d) *Does the individual have any impairment(s) which meets or equals those listed in Part A of Appendix 1?* Where an individual's impairment(s) meets the duration requirement and is either listed in Part A of Appendix 1 or is determined to be medically the equivalent of a listed impairment, a finding of disability shall be made without consideration of the vocational factors.

(e) *Does the individual have any impairment(s) which prevents past relevant work?* Where a finding of disability or no disability cannot be made based on current work activity or on medical considerations alone, and the individual has a severe impairment(s), his or her residual functional capacity and the physical and mental demands of his or her past relevant work shall be evaluated. If the impairment(s) does not prevent the individual from meeting the physical and mental demands of past relevant work, including arduous unskilled physical labor, disability shall be found not to exist.

(f) *Does the individual's impairment(s) prevent other work?* If an individual cannot perform any past relevant work because of a severe impairment(s), but the individual's remaining physical and mental capacities are consistent with his or her meeting the physical and mental demands of a significant number of jobs (in one or more occupations) in the national economy, and the individual has the vocational capabilities (considering age, education, and past work experience) to make an adjustment to work different from that which he or she has performed in the past, it shall be determined that the individual is not under a disability. However, if an individual's physical and mental capacities in conjunction with his or her vocational capabilities (considering age, education, and past work experience) do not permit the individual to adjust to work different from that which he or she has performed in the past, it shall be determined that the individual is under a disability.

§ 416.904 Determining whether disability exists—medical and other considerations.

(a) *Medical considerations.*—(1) *Finding individual not disabled.* Medical considerations alone can justify a finding that an individual is not under a disability where the medically determinable impairment is not severe. A medically determinable impairment is not severe if it does not significantly limit an individual's physical or mental capacity to perform basic work-related functions.

(2) *Finding individual disabled.* Medical considerations alone (including the physiological and psychological manifestations of aging) can justify a finding that an individual is under a disability, absent evidence to the contrary. Medical considerations which justify a finding that an individual is under a disability are those that bring an individual's impairment(s) under the listing in Part A of Appendix 1 of this subpart or which justify a determintion by the Secretary that the impairment(s) is the medical equivalent of an impairment listed in Part A of Appendix 1 of this subpart.

(b) *Relevant work.* Any medically determinable impairment(s) may justify a finding that an individual is under a disability if the impairment(s) is severe and prevents an individual from engaging in substantial gainful activity. In determining whether impairment(s) not listed in Part A of Appendix 1 of this subpart (nor found to be the equivalent of an impairment listed in Part A of Appendix 1) meet this test, additional considerations are

evaluated. These include determining whether an individual can qualify because he or she has only performed arduous unskilled work for a long period of time or, if not, whether he or she can perform vocationally relevant work.

(c) *Vocational Factors.* In those cases in which an individual is found unable to perform vocationally relevant past work, age, education, and work experience must then be considered in addition to the functional limitations imposed by the individual's physical or mental impairment(s).

§ 416.905 Residual functional capacity.

(a) *General.* Physical or mental impairment(s) may impose functional limitations on an individual's ability to engage in substantial gainful activity. The kind and severity of the impairment(s) determine the individual's work limitations and residual functional capacity. The manner in which the impairment(s) affects the individual's ability to perform work-related physical and mental activities, and the kind and extent of function the individual retains, are assessed in determining the individual's residual functional capacity. Where multiple impairments are involved, the assessment of residual functional capacity reflects the totality of restrictions resulting from all impairments. Assessments of residual functional capacity may be based solely on medical evidence where such evidence includes sufficient findings (e.g., signs, symptoms, and laboratory findings) to permit and support the necessary judgments where relevant, with respect to the individual's physical, mental, and sensory capabilities. In establishing disability for purposes of title XVI, the Secretary will assist the individual in meeting that burden by securing and paying for medical evidence needed for a sound determination. (See §§ 416.902, 416.924, 416.927.) Where all reasonably obtainable relevant medical findings alone are not sufficient for an adequate assessment of residual functional capacity, additional factors may be considered. Such additional factors as the individual's description of the impairment, recorded observations of the individual, and any other evidence of record may be considered in conjunction with the medical findings.

(b) *Physical capacities.* Assessment of physical capacities (e.g., strength and exertional capabilities) includes an evaluation of the individual and indicates the individual's maximal residual functional capacity for sustained activity on a regular basis. The assessment also includes the evaluation of the individual's ability to perform significant physical functions such as walking, standing, lifting, carrying, pushing or pulling. The assessment includes the evaluation of other physical traits and sensory characteristics such as reaching, handling, seeing, hearing, and speaking, insofar as limited capacity to perform these functions may also affect the individual's capacity for work for which the individual would otherwise be qualified.

(c) *Mental impairments.* The assessment of impairments because of mental disorders includes a consideration of such factors as the capacity to understand, to carry out and remember instructions, and to respond appropriately to supervision, co-workers and customary work pressures in a routine work setting.

(d) *Non-exertional limitations.* Any medically determinable impairment(s) resulting in non-exertional limitations (such as certain mental, sensory, or skin impairments) must be considered in terms of the limitations resulting from the impairment. When an individual has a non-exertional impairment in addition to an exertional impairment(s), the residual functional capacity must be assessed in terms of the degree of any additional narrowing of the individual's work-related capabilities.

(e) *When assessment is required.* An assessment of residual functional capacity is required only with respect to those specific physical or mental capacities that are in doubt by reason of the individual's allegations or the evidence adduced. Where such doubt does not exist with respect to particular physical or mental capacities, the individual is considered to have no restrictions with respect to those capacities.

(f) *Relationship of residual functional capacity to ability to do work.* Where the residual functional capacity so determined is sufficient to enable the individual to do his or her previous work (i.e., usual work or other vocationally relevant past work), a determination is made that the individual is not under a disability. Where the residual functional capacity so determined is not sufficient to enable the individual to do his or her previous work, it must be determined what work, if any, the individual can do, taking into consideration the individual's residual functional capacity, age, education, and work experience and whether work that the individual can do exists in significant numbers in the national economy.

§ 416.906 Age as a vocational factor.

(a) *General.* The term "age" refers to chronological age and the extent to which it affects the individual's capability to engage in work in competition with others. However, the factor of age in itself is not determinative of disability; the residual functional capacity and the education and work experience of the individual must also be considered. An individual who is unemployed because of age cannot be found incapable of engaging in substantial gainful activity when the individual's impairment and other vocational considerations, e.g., education and work experience, would enable the individual to perform a significant number of jobs which exist in the national economy. The considerations given to age are appropriately reflected in Appendix 2, but are not to be applied mechanically in borderline situations.

(b) *Younger individual.* In the case of a younger individual (under age 50), age in itself is ordinarily not considered to affect significantly the individual's ability to adapt to a new work situation.

(c) *Individual approaching advanced age.* For the individual not of advanced age but who is closely approaching avanced age (age 50–54), the factor of age, in combination with a severe impairment and limited vocational background, may substantially affect the individual's adaptability to a significant number of jobs in a competitive work environment.

(d) *Individual of advanced age.* "Advanced" age (age 55 or over) represents the point where age significantly affects the ability to engage in substantial work. Where a severely impaired individual is of advanced age, such ability may be adversely affected except where the individual has skills that are readily transferable to jobs which exist in significant numbers in the national economy. Those individuals of advanced age who are age 60–64 are further described as closely approaching retirement age.

§ 416.907 Education as a vocational factor.

(a) *General.* The term "education" is primarily used in the sense of formal schooling or other training which contributes to the individual's ability to meet vocational requirements, e.g., reasoning ability, communication skills, and arithmetical ability. Lack of formal schooling is not necessarily proof that the individual is uneducated or lacks such capacities. For individuals with past work experience, the kinds of responsibilities assumed when working may indicate the existence of such intellectual capacities although their formal education is limited. Other evidence of such capacities, for individuals with or without past work experience, may consist of daily activities, hobbies, or the results of testing. The significance of an individual's educational background may be materially affected by the time lapse between the completion of the individual's formal education and the onset of physical or mental impairment(s)

and by what the individual has done with his or her education in a work context. Formal education that was completed many years prior to onset of impairment or unused skills and knowledge that were a part of such formal education may no longer be useful or meaningful in terms of the individual's ability to work. Thus, the numerical grade level of educational attainment may not be representative of an individual's present educational competences which could be higher or lower. However, in the absence of evidence to the contrary, the numerical grade level will be used. The term "education" also indicates whether an individual has the ability to communicate in English, since that ability is often acquired or enhanced through educational exposure. In evaluating the educational level of an individual, the following classifications are used:

(b) *Illiteracy.* Illiteracy refers to the inability to read or write. An individual who is able to sign his or her name, but cannot read or write a simple communication (e.g., instructions, inventory lists), is considered illiterate. Generally, an illiterate individual has had little or no formal schooling.

(c) *Marginal education.* Marginal education refers to competence in reasoning, arithmetic, and language skills which are required for the performance of simple, unskilled types of jobs. Absent evidence to the contrary, formal schooling at a grade level of sixth grade or less is considered a marginal education.

(d) *Limited education.* Limited education refers to competence in reasoning, arithmetic, and language skills which, although more than that which is generally required to carry out the duties of unskilled work, does not provide the individual with the educational qualifications necessary to perform the majority of more complex job duties involved in semi-skilled or skilled jobs. Absent evidence to the contrary, a seventh grade through the eleventh grade level of formal education is considered a limited education.

(e) *High school education and above.* High school education and above refers to competence in reasoning, arithmetic, and language skills acquired through formal schooling at a level of grade twelve or above. Absent evidence to the contrary, these educational capacities qualify an individual for work at a semi-skilled through a skilled level of job complexity.

(f) *Inability to communicate in English.* Ability to communicate in English is often acquired or enhanced through educational exposure, and this may be considered an educational factor. Where there is inability to communicate in English, the dominant language of the national economy, this may be considered a vocational handicap because it often narrows an individual's vocational scope. For example, the inability to communicate in English may preclude an individual from performing jobs which require conversing with peers and supervisors in English, or reading instructions, signs, forms, etc., which are printed in English. However, the inability to communicate in English in no sense implies that an individual lacks formal schooling or intelligence. A person unable to communicate in English may have a vocational handicap which must be considered in assessing what work, if any, the individual can do. The particular non-English language in which an individual may be fluent is generally immaterial.

§ 416.908 Work experience as a vocational factor.

The term "work experience" means skills and abilities acquired through work previously performed by the individual which indicates the type of work the individual may be expected to perform. Work for which the individual has demonstrated a capability is the best indicator of the kind of work that the individual can be expected to do. Such work experience has current vocational relevance where the recency of the work and the skills acquired demonstrate the individual's ability to perform work which exists in the national economy. Work performed 15 years or more prior to the point at which the claim is being considered for adjudication (or when the earnings requirement was last met) is ordinarily not considered vocationally relevant. In our economic system, a gradual transition occurs in the job functions of most jobs so that by the time 15 years have elapsed, it is no longer realistic to assume that skills and abilities acquired in a job performed more than 15 years ago continue to be relevant. The 15-year guide is essentially intended to insure that current vocational relevance is not imputed to remote work experience which could not reasonably be expected to enhance an individual's vocational prospect as of the point of adjudication. An individual who has no prior work experience or has worked only sporadically or for brief periods of time during the 15-year period may be considered to have no relevant work experience. Any skills acquired through work experience are vocational assets unless they are not transferable to other skilled or semi-skilled work within the individual's current capacities. When acquired skills are not transferable, the indivdual is considered capable of only unskilled work. However, an individual need not have work experience to qualify for unskilled work which requires little or no judgment in the performance of simple duties which can be learned in a short period of time.

§ 416.909 Work which exists in the national economy.

(a) *General.* Work is considered to exist in the national economy when it exists in significant numbers either in the region where the individual lives or in several other regions of the country, regardless of whether such work exists in the immediate area in which the individual lives, or whether a specific job vacancy exists for the individual, or whether the individual would be hired if the individual applied for work. A finding that work exists in the national economy is made when there is a significant number of jobs (in one or more occupations) having typical requirements which do not exceed the individual's physical or mental capacities and vocational qualifications. Isolated jobs of a type that exist only in very limited number or in relatively few geographic locations outside of the region where the individual resides are not considered to be "work which exists in the national economy" for purposes of determining whether an individual is under a disability; an individual is not denied benefits on the basis of the existence of such jobs. If work that the individual can do does not exist in the national economy, disability shall be determined to exist. If such work does exist in the national economy, disability shall be determined not to exist.

(b) *Inability of individual to obtain work.* If an individual's residual functional capacity and vocational capabilities are consistent with the performance of work which exists in the national economy but the individual remains unemployed because the individual is unsuccessful in obtaining such work or because such work does not exist in the individual's local area; or because of the hiring practices of employers, technological changes in the industry in which the individual has worked, or cyclical economic conditions; or because there are no job openings for the individual or the individual would not actually be hired to do work the individual could otherwise perform, the individual is considered not to be under a disability as defined in § 416.901.

(c) *Administrative notice of job data.* In the determination of whether jobs as classified by their exertional and skill requirements exist in significant numbers either in the region or the national economy, administrative notice shall be taken of reliable job information available from various governmental and other publications; e.g., "Dictionary of Occupational Titles," published by the Department of Labor; "County Business Patterns," published by the Bureau of the

Census; "Census Reports," also published by the Bureau of the Census; occupational analyses prepared for the Social Security Administration by various State employment agencies; and the "Occupational Outlook Handbook," published by the Bureau of Labor Statistics.

§ 416.910 Exertional requirements.

(a) *General.* For the purpose of determining exertional requirements of work in the national economy, jobs are classified as "sedentary," "light," "medium," "heavy," and "very heavy." Such terms have the same meaning as they have in the "Dictionary of Occupational Titles," published by the Department of Labor, and when used in making disability determinations under this subpart, are defined as follows:

(b) *Sedentary work.* Sedentary work entails lifting 10 pounds maximum and occasionally lifting or carrying such articles as dockets (e.g., files), ledgers, and small tools. Although a sedentary job is defined as one which involves sitting, a certain amount of walking and standing is often necessary in carrying out job duties. Jobs are sedentary if walking and standing are required occasionally and other sedentary criteria are met.

(c) *Light work.* Light work entails lifting 20 pounds maximum with frequent lifting or carrying of objects weighing up to 10 pounds. Even though the weight lifted may be only a negligible amount, a job is in this category when it requires walking or standing to a significant degree, or when it involves sitting most of the time with a degree of pushing and pulling of arm or leg controls. To be considered capable of performing a full or wide range of light work, an individual must be capable of performing substantially all of the foregoing activities. The functional capacity to perform light work includes the functional capacity to perform sedentary work.

(d) *Medium work.* Medium work entails lifting 50 pounds maximum with frequent lifting or carrying of objects weighing up to 25 pounds. The functional capacity to perform medium work includes the functional capacity to perform sedentary work and light work as well.

(e) *Heavy work.* Heavy work entails lifting 100 pounds maximum with frequent lifting or carrying of objects weighing up to 50 pounds. The functional capacity to perform heavy work includes the functional capacity to perform work at all of the lesser functional levels.

(f) *Very heavy work.* Very heavy work entails lifting objects in excess of 100 pounds with frequent lifting or carrying of objects weighing 50 pounds or more. The functional capacity to perform very heavy work includes the functional capacity to perform work at all of the lesser functional levels.

§ 416.911 Skill requirements.

(a) *General.* For purposes of assessing the skills reflected by an individual's work experience, and of determining the existence in the national economy of work the individual is competent to do, occupations are classified as unskilled, semi-skilled, and skilled. When used in making disability determinations under this subpart, these terms are used in the following sense:

(b) *Unskilled work.* Unskilled work denotes work which requires little or no judgment in the preformance of simple duties that can be learned on the job in a short period of time. Considerable strength may or may not be required. As an example, where the primary work function of occupations consists of handling, feeding, and offbearing (i.e., placing or removing materials from machines which are automatic or operated by others), or machine tending, and average successful job performance can ordinarily be achieved within 30 days, such occupations are considered unskilled. Other types of jobs requiring little specific vocational preparation and little judgment are likewise unskilled. No acquired work skills can be attributed to individuals who have performed only unskilled work.

(c) *Semi-skilled work.* Semi-skilled work denotes work in which some skills are involved but the more complex work functions are not required. Semi-skilled jobs may require alertness and close attention to watching machine processes; or inspecting, testing or otherwise detecting irregularities; or tending or guarding equipment, property, materials, or persons against loss, damage or injury; or other types of activities involving work functions of similar complexity. A job may be classified as semi-skilled where coordination and dexterity are necessary as in the use of the hands or feet for the rapid performance of repetitive tasks.

(d) *Skilled work.* Skilled work requires qualifications in which the independent judgment of the individual determines the machine and manual operations to be performed in obtaining the proper form, quality, or quantity of material to be produced. The individual may be required to lay out work, to estimate quality, suitability and needed quantities of materials, to make precise measurements, to read blueprints or other specifications, or to make necessary computations or mechanical adjustments to control or regulate processes. Other skilled jobs may require dealing with personnel, data, or abstract ideas at a high level of complexity.

(e) *Transferable work skills.* An individual is considered to have transferable skills when the skilled or semi-skilled work functions which he or she has demonstrated in his or her past work can be applied to meet the requirements of skilled or semi-skilled work functions of other jobs or kinds of work. Transferability depends largely on the similarity of occupationally significant work functions among jobs. Transferability is most probable and meaningful among jobs in which the same or a lesser degree of skill is required; and the same or similar tools and machines are used; and the same or similar raw materials, products, processes, or services are involved. There are degrees of transferability ranging from a close approximation of work functions involving all three factors to only remote and incidental similarities among jobs. A complete similarity of all three factors is not necessary to warrant the inference of transferability. Where an individual's work skills are so specialized or have been acquired in such a limited vocational setting that they are not readily usable in other industries, jobs and work environments, they are not transferable and the individual may be considered as if he or she is unskilled. (Also see Appendix 2, § 201.00 (e), (f), and § 202.00 (e), (f).)

§ 416.912 Effect of performance of arduous unskilled physical labor.

Where an individual with a marginal education and long work experience (e.g., 35 to 40 years or more) limited to the performance of arduous unskilled physical labor is not working and is no longer able to perform such labor because of a significant impairment or impairments and, considering his or her age, education, and vocational background is unable to engage in lighter work, such individual may be found to be under a disability. On the other hand, a different conclusion may be reached where it is found that such individual is working or has worked despite his or her impairment or impairments (except where such work is sporadic or is medically contraindicated) depending upon all the facts in the case. In addition, an individual who was doing heavy physical work at the time he or she suffered such impairment might not be considered unable to engage in any substantial gainful activity if the evidence shows that he or she has the training or past work experience which qualifies him or her for substantial gainful work in another occupation consistent with his or her impairment, either on a full-time or a reasonably regular part-time basis.

Example. B, a 60-year old miner, with a fourth grade education, after a life-long history of arduous physical labor alleged that he was under a disability because of arthritis of the spine, hips, and knees and other impairments. Medical evidence shows a combination of impairments and establishes that these impairments prevent B from performing his usual work or any other type of arduous physical labor. His vocational background does not disclose either through performance or by similarly persuasive evidence that he has skills or capabilities needed to do lighter work which would be readily transferable to another work environment. Under these circumstances, B may be found to be under a disability.

§ 416.913 Listing of medical-vocational guidelines in Appendix 2.

In light of information that is available about jobs (classified by their exertional and skill requirements) that exist in the national economy, Appendix 2 sets forth rules reflecting the major functional and vocational patterns which are encountered in cases which do not fall within the criteria of § 416.904 (a) and (b) or § 416.912, where an individual is not engaging in substantial gainful activity and is prevented by medically determinable impairment from performing his or her vocationally relevant past work. The Appendix 2 rules do not encompass all possible variations of factors and, as explained in § 200.00 of Appendix 2, are not applicable in any case where any one of the findings of fact made with respect to the individual's vocational factors and residual functional capacity does not coincide with the corresponding criterion of a rule. In such instances, full consideration must be given to all relevant facts in accordance with the definitions and discussions of each factor in §§ 416.905–416.911. However, when the findings of fact made as to all factors coincide with the criteria of a rule, that rule directs a conclusion of disabled or not disabled.

8. Subpart I of Part 416 is further amended by adding a new Appendix 2, to read as follows:

APPENDIX 2—MEDICAL—VOCATIONAL GUIDELINES

Secs.

200.00 Introduction.
201.00 Maximum sustained work capability limited to sedentary work as a result of severe medically determinable impairment(s).
202.00 Maximum sustained work capability limited to light work as a result of severe medically determinable impairment(s).
203.00 Maximum sustained work capability limited to medium work as a result of severe medically determinable impairment(s).
204.00 Maximum sustained work capability limited to heavy work (or very heavy work) as a result of severe medically determinable impairment(s).

200.00 *Introduction.* (a) The following rules reflect the major functional and vocational patterns which are encountered in cases which do not fall within the criteria of § 416.904 (a) and (b) or § 416.912, where an individual with a severe medically determinable physical or mental impairment(s) is not engaging in substantial gainful activity and the individual's impairment(s) prevents the performance of his or her vocationally relevant past work. They also reflect the analysis of the various vocational factors (i.e., age, education, and work experience) in combination with the individual's residual functional capacity (used to determine his or her maximum sustained work capability for sedentary, light, medium, heavy, or very heavy work) in evaluating the individual's ability to engage in substantial gainful activity in other than his or her vocationally relevant past work. Where the findings of fact made with respect to a particular individual's vocational factors and residual functional capacity coincide with all of the criteria of a particular rule, the rule directs a conclusion as to whether the individual is or is not disabled. However, each of these findings of fact is subject to rebuttal and the individual may present evidence to refute such findings. Where any one of the findings of fact does not coincide with the corresponding criterion of a rule, the rule does not apply in that particular case and, accordingly, does not direct a conclusion of disabled or not disabled. In any instance where a rule does not apply, full consideration must be given to all of the relevant facts of the case in accordance with the definitions and discussions of each factor in §§ 416.905–416.911.

(b) The existence of jobs in the national economy is reflected in the "Decisions" shown in the rules; i.e., in promulgating the rules, administrative notice has been taken of the numbers of unskilled jobs that exist throughout the national economy at the various functional levels (sedentary, light, medium, heavy, and very heavy) as supported by the "Dictionary of Occupational Titles" and the "Occupational Outlook Handbook," published by the Department of Labor; the "County Business Patterns" and "Census Surveys" published by the Bureau of the Census; and occupational surveys of light and sedentary jobs prepared for the Social Security Administration by various State employment agencies. Thus, when all factors coincide with the criteria of a rule, the existence of such jobs is established. However, the existence of such jobs for individuals whose remaining functional capacity or other factors do not coincide with the criteria of a rule must be further considered in terms of what kinds of jobs or types of work may be either additionally indicated or precluded.

(c) In the application of the rules, the individual's residual functional capacity (i.e., the maximum degree to which the individual retains the capacity for sustained performance of the physical-mental requirements of jobs), age, education, and work experience must first be determined.

(d) The correct disability decision (i.e., on the issue of ability to engage in substantial gainful activity) is found by then locating the individual's specific vocational profile. If an individual's specific profile is not listed within this Appendix 2, a conclusion of disabled or not disabled is not directed. Thus, for example, an individual's ability to engage in substantial gainful work where his or her residual functional capacity falls between the ranges of work indicated in the rules (e.g., the individual who can perform more than light but less than medium work), is decided on the basis of the principles and definitions in the regulations, giving consideration to the rules for specific case situations in this Appendix 2. These rules represent various combinations of exertional capabilities, age, education and work experience and also provide an overall structure for evaluation of those cases in which the judgments as to each factor do not coincide with those of any specifc rule. Thus, when the necessary judgments have been made as to each factor and it is found that no specific rule applies, the rules still provide guidance for decisionmaking, such as in cases involving combinations of impairments. For example, if the strength limitations resulting from an individual's impairment(s) considered with the judgments made as to the individual's age, education and work experience correspond to (or closely approximate) the factors of a particular rule, the adjudicator then has a frame of reference for considering the jobs or types of work precluded by other, non exertional impairments in terms of numbers of jobs remaining for a particular individual.

(e) Since the rules are predicated on an individual's having an impairment which manifests itself by limitations in meeting the strength requirements of jobs, they may not be fully applicable where the nature of an individual's impairment does not result in such limitations, e.g., certain mental, sensory, or skin impairments. In addition, some impairments may result solely in postural and manipulative limitations or environmental restrictions. Environmental restrictions are those restrictions which result in inability to tolerate some physical features(s) of work settings that occur in certain industries or types of work, e.g., an inability to tolerate dust or fumes.

(1) In the evaluation of disability where the individual has solely a nonexertional type of impairment, determination as to whether disability exists shall be based on the principles of §§ 416.905–416.911, giving consideration to the rules for specific case situations in this Appendix 2. The rules do not direct factual conclusions of disabled or not disabled for individuals with solely nonexertional types of impairments.

(2) However, where an individual has an impairment or combination of impairments resulting in both strength limitations and nonexertional limitations, the rules in this subpart are considered in determining first whether a finding of disabled may be possible based on the strength limitations alone and, if not, the rule(s) reflecting the individual's maximum residual strength capabilities, age, education, and work experience provide a framework for consideration of how much the individual's work capability is further diminished in terms of any types of jobs that would be contraindicated by the nonexertional limitations. Also, in these combinations of nonexertional and exertional limitations which cannot be wholly determined under the rules in this Appendix 2, full consideration must be given to all of the relevant facts in the case in accordance with the definitions and discussion of each factor in §§ 416.905–416.911, which will provide insight into the adjudicative weight to be accorded each factor.

201.00 *Maximum sustained work capability limited to sedentary work as a result of severe medically determinable impairment(s).* (a) Most sedentary occupations fall within the skilled, semi-skilled, professional, administrative, technical, clerical, and benchwork classifications. Approximately 200 separate unskilled sedentary occupations can be identified, each representing numerous jobs in the national economy. Approximately 85 percent of these jobs are in the machine trades and benchwork occupational categories. These jobs (unskilled sedentary occupations) may be performed after a short demonstration or within 30 days.

(b) These unskilled sedentary occupations are standard within the industries in which they exist. While sedentary work represents a significantly restricted range of work, this range in itself is not so prohibitively restricted as to negate work capability for substantial gainful activity.

(c) Vocational adjustment to sedentary work as defined in §416.910(b) may be expected where the individual has special skills or experience relevant to sedentary work or where age and basic educational competences provide sufficient occupational mobility to adapt to the major segment of unskilled sedentary work. Inability to engage in substantial gainful activity would be indicated where an individual who is restricted to sedentary work because of a severe medically determinable impairment lacks special skills or experience relevant to sedentary work, lacks educational qualifications relevant to most sedentary work (e.g., has a limited education or less) and the individual's age, though not necessarily advanced, is a factor which significantly limits vocational adaptability.

(d) The adversity of functional restriction to sedentary work at advanced age (55 and over) for individuals with no relevant past work or who can no longer perform vocationally relevant past work, and have no transferable skills, warrants a finding of disabled in the absence of the rare situation where the individual has recently completed education which provides a basis for direct entry into skilled sedentary work. Advanced age and a history of unskilled work or no work experience would ordinarily offset any vocational advantages that might accrue by reason of any remote past education, whether it is more or less than limited education.

(e) The presence of acquired skills that are readily transferable to a significant range of skilled work within an individual's residual functional capacity would ordinarily warrant a finding of ability to engage in substantial gainful activity regardless of the adversity of age, or whether the individual's formal education is commensurate with his or her demonstrated skill level. The acquisition of work skills demonstrates the ability to perform work at the level of complexity demonstrated by the skill level attained regardless of the individual's formal educational attainments.

(f) In order to find transferability of skills to skilled sedentary work for individuals who are of advanced age (55 and over), there must be very little, if any, vocational adjustment required in terms of tools, work processes, work settings, or the industry.

(g) Individuals approaching advanced age (age 50–54) may be significantly limited in vocational adaptability if they are restricted to sedentary work. When such individuals have no past work experience or can no longer perform vocationally relevant past work and have no transferable skills, a finding of disabled ordinarily obtains. However, recently completed education which provides for direct entry into sedentary work will preclude such a finding. For this age group, even a high school education or more (ordinarily completed in the remote past) would have little impact for effecting a vocational adjustment unless relevant work experience reflects use of such education.

(h) The term "younger individual" is used to denote an individual age 18 through 49. For those within this group who are age 45–49, age is a less positive factor than for those who are age 18–44. Accordingly, for such individuals (1) who are restricted to sedentary work, (2) who are unskilled or have no transferable skills, (3) who have no relevant past work or who can no longer perform vocationally relevant past work, and (4) who are either illiterate or unable to communicate in the English language, a finding of disabled is warranted. On the other hand, age is a more positive factor for those who are under age 45 and is usually not a significant factor in limiting such an individual's ability to make a vocational adjustment, even an adjustment to unskilled sedentary work, and even where the individual is illiterate or unable to communicate in English. However, a finding of disabled is not precluded for those individuals under age 45 who do not meet all of the criteria of a specific rule and who do not have ability to perform a full range of sedentary work. The following examples are illustrative: Example 1: An individual under age 45 with a high school education can no longer do past work and is restricted to unskilled sedentary jobs because of a severe medically determinable cardiovascular impairment (which does not meet or equal the listings in Part A of Appendix 1). A permanent injury of the right hand limits the individual to sedentary jobs which do not require bilateral manual dexterity. None of the rules in Appendix 2 are applicable to this particular set of facts, because this individual cannot perform the full range of work defined as sedentary. Since the inability to perform jobs requiring bilateral manual dexterity significantly compromises the only range of work for which the individual is otherwise qualified; (i.e., sedentary), a finding of disabled would be appropriate. Example 2: An illiterate 41 year old individual with mild mental retardation (IQ of 78) is restricted to unskilled sedentary work and cannot perform vocationally relevant past work, which had consisted of unskilled agricultural field work; his or her particular characteristics do not specifically meet any of the rules in Appendix 2, because this individual cannot perform the full range of work defined as sedentary. In light of the adverse factors which further narrow the range of sedentary work for which this individual is qualified, a finding of disabled is appropriate.

(i) While illiteracy or the inability to communicate in English may significantly limit an individual's vocational scope, the primary work functions in the bulk of unskilled work relate to working with things (rather than with data or people) and in these work functions at the unskilled level, literacy or ability to communicate in English has the least significance. Similarly, the lack of relevant work experience would have little significance since the bulk of unskilled jobs require no qualifying work experience. Thus, the functional capability for a full range of sedentary work represents sufficient numbers of jobs to indicate substantial vocational scope for those individuals age 18–44 even if they are illiterate or unable to communicate in English.

TABLE No. 1.—*Residual functional capacity: Maximum sustained work capability limited to sedentary work as a result of severe medically determinable impairment(s)*

Rule	Age	Education	Previous work experience	Decision
201.01	Advanced age	Limited or less	Unskilled or none	Disabled.
201.02	do	do	Skilled or semiskilled—skills not transferable [1].	Do.
201.03	do	do	Skilled or semiskilled—skills transferable [1].	Not disabled.
201.04	do	High school graduate or more—does not provide for direct entry into skilled work [2].	Unskilled or none	Disabled.
201.05	do	High school graduate or more—provides for direct entry into skilled work [2].	do	Not disabled.
201.06	do	High school graduate or more—does not provide for direct entry into skilled work [2].	Skilled or semiskilled—skills not transferable [1].	Disabled.
201.07	do	do. [2]	Skilled or semiskilled—skills transferable [1].	Not disabled.
201.08	do	High school graduate or more—provides for direct entry into skilled work [2].	Skilled or semiskilled—skills not transferable [1].	Do.
201.09	Closely approaching advanced age.	Limited or less	Unskilled or none	Disabled.
201.10	do	do	Skilled or semiskilled—skills not transferable.	Do.
201.11	do	do	Skilled or semiskilled—skills transferable.	Not disabled.
201.12	do	High school graduate or more—does not provide for entry into skilled work [2].	Unskilled or none	Disabled.
201.13	do	High school graduate or more—provides for direct entry into skilled work [2].	do	Not disabled.

TABLE No. 1.—*Residual functional capacity: Maximum sustained work capability limited to sedentary work as a result of severe medically determinable impairment(s)*—Continued

Rule	Age	Education	Previous work experience	Decision
201.14	do	High school graduate or more—does not provide for direct entry into skilled work [3].	Skilled or semiskilled—skills not transferable.	Disabled.
201.15	do	do. [3]	Skilled or semiskilled—skills transferable.	Not disabled.
201.16	do	High school graduate or more—provides for direct entry into skilled work [3].	Skilled or semiskilled—skills not transferable.	Do.
201.17	Younger individual, age 45 to 49.	Illiterate or unable to communicate in English.	Unskilled or none	Disabled.
201.18	do	Limited or less—at least literate and able to communicate in English.	do	Not disabled.
201.19	do	Limited or less	Skilled or semiskilled—skills not transferable.	Do.
201.20	do	do	Skilled or semiskilled—skills transferable.	Do.
201.21	do	High school graduate or more.	Skilled or semiskilled—skills not transferable.	Do.
201.22	do	do	Skilled or semiskilled—skills transferable.	Do.
201.23	Younger individual, age 18 to 44.	Illiterate or unable to communicate in English.	Unskilled or none	Do. [4]
201.24	do	Limited or less—at least literate and able to communicate in English.	do	Do. [4]
201.25	do	Limited or less	Skilled or semiskilled—skills not transferable.	Do. [4]
201.26	do	do	Skilled or semiskilled—skills transferable.	Do. [4]
201.27	do	High school graduate or more.	Unskilled or none	Do. [4]
201.28	do	do	Skilled or semiskilled—skills not transferable.	Do. [4]
201.29	do	do	Skilled or semiskilled—skills transferable.	Do. [4]

[1] See 201.00(f).
[2] See 201.00(d).
[3] See 201.00(g).
[4] See 201.00(h).

202.00 *Maximum sustained work capability limited to light work as a result of severe medically determinable impairment(s).* (a) The functional capacity to perform a full range of light work as defined in § 416.910(c) includes the functional capacity to perform sedentary as well as light work. Approximately 1,600 separate sedentary and light unskilled occupations can be identified in eight broad occupational categories, each occupation representing numerous jobs in the national economy. These jobs can be performed after a short demonstration or within 30 days, and do not require special skills or experience.

(b) The functional capacity to perform a wide or full range of light work represents substantial work capability compatible with making a work adjustment to substantial numbers of unskilled jobs and, thus, generally provides sufficient occupational mobility even for severely impaired individuals who are not of advanced age and have sufficient educational competences for unskilled work.

(c) However, for individuals of advanced age who can no longer perform vocationally relevant past work and who have a history of unskilled work experience, or who have only skills that are not readily transferable to a significant range of Semi-skilled or skilled work that is within the individual's functional capacity, or who have no work experience, the limitations in vocational adaptability represented by functonal restriction to light work warrant a finding of disabled. Ordinarily, even a high school education or more which was completed in the remote past will have little positive impact on effecting a vocational adjustment unless relevant work experience reflects use of such education.

(d) Where the same factors in paragraph (c) of this section regarding education and work experience are present, but where age, though not advanced, is a factor which significantly limits vocational adaptability (i.e., closely approaching advanced age, 50–54) and an individual's vocational scope is further significantly limited by illiteracy or inability to communicate in English, a finding of disabled is warranted.

(e) The presence of acquired skills that are readily transferable to a significant range of semi-skilled or skilled work within an individual's residual functional capacity would ordinarily warrant a finding of not disabled regardless of the adversity of age, or whether the individual's formal education is commensurate with his or her demonstrated skill level. The acquisition of work skills demonstrates the ability to perform work at the level of complexity demonstrated by the skill level attained regardless of the individual's formal educational attainments.

(f) For a finding of transferability of skills to light work for individuals of advanced age who are closely approaching retirement age (age 60–64), there must be very little, if any, vocational adjustment required in terms of tools, work processes, work settings, or the industry.

(g) While illiteracy or the inability to communicate in English may significantly limit an individual's vocational scope, the primary work functions in the bulk of unskilled work relate to working with things (rather than with data or people) and in these work functions at the unskilled level, literacy or ability to communicate in English has the least significance. Similarly, the lack of relevant work experience would have little significance since the bulk of unskilled jobs require no qualifying work experience. The capability for light work, which includes the ability to do sedentary work, represents the capability for substantial numbers of such jobs. This, in turn, represents substantial vocational scope for younger individuals (age 18–49) even if illiterate or unable to communicate in English.

TABLE No. 2.—*Residual functional capacity: Maximum sustained work capability limited to light work as a result of severe medically determinable impairment(s)*

Rule	Age	Education	Previous work experience	Decision
202.01	Advanced age	Limited or less	Unskilled or none	Disabled.
202.02	do	do	Skilled or semiskilled—skills not transferable.	Do.

TABLE NO. 2.—*Residual functional capacity: Maximum sustained work capability limited to light work as a result of severe medically determinable impairment(s)* —Continued

Rule	Age	Education	Previous work experience	Decision
202.03	....do	....do	Skilled or semiskilled—skills transferable [1].	Not disabled.
202.04	....do	High school graduate or more—does not provide for direct entry into skilled work [2].	Unskilled or none	Disabled.
202.05	....do	High school graduate or more—provides for direct entry into skilled work [2].	....do	Not disabled.
202.06	....do	High school graduate or more—does not provide for direct entry into skilled work [2].	Skilled or semiskilled—skills not transferable.	Disabled.
202.07	....do	....do. [2]	Skilled or semiskilled—skills transferable [1].	Not disabled.
202.08	....do	High school graduate or more—provides for direct entry into skilled work [2].	Skilled or semiskilled—skills not transferable.	Do.
202.09	Closely appoaching advanced age.	Illiterate or unable to communicate in English.	Unskilled or none	Disabled.
202.10	....do	Limited or less—at least literate and able to communicate in English.	....do	Not disabled.
202.11	....do	Limited or less	Skilled or semiskilled—skills not transferable.	Do.
202.12	....do	....do	Skilled or semiskilled—skills transferable.	Do.
202.13	....do	High school graduate or more.	Unskilled or none	Do.
202.14	....do	....do	Skilled or semiskilled—skills not transferable.	Do.
202.15	....do	....do	Skilled or semiskilled—skills transferable.	Do.
202.16	Younger individual.	Illiterate or unable to communicate in English.	Unskilled or none	Do.
202.17	....do	Limited or less—at least literate and able to communicate in English.	....do	Do.
202.18	....do	Limited or less	Skilled or semiskilled—skills not transferable.	Do.
202.19	....do	....do	Skilled or semiskilled—skills transferable.	Do.
202.20	....do	High school graduate or more.	Unskilled or none	Do.
202.21	....do	....do	Skilled or semiskilled—skills not transferable.	Do.
202.22	....do	....do	Skilled or semiskilled—skills transferable.	Do.

[1] See 202.00(f)
[2] See 202.00(c)

203.00 *Maximum sustained work capability limited to medium work as a result of severe medically determinable impairment(s).* (a) The functional capacity to perform medium work as defined in 416.910(d) includes the functional capacity to perform sedentary, light, and medium work. Approximately 2,500 separate sedentary, light, and medium occupations can be identified, each occupation representing numerous jobs in the national economy which do not require skills or previous experience and which can be performed after a short demonstration or within 30 days.

(b) The functional capacity to perform medium work represents such substantial work capability at even the unskilled level that a finding of disabled is ordinarily not warranted in cases where a severely impaired individual retains the functional capacity to perform medium work. Even the adversity of advanced age (55 and over) and a work history of unskilled work may be offset by the substantial work capability represented by the functional capacity to perform medium work. (Note that the provisions of § 416.912 must have been given prior consideration.)

(c) However, the absence of any relevant work experience becomes a more significant adversity for individuals of advanced age (55 and over). Accordingly, this factor, in combination with a limited education or less, militates against making a vocational adjustment to even this substantial range of work and a finding of disabled is appropriate. Further, for individuals closely approaching retirement age (60–64) with a work history of unskilled work and with marginal education or less, a finding of disabled is appropriate.

TABLE NO. 3.—*Residual functional capacity: Maximum sustained work capability limited to medium work as a result of severe medically determinable impairment(s)*

Rule	Age	Education	Previous work experience	Decision
203.01	Closely approaching retirement age.	Marginal or none	Unskilled or none	Disabled.
203.02	....do	Limited or less	None	Do.
203.03	....do	Limited	Unskilled	Not disabled.
203.04	....do	Limited or less	Skilled or semiskilled—skills not transferable.	Do.
203.05	....do	....do	Skilled or semiskilled—skills transferable.	Do.
203.06	....do	High school graduate or more.	Unskilled or none	Do.
203.07	....do	High school graduate or more—does not provide for direct entry into skilled work.	Skilled or semiskilled—skills not transferable.	Do.

TABLE No. 3.—*Residual functional capacity: Maximum sustained work capability limited to medium work as a result of severe medically determinable impairment(s)*—Continued

Rule	Age	Education	Previous work experience	Decision
203.08	do	do	Skilled or semiskilled—skills transferable.	Do.
203.09	do	High school graduate or more—provides for direct entry into skilled work.	Skilled or semiskilled—skills not transferable.	Do.
203.10	Advanced age	Limited or less	None	Disabled.
203.11	do	do	Unskilled	Not disabled.
203.12	do	do	Skilled or semiskilled—skills not transferable.	Do.
203.13	do	do	Skilled or semiskilled—skills transferable.	Do.
203.14	do	High school graduate or more.	Unskilled or none	Do.
203.15	do	High school graduate or more—does not provide for direct entry into skilled work.	Skilled or semiskilled—skills not transferable.	Do.
203.16	do	do	Skilled or semiskilled—skills transferable.	Do.
203.17	do	High school graduate or more—provides for direct entry into skilled work.	Skilled or semiskilled—skills not transferable.	Do.
203.18	Closely approaching advanced age.	Limited or less	Unskilled or none	Do.
203.19	do	do	Skilled or semiskilled—skills not transferable.	Do.
203.20	do	do	Skilled or semiskilled—skills transferable.	Do.
203.21	do	High school graduate or more.	Unskilled or none	Do.
203.22	do	High school graduate or more—does not provide for direct entry into skilled work.	Skilled or semiskilled—skills not transferable.	Do.
203.23	do	do	Skilled or semiskilled—skills transferable.	Do.
203.24	do	High school graduate or more—provides for direct entry into skilled work.	Skilled or semiskilled—skills not transferable.	Do.
203.25	Younger individual.	Limited or less	Unskilled or none	Do.
203.26	do	do	Skilled or semiskilled—skills not transferable.	Do.
203.27	do	do	Skilled or semiskilled—skills transferable.	Do.
203.28	do	High school graduate or more.	Unskilled or none	Do.
203.29	do	High school graduate or more—does not provide for direct entry into skilled work.	Skilled or semiskilled—skills not transferable.	Do.
203.30	do	do	Skilled or semiskilled—skills transferable.	Do.
203.31	do	High school graduate or more—provides for direct entry into skilled work.	Skilled or semiskilled—skills not transferable.	Do.

204.00 *Maximum sustained work capability limited to heavy work (or very heavy work) as a result of severe medically determinable impairment(s).* The residual functional capacity to perform heavy work as defined in § 416.910(e), or very heavy work as defined in § 416.910(f) includes the functional capability for work at the lesser functional levels as well, and represents substantial work capability for jobs in the national economy at all skill and physical demand levels. Individuals who retain the functional capacity to perform heavy work (or very heavy work) ordinarily will not have a severe impairment or will be able to do their past work—either of which would have already provided a basis for a decision of "not disabled". Environmental restrictions ordinarily would not significantly affect the range of work existing in the national economy for individuals with the physical capability for heavy work (or very heavy work). Thus, an impairment which does not preclude heavy work (or very heavy work) would not ordinarily be the primary reason for unemployment, and generally is sufficient for a finding of not disabled even though age, education, and skill level of prior work experience may be considered adverse.

[FR Doc. 78-32393 Filed 11-27-78; 8:45 am]

[4110-07-M]

[Regulations No. 16]

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart B—Eligibility

ELIGIBILITY OF INDIVIDUALS RESIDING IN PUBLICLY OPERATED COMMUNITY RESIDENCES SERVING NO MORE THAN 16 RESIDENTS

AGENCY: Social Security Administration, HEW.

ACTION: Final regulations.

SUMMARY: This final rule provides that the term "public institution" does not include publicly operated community residences which serve no more than 16 residents and defines this kind of residence. Thus, individuals who are residing in publicly operated community residences which serve no more than 16 residents, and who are otherwise qualified, are eligible for Supplemental Security Income (SSI) benefits.

This rule encourages the development of small residential facilities as an alternative to care in large institutions for persons who would benefit from a living arrangement closely approximating independent living in a community setting while, at the same time, receiving supportive care and some degree of supervision. These provisions are designed to acclimate residents to community living and to ease the transition into an independent living situation.

EFFECTIVE DATE: November 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. S. J. Weissman, Legal Assistant, Social Security Administration, 6401 Security Boulevard, Baltimore, Md. 21235, telephone 301-594-7341.

SUPPLEMENTARY INFORMATION: On January 31, 1978, this amendment was published in the FEDERAL REGISTER (43 FR 4004) as an interim regulation.

BACKGROUND

Prior to the enactment of section 505(a) of Pub. L. 94-566, section 1611(e)(1) of the Act provided only one exception to the general rule that no person shall be eligible to receive SSI benefits for any month throughout which the individual is an inmate of a public institution. The previous exception, which continues in effect, provides that an individual who is throughout a month in a public institution may be eligible for SSI benefits if the institution is receiving payments under a State plan approved under Title XIX (Medicaid) on his or her behalf, assuming all other SSI eligibility criteria are met. In this situation, the standard payment amount is $25 for each full month of such institutionalization. This amount is then subject to reduction for any countable income which the individual may have. However, if the public institution is not receiving title XIX (Medicaid) payments on his or her behalf, the individual is ineligible for SSI benefits. The rules implementing these statutory provisions are found in Title 20 of the Code of Federal Regulations, § 416.231.

SCOPE OF RULES

1. Section 505(a) of Pub. L. 94-566 added a second exception to the exclusion of inmates of public institutions. Section 1611(e)(1)(C) of the Act now

provides that the term "public institution" does not include publicly operated community residences which serve no more than 16 residents. Accordingly, we have amended § 416.231 by adding a new paragraph (a)(3) to state that for purposes of § 416.231 the term public institution does not include publicly operated community residences which serve no more than 16 residents. Thus, individuals residing in residences of this type are eligible for SSI benefits if all other SSI criteria are met.

2. We have also amended § 416.231 by adding a new paragraph (b)(6)(i). This paragraph defines publicly operated community residences which serve no more than 16 residents as follows:

It must be publicly operated as defined in § 416.231(b)(2); and

It must be planned and designed to serve no more than 16 residents, or the plan and design was changed to serve no more than 16 residents; and

It must be serving no more than 16 residents; and

It must make available some services beyond food and shelter such as social services or help with personal living activities, or training in socialization and life skills; occasional or incidental medical or remedial care may also be provided (as defined in 45 CFR 228.1).

In developing this definition we looked to the wording of the statute. We also considered the background materials contained in the legislative history of the statute. (See Hearing on H.R. 10210 Before the Subcommittee on Public Assistance of the House Committee on Ways and Means, 94th Cong., 2nd Sess. (1976). Also see S. Rep. No. 1265, 94th Cong., 2nd Sess. page 29 (1976).)

The central theme in these materials is the underlying philosophy that community residences provide a desirable alternative to large institutions because they can provide not only life sustaining services of food and shelter, but also can encourage personal independence in an atmosphere of mutual acceptance and support for emotional growth and life enrichment activities. Based on this information, the critical factors used in developing this definition were size, location, and purpose.

We also considered the problems which can arise because of fluctuating occupancy levels in this type of facility. We believe the most feasible and equitable way to meet the intent of the legislation is to look to the number of residents the facility is designed or planned to serve. This is in keeping with the intent of the statute which envisions a 16 resident capacity as an outer limit applicable to community residences. The test is whether or not community residences are designed or planned, according to their specifications, to house and provide services for no more than 16 residents, and whether no more than 16 persons are actually residing in the residence.

A publicly operated community residence, while not considered a "public institution" for purposes of making residents ineligible for SSI under section 161(a)(1)(A) of the Act, is nevertheless an institution, and as such is expected to provide some services beyond food and shelter (§ 416.231(b)(1)). Thus, a publicly operated community residence must make available some other services such as social services, or help with personal living activities, or training in socialization and life skills. Such services may also include occasional or incidental medical or remedial care. It is intended that these services will provide the individual with the skills necessary to return to community living.

3. To further insure clarity of the above definition, we also added a new paragraph (b)(6)(ii) to § 416.231. It describes those public facilities which are not considered community residences even if their accommodations are for 16 or fewer residents. Excluded are educational or vocational training institutions, correctional or holding facilities, medical treatment facilities, and residential facilities located on the grounds of or immediately adjacent to any large institution or multiple-purpose complex.

Educational and vocational training institutions are designed to provide individuals with approved, accredited or recognized educational or training programs preparatory to gainful employment. A publicly operated community residence is designed to acclimate its residents to community living, thereby easing their transition into independent living situations. Since each differs in its primary goal, educational and vocational training institutions cannot qualify as publicly operated community residences. Even though individuals residing in educational or vocational training institutions would not be eligible for SSI benefits under this final rule, such individuals may be eligible for SSI benefits under § 416.231(b)(3). This is so because § 416.231(b)(3) provides that a person is not considered an "inmate of a public institution" when he or she is in a public educational or vocational training institution for purposes of securing education or vocational training.

Correctional or holding facilities are part of the criminal justice system, and medical treatment facilities primarily focus on providing medical or remedial care. Since none of these institutions is designed to provide the desired living arrangement envisioned by the statute, they are excluded from the definition of publicly operated community residences.

Residential facilities located on the grounds of or adjacent to a larger institution or multiple-purpose complex are excluded because their location is inconsistent with the statutory provisions and purposes regarding community residences. Colocated residential facilities are an integral part of the larger institution. Therefore, such a living arrangement would not be considered as an alternative to institutional living. Moreover, a facility so situated is really not part of the community and thus could not as readily accomplish the intended goal.

Discussion of Comments

Interested persons were given the opportunity to submit, within 90 days, data, views, or arguments with regard to the interim regulation. A number of comments were received from private, State, and local organizations. Responses to the comments are discussed below.

Comment: One commenter recommended that a payment of graded higher allowances be allowed based on the number of services provided by halfway houses and that those which do not furnish specified minimum services be eliminated by closing their doors.

Response: Concerning the first part of the comment, there is no statutory provision for varying the amount of Federal SSI benefits based on the number of services a community residence may provide. The second part of the comment relates to the regulations published by the Office of Human Development Services (OHDS) on January 31, 1978 (43 FR 4016) which provides for States to establish standards for such facilities. Accordingly, this comment was forwarded to OHDS for their consideration of that issue.

Comment: Two commenters objected to § 416.231(b)(6)(ii)(*a*) because it excludes from the definition of "publicly operated community residences which serve no more than 16 residents" residential facilities located on the grounds of or immediately adjacent to any large institution or multiple-purpose complex. They state that this exclusion is inconsistent with the intent and purposes of the statute, constitutes poor social policy, and presents an unnecessary obstacle to the States.

Response: All of the pertinent background information relating to section 505(a) of Pub. L. 94-566 shows that the Congress and other concerned organizations intimately involved in the development of the statute, specifically indicated the need for the limitation in § 416.231(b)(6)(ii)(*a*). The Congress intentionally chose the term "community residence" to refer to a small, free-standing, community-based living unit and clearly intended that facilities on the grounds of large institutions or immediately adjacent to them be excluded from the definition of "publicly operated community resi-

dences which serve no more than 16 residents," because these living arrangements are not considered to be alternatives to institutional living.

This is borne out in a letter we received from Congressman William Brodhead and Congresswoman Martha Keys (co-sponsors of this legislation) shortly after enactment of this statute in which they shared with us their thoughts on the direction the regulations should take. They specifically stated that "small houses on the grounds of large institutions or immediately adjacent to them should not be considered community residences." Since it was clearly the intent of Congress to exclude this type of residential facility, we are not adopting this recommendation.

Comment: One commenter viewed the interim regulation as a positive step and hoped it would become permanent.

Response: This amendment adopts the interim regulation as a final rule.

Comment: One commenter proposed that: (1) the interim regulation be revised to exclude SSI benefits only from those residences in which more than 16 people are receiving SSI benefits; and (2) the definition of "inmate" be revised to include anyone placed in an institution by court or doctor's order.

Response: The first proposal cannot be adopted because it is not consistent with section 1611(e)(1)(C) of the Social Security Act and its legislative history. That section states "not more than 16 residents." Congress intended that these residential facilities be small enough so that a financial incentive would not exist for the States to fragment their institutions which provide custodial care to those who need it. Throughout the hearings and committee reports on the amendment, the term "small residential facility" is used to refer to small, free-standing, community living units.

With respect to the second proposal, the term "inmate of a public institution" is defined in current regulations (§ 416.231(b)(3)) as a person who is living in a public institution and receiving treatment or services which are appropriate to the person's requirements. This provision is based on section 1611(e)(1) (A) and (B) of the Act. These provisions were not changed by Pub. L. 94-566.

Comment: One commenter suggested that the interim regulation be revised to include people who reside in private homes, private apartments, and family care centers. The commenter also suggested changes concerning the trial work period as it relates to sheltered workshop employment, increasing the limitation on resources, and a number of other points not related to this regulation.

Response: Individuals residing in private homes, private apartments, or family care facilities are not affected by this amendment. This rule concerns only public residences. Qualified individuals residing in private facilities have been and continue to be eligible for the full standard payment amount, unless the facility is receiving payments under a State plan approved under Title XIX (Medicaid) in which case the standard payment amount is $25. Thus, no change is made on this point.

With respect to the commenter's suggestion that the limitation on resources be increased, a Notice of Proposed Rule Making proposing an increase for certain resources (e.g., automobile, personal effects, and household goods) was published in the FEDERAL REGISTER of April 28, 1978 (43 FR 18206). However, the limitation of $1,500 for an individual ($2,250 for a couple) is set by law and cannot be increased by regulations. The commenter's other suggestions not related to this amendment will be studied and given further consideration.

TECHNICAL CHANGES

Section 416.231(a)(3) was reserved at the time this amendment was published as an interim regulation. This reserved paragraph is being deleted and § 416.231(a)(4) is being redesignated § 416.231(a)(3). Conforming editorial corrections have been made to § 416.231(a) and to § 416.231(b)(6)(i) to reflect this change.

Accordingly, with these editorial changes, the amendment is adopted as set forth below.

(Sections 1102, 1611, and 1631 of the Social Security Act as amended, 49 Stat. 647, as amended, 86 Stat. 1466 and 1475; 42 U.S.C. 1302, 1382(e) and 1383(d)(1).)

(Catalog of Federal Domestic Assistance Program No. 13.807, Supplemental Security Income Program.)

Dated: August 18, 1978.

DON WORTMAN,
Acting Commissioner of Social Security.

Approved: November 17, 1978.

HALE CHAMPION,
Acting Secretary of Health, Education, and Welfare.

Part 416 of Chapter III of Title 20 of the Code of Federal Regulations is amended as set forth below:

Section 416.231 is amended by revising paragraph (a)(1) and adding paragraphs (a)(3), (b)(6)(i), and (b)(6)(ii) to read as follows:

§ 416.231 Limitation on eligibility due to institutional status.

(a) *General.* (1) Except as provided in subparagraphs (2) and (3) of this paragraph, no person shall be an eligible individual or eligible spouse for purposes of title XVI of the Act with respect to any month if throughout such month the person is an inmate of a public institution.

* * * * *

(3) The term "public institution," as used in this section does not include a publicly operated community residence which serves no more than 16 residents. Where it is determined that a community residence is not publicly operated such residence is not a public institution as defined in § 416.231(b)(2) and this section will not apply.

(b) *Definitions.* For purposes of this part the following definitions shall apply:

* * * * *

(6)(i) The term "publicly operated community residence which serves no more than 16 residents" (see § 416.231(a)(3)) means:

(*a*) It must be publicly operated as defined in § 416.231(b)(2); and

(*b*) It must be designed and planned to serve no more than 16 residents, or the plan and design was changed to serve no more than 16 residents; and

(*c*) It must be serving 16 or fewer residents; and

(*d*) It must make available some services beyond food and shelter such as social services, or help with personal living activities, or training in socialization and life skills; occasional or incidental medical or remedial care may also be provided (as defined in 45 CFR 228.1).

(ii) Excluded from the definition of "publicly operated community residences" are the following facilities, even if their accommodations are for 16 residents or less:

(*a*) Residential facilities located on the grounds of or immediately adjacent to any large institution or multiple-puprose complex: and

(*b*) Educational or vocational training institutions that primarily provide an approved or accredited or recognized program to some or all of the individuals residing within it; and

(*c*) Correctional or holding facilities which provide for individuals whose personal freedom is restricted because of a court sentence to confinement (prisoners), court ordered holding (material witness, juvenile) or a pending disposition of charges or status (individuals who have been arrested or detained); and

(*d*) Medical treatment facilities (hospitals and skilled nursing facilities, see 42 U.S.C. 1395x and intermediate care facilities, see 42 U.S.C. 1396d) which provide medical or remedial care on an inpatient basis.

[FR Doc. 78-33192 Filed 11-27-78; 8:45 am]

[4110-03-M]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER D—DRUGS FOR HUMAN USE

[Docket No. 78N-0294]

ANTIBIOTIC DRUGS

Certification of Natamycin

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the antibiotic drug regulations to provide for the certification of natamycin. The manufacturer has supplied sufficient data and information to establish the safety and efficacy of natamycin.

DATES: Effective November 28, 1978; comments by January 29, 1979.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Joan Eckert, Bureau of Drugs (HFD-140), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4290.

SUPPLEMENTARY INFORMATION: The Commissioner of Food and Drugs has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as amended, with respect to providing for the certification of natamycin and concludes that the data supplied by the manufacturer concerning this antibiotic drug product are adequate to establish its safety and efficacy when the drug is used as directed in the labeling and that the regulations should be amended in Parts 430, 436, and 449 (21 CFR Parts 430, 436, and 449) to provide for the drug's certification.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357)) and under authority delegated to the Commissioner (21 CFR 5.1), Parts 430, 436, and 449 are amended as follows:

PART 430—ANTIBIOTIC DRUGS; GENERAL

1. Part 430 is amended as follows:

a. In § 430.4 by adding new paragraph (a)(45) to read as follows:

§ 430.4 Definitions of antibiotic substances.

(a) * * *

(45) *Natamycin.* Each of the antibiotic substances produced by the growth of *Streptomyces natalensis,* and each of the same substances produced by any other means, is a kind of natamycin.

b. In § 430.5 by adding new paragraphs (a)(63) and (b)(63) to read as follows:

§ 430.5 Definitions of master and working standards.

(a) * * *

(63) *Natamycin.* The term "natamycin master standard" means a specific lot of natamycin designated by the Commissioner as the standard of comparison in determining the potency of the natamycin working standard.

(b) * * *

(63) *Natamycin.* The term "natamycin working standard" means a specific lot of a homogeneous preparation of natamycin.

c. In § 430.6 by adding a new paragraph (b)(65) to read as follows:

§ 430.6 Definitions of the terms "unit" and "microgram" as applied to antibiotic substances.

* * * * *

(b) * * *

(65) *Natamycin.* The term "microgram" applied to natamycin means the natamycin activity (potency) contained in 1.0846 micrograms of the natamycin master standard.

PART 436—TESTS AND METHODS OF ASSAY OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

2. Part 436 is amended:

a. In § 436.105(a) and (b) by alphabetically inserting a new item into the tables, as follows:

§ 436.105 Microbiological agar diffusion assay.

* * * * *

(a) * * *

[4110-03-C]

Antibiotic	Media to be used (as listed by medium number in § 436.102(b))		Milliliters of media to be used in the base and seed layers		Test Organism	Suggested volume of standardized inoculum to be added to each 100 milliliters of seed agar	Incubation Temperature for the plates
	Base layer	Seed layer	Base layer	Seed layer			
						Milliliters	Degrees C.
* * *	* * *	* * *	* * *	* * *	* * *	* * *	* * *
Natamycin	None	19	None	8	E	0.25	30
* * *	* * *	* * *	* * *	* * *	* * *	* * *	* * *

Antibiotic	Working standard stock solutions					Standard response line concentrations	
	Drying conditions (method number as listed in § 436.200)	Initial solvent	Diluent (solution number as listed in § 436.101(a))	Final concentration units or milligrams per milliliter	Storage time under refrigeration	Diluent	Final concentrations, units or micrograms of antibiotic activity per milliliter
* * *	* * *	* * *	* * *	* * *	* * *	* * *	* * *
Natamycin			Dimethylsulfoxide 1 mg [5/]		Use same day	10	3.20, 4.00, 5.00 6.25, 7.81 µg. (Prepare the standard response line solutions simultaneously with the sample solution to be tested using red low actinic glassware. Use solutions within 2 hours after preparation.)
* * *	* * *	* * *	* * *	* * *	* * *	* * *	* * *

[5/] Further dilute aliquots of the working standard stock solution with dimethylsulfoxide to give concentrations 64.0, 80.0, 100, 125, and 156 micrograms per milliliter.

* * * * *

PART 449—ANTIFUNGAL ANTIBIOTIC DRUGS

3. Part 449 is amended as follows:

a. In Subpart A, by adding new § 449.40 to read as follows:

§ 449.40 Natamycin.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Natamycin is 22-[(3 - amino - 3,6 - dideoxy -β-D-mannopyranosyl) - oxy] - 1,3,26-trihydroxy - 12-methyl-10-oxo-6,11,28-trioxatricyclo [22.3.1.0^{5,7}] octacosa-8,14,16,18,20 - pentaene-25-carboxylic acid. It is an off-white to cream colored powder which may contain up to 3 moles of water. It is practically insoluble in water, slightly soluble in methanol, and soluble in glacial acetic acid and dimethylformamide. It is so purified and dried that:

(i) Its potency is not less than 900 micrograms of natamycin per milligram on an anhydrous basis.

(ii) Its moisture content is not less than 6.0 percent and not more than 9.0 percent.

(iii) Its pH in a 1 percent aqueous suspension is not less than 5.0 and not more than 7.5.

(iv) It passes the identity test.

(v) It is crystalline.

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

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

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

(ii) Samples required: 10 packages, each containing approximately 500 milligrams.

(b) *Tests and methods of assay.* Dilute solutions of natamycin are very sensitive to light and should be kept in the dark as much as possible or substantial decomposition will take place.

(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample in dimethylsulfoxide and further dilute with sufficient dimethylsulfoxide to give a concentration of 100 micrograms of natamycin per milliliter (estimated). Further dilute with 0.2*M* potassium phosphate buffer, pH 10.5 (solution 10), to the reference concentration of 5.0 micrograms of natamycin per milliliter (estimated).

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using a 1.0 percent aqueous suspension.

(4) *Identity.* Accurately weigh approximately 50 milligrams of the sample into a 200-milliliter volumetric flask. Add approximately 5.0 milliliters of distilled water, and completely moisten the sample. Then add approximately 100 milliliters of an acid-alcohol solvent (0.1 percent glacial acetic acid in methyl alcohol) and stir or shake mechanically in the dark until solution is complete. Dilute to volume with the acid-alcohol mix. Transfer 2.0 milliliters of this solution to a 100-milliliter volumetric flask and dilute to volume with the acid-alcohol mix. Using a suitable spectrophotometer with 1-centimeter cells and the acid-alcohol as a blank, record the ultraviolet absorption spectrum from 215 to 330 nanometers. The spectrum compares qualitatively to that of the natamycin working standard similarly treated.

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

b. By adding new Subpart D, consisting of new § 449.340, to read as follows:

Subpart D—Ophthalmic Dosage Forms

§ 449.340 Natamycin ophthalmic suspension.

(a) *Requirements for certification—*(1) *Standards of identity, strength, quality, and purity.* Natamycin ophthalmic suspension contains natamycin with one or more suitable and harmless preservatives in a suitable and harmless aqueous vehicle. Each milliliter contains 50 milligrams of natamycin. Its potency is satisfactory if it is not less than 90 percent and not more than 125 percent of the number of milligrams of natamycin that it is represented to contain. It is sterile. Its pH is not less than 6.0 and not more than 7.5. The natamycin used conforms to the standards prescribed by § 449.40(a)(1).

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

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

(i) Results of tests and assays on:

(*a*) The natamycin used in making the batch for potency, moisture, pH, identity, and crystallinity.

(*b*) The batch for potency, sterility, and pH.

(ii) Samples required:

(*a*) The natamycin used in making the batch: 10 packages, each containing not less than 500 milligrams.

(*b*) The batch:

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

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

(b) *Tests and methods of assay.* Dilute solutions of natamycin are very sensitive to light and should be kept in the dark as much as possible or substantial decomposition will take place.

(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Dilute an accurately measured representative portion of the sample with sufficient dimethylsulfoxide to give a stock solution of convenient concentration. Further dilute an aliquot of the stock solution with dimethylsulfoxide to a concentration of 100 micrograms of natamycin per milliliter (estimated). Further dilute an aliquot with 0.2*M* potassium phosphate buffer, pH 10.5 (solution 10), to the reference concentration of 5.0 micrograms of natamycin per milliliter (estimated).

(2) *Sterility.* Proceed as directed in § 436.20 of this chapter, using the method described in paragraph (e)(2) of that section, except use 0.25 milliliter of sample in lieu of 1.0 milliliter.

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

Because the conditions prerequisite to providing for certification of this drug have been complied with and because the matter is noncontroversial, the Commissioner finds for good cause that prior notice and public procedure are impracticable and unnecessary, and that the amendment may become effective November 28, 1978.

Interested persons may, on or before January 29, 1979, file with the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments, in four copies and identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the office of the Hearing Clerk between the hours of 9 a.m. and 4 p.m., Monday through Friday. Any changes in this regulation justified by such comments will be the subject of a further amendment.

Effective date. This regulation shall be effective November 28, 1978.

(Sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357))

Dated: November 21, 1978.

MARY A. MCENIRY,
Assistant Director for Regulatory Affairs, Bureau of Drugs.

[FR Doc. 78-33226 Filed 11-27-78; 8:45 am]

[4110-03-M]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Caramiphen Ethanedisulfonate and Ammonium Chloride Tablets

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: This document amends the regulations to reflect an approved new animal drug application (NADA) sponsored by Fort Dodge Laboratories providing for the use of caramiphen ethanedisulfonate and ammonium chloride tablets for the relief of cough in dogs. A previously approved supplement reflects this product's compliance with the conclusions of the National Academy of Sciences/National Research Council (NAS/NRC) evaluation of the product.

EFFECTIVE DATE: November 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Donald A. Gable, Bureau of Veterinary Medicine (HFV-114), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3420.

SUPPLEMENTARY INFORMATION: Fort Dodge Laboratories, 800 5th St. NW., Fort Dodge, IA 50501, is the sponsor of a new animal drug application (NADA 9-339V), which was originally approved April 1, 1954 for the relief of cough in small animals.

The product was the subject of a NAS/NRC review published in the FEDERAL REGISTER of December 6, 1968 (33 FR 18204). The Academy concluded, and the agency concurred, that the drug was probably effective, but the label claim "for use in small animals for relief of cough" was too broad. The Academy stated: (1) That the label should show species and dosage; (2) that data submitted would support use in dogs and cats; (3) that additional toxicity and effectiveness data would be required for other animals; (4) and that dosage studies were inadequate to allow for a complete evaluation. The firm responded with a supplement to its application bringing it into compliance with the results of the NAS/NRC review. The supplement was approved on April 7, 1969. This document codifies the conditions of that approval.

The conditions are those for which approval of an NADA for a similar product does not require efficacy data as specified by §§ 514.1(b)(8)(ii) or 514.111(a)(5)(vi) of the animal drug regulations (21 CFR 514.1(b)(8)(ii) or 514.111(a)(5)(vi)). These conditions, indicated by footnote, are those for which approval may require bioequivalency or similar data as suggested in the guideline for submitting NADA's for NAS/NRC reviewed generic drugs, on file in the office of the Hearing Clerk (HFA-305), Food and Drug Administration.

This action, reflecting an approved NADA, does not constitute reaffirmation of the drug's safety or efficacy. Since the application was originally approved before July 1, 1975, a summary of safety and effectiveness data and other information submitted to support approval of the application in accordance with § 514.11(e)(2)(ii) is not required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), Part 520 is amended by adding a new § 520.310 to read as follows:

§ 520.310 Caramiphen ethanedisulfonate and ammonium chloride tablets.

(a) *Specifications.* Each tablet contains 10 milligrams of caramiphen ethanedisulfonate and 80 milligrams of ammonium chloride.[1]

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

c) *Conditions of use in dogs*—(1) *Amount.* One tablet per 15 to 30 pounds of body weight every 4 to 6 hours.[1]

(2) *Indications for use.* For relief of cough.[1]

Effective date. This regulation is effective November 28, 1978.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: November 20, 1978.

LESTER M. CRAWFORD,
Director of Bureau of Veterinary Medicine.

[FR Doc. 78-33225 Filed 11-27-78; 8:45 am]

[4110-03-M]

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Primidone Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The regulations are amended to reflect approval of a new animal drug application (NADA) sponsored by Fort Dodge Laboratories. The NADA provides for the use of a 250-milligram primidone tablet for treating dogs for convulsions associated with certain forms of epilepsy, distemper, and hardpad disease. A previously approved supplement reflects this product's compliance with the conclusions of the National Academy of Sciences/National Research Council, Drug Efficacy Study Group (NSA/NRC) review.

EFFECTIVE DATE: November 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Donald A Gable, Bureau of Veterinary Medicine (HFV-114), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3420.

SUPPLEMENTARY INFORMATION: Fort Dodge Laboratories, 800 5th St. NW., Fort Dodge, IA 50501, is a sponsor of an NADA (10-091V) which was originally approved October 18, 1955. The product was one of two which were the subject of an NAS/NRC review published in the FEDERAL REGISTER of February 14, 1969 (34 FR 2214). The NAS/NRC concluded, and the agency concurred, that the product was probably effective but that a proper package insert was needed. The NAS/NRC review set forth information which substantially reflects the conditions of use of the drug.

In response to the NAS/NRC review, the firm submitted a supplement to its application to bring it into compliance with the NAS/NRC conclusions. The supplement, approved April 24, 1969, provides for conditions of use which are the same as those in § 520.1900 of the regulations (21 CFR 520.1900) for an identical drug, as published in the FEDERAL REGISTER of December 6, 1977 (42 FR 61594) and amended December 20, 1977 (42 FR 63773). The December 6, 1977 publication provides for the NAS/NRC conditions of use.

This action, reflecting an approved NADA, does not constitute reaffirmation of the drug's safety or effectiveness. Because this application was approved before July 1, 1975, a summary of safety and effectiveness data and information submitted in accordance with § 514.11(e)(2)(ii) to support this application is not required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

Veterinary Medicine (21 CFR 5.83), § 520.1900 is amended by revising paragraph (b) to read as follows:

§ 520.1900 Primidone tablets.

* * * * *

(b) *Sponsor.* See No. 000046 in § 510.600(c) of this chapter for use of 50- and 250-milligram tablets and Nos. 000725 and 000856 in § 510.600(c) of this chapter for use of 250-milligram tablets.

* * * * *

Effective date. This regulation shall be effective November 28, 1978.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: November 28, 1978.

LESTER M. CRAWFORD,
Director, Bureau of Veterinary Medicine.

[FR Doc. 78-33136 Filed 11-27-78; 8:45 am]

[4110-03-M]

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Promazine Hydrochloride Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The regulations are amended to reflect a previously approved new animal drug application (NADA) sponsored by Wyeth Labs. The NADA provides for use of promazine hydrochloride tablets as a tranquilizer in dogs and cats. A previously approved supplement reflects this product's compliance with the conclusions of the National Academy of Sciences—National Research Council, Drug Efficacy Study Group (NAS/NRC) review.

EFFECTIVE DATE: November 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Donald A. Gable, Bureau of Veterinary Medicine (HFV-114), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3420.

SUPPLEMENTARY INFORMATION: Wyeth Laboratories, Division of American Home Products Corp., P.O. Box 8299, Philadelphia, PA 19101, is sponsor of an NADA (10-783V) which was originally approved May 1, 1957. The product was one of several which were the subject of an NAS/NRC evaluation published in the FEDERAL REGISTER of November 18, 1969 (34 FR 18394). The NAS/NRC concluded, and the agency concurred, that the product was probably effective for veterinary use as a tranquilizer. The evaluation described certain labeling changes and additional information needed to upgrade the product from probably effective to effective.

Wyeth Labs complied with the NAS/NRC review by submitting a supplemental NADA (10-783V) which revised the labeling as recommended. No new efficacy data were required to upgrade the application from probably effective to effective.

Applications need not include efficacy data as specified by § 514.1(b)(8)(ii) or § 514.111(a)(5)(vi) (21 CFR 514.1(b)(8)(ii) or 514.111(a)(5)(vi)) of the animal drug regulations for similar products having the same conditions of use. However, approval may require bioequivalency or similar data as suggested in the guidelines for submitting NADA's for generic drugs reviewed by NAS/NRC. The guidelines are available from the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

This action, reflecting an approved NADA, does not constitute reaffirmation of the safety and effectiveness data supporting this approval. Because the NADA was approved before July 1, 1975, a summary of safety and effectiveness data and information submitted in accordance with § 514.11 (e)(2)(ii) to support this approval is not required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), Part 520 is amended in § 520.1962 by redesignating the existing paragraphs (a), (b), (c), (d), and (e) as paragraph (a)(1), (2), (3), (4), and (5) and adding new paragraph (b) to read as follows:

§ 520.1962 Promazine hydrochloride.

* * * * *

(b)(1) *Specifications.* Each tablet contains 25, 50, or 100 milligrams of promazine hydrochloride.

(2) *Sponsor.* No. 000008 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Amount—Dogs and cats.* 1 to 3 milligrams orally per pound of body weight in intervals of 4 to 6 hours.[1]

(ii) *Indications for use.* The drug is used for control of central nervous system excitation; allaying anxiety, nervousness and apprehension; calming agitated animals; and minimizing injury during shipment. As a preanesthetic agent, the drug potentiates effects of general anesthesia. It is indicated during physical and/or radiographic examination, radiographic diagnosis or therapy, and surgery. It reduces self-mutilation associated with sutures, bandages, eczema, pruritis, and otitis. Oral administration before vermifuge prevents emesis in cats.[1]

(iii) *Limitations.* As with all phenothiazine-derived compounds, promazine should not be used in conjunction with organophosphates because their toxicity may be potentiated, nor with procaine hydrochloride for its activity may be increased. Prolonged depression or motor restlessness may occur in sensitive animals or on excessive dosing. For use only by or on the order of a licensed veterinarian.[1]

Effective date. This regulation shall be effective November 28, 1978.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: November 17, 1978.

LESTER M. CRAWFORD,
Director, Bureau of Veterinary Medicine.

[FR Doc. 78-33135 Filed 11-27-78; 8:45 am]

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bio-equivalency and safety information.

[4110-03-M]

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

Ferrous Fumarate

AGENCY: Food and Drug Adminisration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect withdrawal of approval of a new animal drug application (NADA) held by ConAgra, Inc. This action was requested by the firm.

EFFECTIVE DATE: November 28, 1978.

FOR FURTHER INFORMATION:

David N. Scarr, Bureau of Veterinary Medicine (HFV-214), Food and Drug Administraion, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1846.

SUPPLEMENTARY INFORMATION: In a separate document published elsewhere in this issue of the FEDERAL REGISTER, the agency is withdrawing approval of NADA 31-876 for Boost-O-Iron (20 percent ferrous fumarate) sponsored by ConAgra, Inc., 3801 Harney St., Omaha, NE 68131.

The NADA was approved in conjunction with publication of a new food additive regulation, § 121.297 *Ferrous fumarate* (21 CFR 121.297, subsequently recodified as § 558.258) in the FEDERAL REGISTER of February 14, 1967 (32 FR 2846). The regulation was issued in response to NADA 31-876 and food additive petition 5D1685 filed by Nixon & Co., Omaha, NE 68131, since renamed ConAgra, Inc. Accordingly, the new animal drug regulations are being amended to revoke § 558.258.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.84), Part 558 is amended by revoking § 558.258 *Ferrous fumarate.*

Effective date. This regulation is effective November 28, 1978.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360(i)).)

Dated: November 17, 1978.

LESTER M. CRAWFORD,
Acting Director,
Bureau of Veterinary Medicine.

[FR Doc. 78-33134 Filed 11-27-78; 8:45 am]

[41-1003-M]

SUBCHAPTER J—RADIOLOGICAL HEALTH

[Docket No. 77N-0074]

PART 1040—PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

Laser Products

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This rule amends the laser products performance standard to remove unneeded criteria for determining human access to laser or collateral radiation; specify more appropriate parameters for measuring the accessible emission levels of laser and collateral radiation, including scanned laser radiation; relax the accessible emission limits for collateral radiation in the wavelength range of greater than 400 nanometers (nm); relax the labeling and performance requirements for some Class II laser products; and allow more administrative flexibility in determining the wording of warning labels.

DATES: Effective December 8, 1978, except for § 1040.10(h)(2) (i) and (ii) which will be effective January 29, 1979, for laser products that are manufactured on or after these dates; comments by January 29, 1979.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn E. Conklin, Bureau of Radiological Health (HFX-460), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: The Commissioner of Food and Drugs issued a notice of intent, published in the FEDERAL REGISTER of April 1, 1977 (42 FR 17495), to amend the performance standard for laser products (§ 1040.10 (21 CFR 1040.10)). That notice described the amendments being considered as a result of experience gained in administering the performance standard. Interested persons were invited to submit written data, views, or arguments concerning those amendments and any associated potential environmental and economic impact. A draft of the amendments was distributed widely to manufacturers, professional associations, consumer groups, government agencies, and individuals who had requested information about laser products from the Bureau of Radiological Health of the Food and Drug Administration (FDA). Subsequently, the draft amendments and the basic concepts for them were discussed publicly at the May 5, 1977 meeting of the Technical Electronic Product Radiation Safety Standards Committee. Under the Radiation Control for Health and Safety Act of 1968, this statutory committee must be consulted prior to the establishment of any electronic product performance standard. The Committee and others generally supported the concepts involved in the amendments and suggested revisions to eliminate possible ambiguities.

The Commissioner therefore finds that further notice and public procedure on these amendments are unnecessary, and that more than adequate notice and opportunity for comment have already been provided.

EFFECTIVE DATE

These amendments would reduce the burden on affected manufacturers and the cost to the consumers without compromising the public health and safety. Also, no manufacturer with a currently compliant product would need to redesign his or her products in order to comply with the proposed amendments, and there would be greater design latitude within each of the graded risk classes for laser products. Therefore, it has been determined that pre-effectiveness delay concerning these amendments is unnecessary and would be contrary to the public interest by delaying realization of the cost savings that are anticipated to result from their implementation.

The Commissioner concludes, therefore, that good cause exists and that the public interest would best be served by making this amendment to the performance standard effective December 8, 1978, except for § 1040.10(h)(2) (i) and (ii) which will be effective January 29, 1979; the purchasing and servicing information specified in § 1040.10(h)(2) pertaining to Class IIa laser products will need to be printed.

At the same time, the Commissioner invites and encourages public comment on this action. Interested persons may on or before Janaury 29, 1979, file with the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, four copies of written comments on this amendment, identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the office of the Hearing Clerk between 9 a.m. and 4 p.m., Monday through Friday. Any changes in this regulation justified by the comments will be the subject of a further amendment.

HUMAN ACCESS

As indicated in the April 1, 1977 notice, the Commissioner has reviewed the criteria of § 1040.10 for determining human access to laser and collateral radiation and has concluded that some of these criteria can be eliminated without affecting the protection afforded the public by the standard.

The current definition of "human access" in § 1040.10(b)(12) involves the concepts of access to laser or collateral radiation at a point by any part of the human body, by a straight line having an unobstructed length of 100 centimeters (cm), or by any line having an unobstructed length of 10 cm. The reference to a 10-cm line was included in the original definition to account for the possible insertion of flexible optical fibers, mirrors, or similar materials into a laser product. However, the Commissioner has concluded that the additional degree of safety provided by this requirement does not justify the added design difficulty that it poses. The Commissioner also finds the definition of "human access" overly restrictive when the criterion involving a 100-cm straight line is applied to collateral radiation. Collateral radiation arises from other than point sources and is difficult to collect and to focus into a diffraction-limited spot. Therefore, the Commissioner has revised the definition for "human access" to clarify the definition and to

delete (1) any reference to a 10-cm line and (2) reference to a 100-cm line for collateral radiation. The revised definition now clearly states that human access means access at a particular point to laser or collateral radiation by any part of the human body or access to laser radiation (but not collateral radiation) by a straight unobstructed path of up to 100 cm from any part of the body, including the eye.

The Commissioner notes that, after reviewing the draft amendments and in response to the April 1, 1977 notice, several persons, including members of the Technical Electronic Product Radiation Safety Standards Committee, suggested that the definition of "human access" should specify a minimum diameter for the 100-cm straight line.

The Commissioner disagrees with this suggestion and notes that a test object of specified diameter was included in the performance standard for microwave ovens in § 1030.10 (21 CFR 1030.10) and was found unsatisfactory as a concealed safety interlock criterion. Products could be designed to meet the literal requirements of this criterion, although many common household objects could be used to circumvent its intent (see 40 FR 27038 (June 26, 1975) and 40 FR 52007 (Nov. 7, 1975)). The new definition for human access and the acceptance angle and collimating optics (discussed later in this preamble) will enable manufacturers to design a more open protective housing using perforated or grille panels for their products, as long as the design does not permit any unobstructed straight-line path of less than 100 cm through the protective housing to the laser radiation. The Commissioner concludes that specifying a minimum diameter for the line would defeat the benefits of the new definition without any apparent increase in protection of the public health.

Other portions of § 1040.10 have been revised to clarify concepts of human access. The definition of "accessible emission level" in § 1040.10(b)(1) has been changed to express more clearly that the term refers to the magnitude of the radiation at a particular point. Section 1040.10(f)(3) concerning the remote control connector has been clarified by substituting "available" for "accessible." For consistency, "human" has been added to § 1040.10(h)(2)(ii) so that the requirement reads, in part, "displaceable portions of the protective housing that could allow human access to laser or collateral radiation."

The experience of FDA is that the beam attenuator specified in § 1040.10(f)(6) is used only with laser products for which access to laser and collateral radiation during operation is necessary to perform the product's function, and that the criteria of § 1040.10(b)(12) for determining human access to the radiation are not appropriate. Thus, the Commissioner is amending § 1040.10(f)(6) to specify that the beam attenuator, when in use, shall simply prevent access to radiation by any part of the human body. The emission indicator and aperture label would still indicate the possible presence of the laser radiation.

A comment made by some members of the Technical Electronic Product Radiation Safety Standards Committee indicated the term "viewable" in § 1040.10(f)(8) was not clear.

The Commissioner agrees with this comment, and the viewing optic requirement in § 1040.10(f)(8) has been restated to include the specific concept of accessibility of laser and collateral radiation to the human eye only by means of viewing optics, viewports, or display screens, rather than the generalized concept of accessible radiation; access of the human eye to laser or collateral radiation is the key issue.

Acceptance Angle and Collimating Optics for Measurements

The accessible emission limits for laser products, expressed in terms of irradiance, radiant energy, or radiant power, are based in part on collimated laser and collateral radiation that can be collected in an optical system having a small angle of acceptance and can be made equivalent to a narrower beam of radiation. The Commissioner concludes that the performance standard is overly restrictive with regard to multiple, extended, and divergent sources of radiation, and that different parameters for measuring the accessible emission levels of laser and collateral radiation need to be specified. Therefore, the Commissioner is amending § 1040.10(b)(18), (e)(3), and (e)(4) to include the concepts of the acceptance angle and collimating optics. By this change the standard will be more appropriate for multiple, extended, and divergent sources of radiation that do not present the same hazard as virtual point sources capable of producing highly collimated beams. The Commissioner is not amending that part of § 1040.10(e)(3)(ii) relating to the measurement of radiant exposure because these measurements of accessible laser radiation are needed only to determine if the upper limits of Class III, as specified in Table I-C of § 1040.10(d), are exceeded and these levels of laser radiation are both eye and skin hazards even upon diffuse reflection.

The Commissioner adds that, except for radiance measurements, the acceptance angle for the measurement of the other radiometric quantities is not specified directly in the standard. An acceptance angle of 2 pi steradians, established as part of the tests for determining compliance, is however based upon the criteria in § 1040.10(e)(2) and considers the maximum collectible radiation. This regulatory interpretation was necessary to account for the most hazardous situation, but may be unnecessarily restrictive with regard to multiple, extended, and divergent sources, when the question to be considered is how well collimated the laser and collateral radiation must be to be collected and focused on a small area of the skin, cornea, or retina.

One comment in response to the April 1977 notice suggested the introduction of a variable acceptance angle to match the dual accessible emission limits specified in § 1040.10(d)(4) to determine if laser or collateral radiation exceeds the limits of Class I. The comment recommended that magnitudes of the limiting angular subtense (α(min)) in the American National Standard Z136.1-1976 be used for the acceptance angle.

The Commissioner rejects the comment and maintains that using a varible acceptance angle for the instrumentation would unnecessarily complicate the measurements needed to determine a product's compliance with the standard. Further, the Commissioner intended the integrated radiance alternative of the dual limits included in § 1040.10(d)(4) to accommodate extended sources (real or virtual) such as holographic images, diffuse reflections, transmissions through diffusers, or diffuse collateral radiation, and notes that the dual limits of Class I are exceeded only if the limits for radiant energy and integrated radiance are exceeded; consequently, the dual limits of Class I are less restrictive than if a variable acceptance angle were used.

The standard in § 1040.10(d)(4) establishes limits for Class I from two perspectives. One limit, expressed as integrated radiance, pertains to the accessible emission level measured as a function of the brightness of the source; the other relates to the accessible emission level measured as the radiant energy incident upon the detector. The largest acceptance angle derived from these accessible emission limits for radiant energy measurements is 5×10^{-4} steradian, using a 7-millimeter (mm) diameter aperture stop. A somewhat larger solid angle of acceptance of 1×10^{-3} steradian provides more safety and is equivalent to a circular cone of acceptance of approximately 2 degrees diameter. Therefore the standard is being amended in § 1040.10(e)(3) and (e)(4), where appropriate, to require a specific acceptance angle of 1×10^{-3} steradian when determining the accessible

emission levels of laser and collateral radiation.

The Commissioner has determined that § 1040.10(e) is ambiguous as to the minimum size of a source of laser or collateral radiation that must be considered when measuring the radiance or integrated radiance because a source may be small or have a nonuniform spatial distribution. The size of the source to be considered depends upon the distance of the detector from the product. The closest approach of a person's eye to a point source of light at which a sharply focused retinal image is still produced is called the distance of maximum accommodation; moving closer to the point source would cause the spot formed on the retina to enlarge and the image to blur. According to published research, 20 cm is the average distance of maximum accommodation expected for 37-year old humans; older persons are expected to have a greater accommodation distance and younger persons a lesser distance (Ref. 1). A power of 5 diopters (the focusing power of a lens, expressed in diopters, is the reciprocal of the focal length, expressed in meters) for the collimating optics represents a 20-cm minimum focal distance. Utilizing the collimating optics of 5 diopters or less means that the source area of approximately 0.7 mm or larger in diameter that results in the maximum level will be considered in determining the accessible emission level in terms of radiance. Therefore, the standard is being amended to require collimating optics of 5 diopters or less as an additional measurement parameter to be used in conjunction with the aperture stops in the tests for determining compliance.

The Commissioner also recognizes that the combination of collimating optics and aperture stop establishes a collection angle for the aperture stop for divergent radiation emitted by a point source. The collection angle is twice that angle whose tangent is the ratio of the aperture stop radius to the distance of the aperture stop from point of emission of radiation on the product. In most instances this distance will be the focal distance of the collimating optics, modified by the acceptance angle of the aperture stop to maximize the collection of accessible radiation. The maximum collection angle is about 22 degrees for the 80-mm diameter aperture stop and about 2 degrees for the 7-mm diameter aperture stop.

The concepts of the acceptance angle of 1×10^{-3} steradian and the collimating optics of 5 diopters have been developed using information applicable primarily to the visible spectrum; however, the original intent of the agency is retained when these concepts are utilized in the ultraviolet and infrared spectral regions. Simple focusing optics are available that will concentrate well collimated radiation in these spectral regions.

Radiation Intended To Be Viewed

Laser products have accessible laser and collateral radiation that may be grouped into two categories: (1) radiation that is intended to be viewed directly and frequently, though not exclusively, by way of display screens, viewports, or microscopes when such viewing is necessary to achieve the intended function of the product; and (2) radiation that is not likely to be viewed for extended periods of time, either because use of the product would not require operators and others to view the radiation to perform the functions of the product or because no characteristics of the radiation would attract a person's gaze for long periods. The Commissioner believes the second category can be incorporated into the standard for appropriate types of laser products.

Accessible laser radiation of Class III is at levels at which biological damage to human tissue is possible from acute direct exposure. Similarly, accessible laser radiation of Class IV is at levels at which biological damage is possible from acute direct or diffuse exposure. Thus, the requirements relating to Class III and IV cannot be relaxed on the above basis. By contrast, Class II accessible laser radiation is at levels of visible radiation at which eye damage from chronic exposure is possible. However, Class II laser radiation is bright and can be uncomfortable to view, especially the higher levels of Class II. The Commissioner believes a person would not view such a light source for more than 1×10^3 seconds (16.7 minutes), unless there were some compelling reason. Chance viewing of Class II levels of laser radiation that do not exceed the accessible emission limits of Class I for any emission duration less than or equal to 1×10^3 seconds is not expected to be hazardous.

Therefore, the Commissioner is amending the standard to add a new subclass for laser products, Class IIa, and to amend § 1040.10 (f)(5), (f)(6), (g)(1), and (g)(4) to provide for special considerations within Class IIa. Class IIa products are exempted from the requirements for a laser radiation emission indicator, beam attenuator, Class II warning logotype, and aperture label. As amended, the standard requires Class IIa laser products to bear a class designation label with instructions to avoid long-term viewing of the direct laser radiation. The class designation label, because it does carry a warning statement to the operator of the Class IIa product, must be visible during operation as required by § 1040.10(g)(10) and must be reproduced in purchasing and servicing information as required by § 1040.10(h)(2)(i).

Also, the Commissioner is extending this concept to collateral radiation by amending the standard to increase the long-term level of collateral radiation permitted by reducing the applicable maximum emission duration used in determining the accessible emission level (Table III of § 1040.10(d)). This change for radiation in the wavelength range of greater than 400 nm but less than 13,000 nm decreases the maximum emission duration from 1×10^4 seconds to 1×10^3 seconds, but does not apply either to radiation that is accessible to the human eye by means of viewing optics, viewports, or display screens (§ 1040.10(f)(8)), or to ultraviolet collateral radiation because a cumulative damage mechanism is likely.

Emission Indicators and Collateral Radiation

Some members of the Technical Electronic Products Radiation Safety Standards Committee have commented extensively in their last two meetings concerning the provisions of the laser standard and the agency's policy with respect to the light emitted from the pilot light on laser products.

The standard requires in § 1040.10(f)(5) that each laser product of Class II or greater incorporate an emission indicator. Nowhere does the standard require that the emission indicator be a pilot light, although manufacturers have found a pilot light a convenient means for satisfying the requirements of § 1040.10(f)(5). The Commissioner believes that the radiation from laser product pilot lights should not be considered collateral radiation because, to be collateral radiation, such radiation must be emitted by a laser product as a result of the operation of the laser(s) or be emitted by any component that is physically necessary for the operation of the laser(s) incorporated into that product. Collateral radiation includes, for example, light from the laser-tube plasma glow, light from the flashlamp for exciting the laser medium, and x-radiation from the laser energy source (components that are physically necessary for the operation of the laser). Collateral radiation does not include emissions from a pilot light because it is not physically necessary to the operation of the laser. The Commissioner concludes that the definition for collateral radiation needs clarification and amends § 1040.10(b)(9) accordingly.

Measurement Parameter for Scanned Laser Radiation

A comment received before the effective date of the standard, August 2,

1976, suggested that in some cases, high levels of accessible scanned laser radiation could be reduced below the Class I limits by varying the apparent origin from which the scanned pattern is emitted. This type of radiation source can be regarded as an apparent extended source.

The Commissioner believes the standard should provide for the apparent extended sources of laser radiation. The standard currently provides in § 1040.10(e)(4) that the accessible emission levels of scanned laser radiation shall be determined by the measurement of radiation detectable within a stationary circular aperture stop having a 7-mm diameter. The resulting temporal variation of detected radiation is considered as a pulse or series of pulses. Under § 1040.10(e)(3)(iii), measuring integrated radiance involves a solid angle of acceptance of 1×10^{-5} steradian. However, under § 1040.10(e)(2)(iv) the acceptance angle of the instrument for measuring integrated radiance must be instantaneously so positioned and so oriented with respect to the laser product "as to result in the maximum detection of radiation by the instrument." Conceptually the orientation of the instrument must track the source, but its aperture stop remains stationary. As noted in § 1040.10(e)(3), techniques, including computations, that provide results equivalent to the above are permitted.

Apparent extended sources formed by a moving, well collimated, laser beam can be more hazardous than conventional extended sources. The eye can follow and fix upon a slowly moving source of visible light, but the source can also move so rapidly (e.g., a television image formed by a rapidly scanning electron beam) that the eye cannot follow. The human eye has difficulty tracking an angular motion of 2 radians/second or greater (Refs. 2 and 3.) An effective extended source is achieved when the angular motion of the source transversely to the line of sight of the eye is 5 radians/second or greater. Therefore, the Commissioner is amending § 1040.10(e)(4) to provide that the solid angles of acceptance utilized in the measurement of radiant energy and radiance need not track the source at an angular speed greater than 5 radians/second to maximize the measurement of radiation.

Change in Wavelength Range for Visible Radiation

The introduction of Class IIa into the standard results in anomalies in the classification of certain products that emit accessible laser radiation between 700 nm and 711 nm and at radiant exposure values below the accessible emission limits of Class IIa at 700 nm. For example, a 1-microwatt laser product would be classified in Class IIa if emission were at 699 nm, Class III if emission were at 701 nm, and Class I at 711 nm. However, the original rationale for Class II remains valid because the relative spectral luminous efficiency value, a measure of relative photochemical response of the eye at 710 nm, is still half the value at 700 nanometers (Ref. 4).

Thus, the Commissioner is changing the Class II and Class IIa wavelength boundary to 710 nm where the Class IIa accessible emission limit curve intercepts that for Class I, and all portions of the standard that contain the wavelength 700 nanometers have been revised accordingly.

Flexibility in Labeling

Wording of the warning statements specified in § 1040.10(g) has been found on occasion to be inappropriate. Problems in which the size, configuration, or design of the laser product precludes compliance with the label requirements have been readily resolved using the mechanism established in § 1040.10(g)(10); without this mechanism, the lengthy variance procedure of § 1010.4 would have to be used. The Commissioner concludes that similar provisions are appropriate for wording and is amending § 1040.10(g)(10) to permit the Director, Bureau of Radiological Health, on his own initiative or upon written application by the manufacturer, to approve the use of alternate wording on warning labels when the wording prescribed by the standard is inappropriate or would be ineffective because of the size, configuration, design, or function of the laser product.

The warning required by § 1040.10(g)(8) for invisible radiation is amended to permit use of the words "visible and/or invisible" whenever the product may emit any combination of visible and invisible radiation.

References

1. Davson, Hugh, "The Physiology of the Eye," 3d ed., Academic Press, New York, pp. 402-403, 1972.

2. Barmack, M., "Dynamic Visual Acuity as an Index of Eye Movement Control," *Vision Research*, 10:1377-1391, 1970.

3. Brown, B., "Dynamic Visual Acuity, Eye Movements, and Peripheral Acuity for Moving Targets," *Vision Research*, 12:305-321, 1972.

4. RCA Electro-Optics Handbook, 1974.

Pertinent background data and information supporting the Commissioner's action are available for public review in the office of the Hearing Clerk (HFA-305), Food and Drug Administration.

On the basis of an amendment to the environmental impact analysis report for the performance standard for laser products, the Commissioner concludes that promulation of this amendment to the standard will not significantly affect the quality of the human environment and, therefore, that no environmental impact statement is necessary under § 25.1(b) (21 CFR 25.1(b)). A copy of the FDA environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Therefore, under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f)) and under authority delegated to the Commissioner (21 CFR 5.1), Part 1040 is amended as follows:

1. In § 1040.10, by revising paragraph (b) (1), (6)(i), (9), (12), and (18); the wavelength column in Table I-B and item 1 of Table III in paragraph (d); paragraph (e)(3)(i), (ii), and (iii) and (4); paragraph (f)(3), (5)(i), (6), and (8); paragraph (g)(1), (2)(i), the introductory text of (4), (6)(i)(*a*), (ii)(*b*), and (iii)(*b*), (7)(i)(*a*), (ii)(*b*), and (iii)(*b*), (8)(i) and (ii), and (10); and paragraph (h)(2)(i) and (ii) to read as follows:

§ 1040.10 Laser Products.

* * * * *

(b) * * *

(1) "Accessible emission level" means the magnitude of accessible laser or collateral radiation of a specific wavelength and emission duration at a particular point as measured according to paragraph (e) of this section. Accessible laser or collateral radiation is radiation to which human access is possible, as defined in paragraph (b)(9), (12), and (18) of this section.

* * * * *

(6) * * *

(i) Permits human access to laser radiation in excess of the accessible emission limits of Class I, but not in excess of the accessible emission limits of Class II in the wavelength range of greater than 400 nanometers (nm), but less than or equal to 710 nanometers for emission durations greater than 0.25 second; and

* * * * *

(9) "Collateral radiation" means any electronic product radiation, except laser radiation, emitted by a laser product as a result of the operation of the laser(s) or any component of the laser product that is physically necessary for the operation of the laser(s).

* * * * *

(12) "Human access" means access at a particular point to:

(i) Laser or collateral radiation by any part of the human body, or

(ii) Laser radiation by a straight unobstructed path of up to 100 centimeters from any part of the human body.

* * * * *

(18) "Laser radiation" means all electromagnetic radiation emitted by a laser product within the spectral range specified in paragraph (b)(15) of this section that is produced as a result of controlled stimulated emission or that is detectable with radiation so produced through the appropriate aperture stop and within the appropriate solid angle of acceptance, as specified in paragraph (e) of this section.

* * * * *

(d) * * *

TABLE I–B

CLASS II ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

Wavelength (nanometers)	Emission duration (seconds)	Class II – Accessible emission limits
>400 but ≤710	$>2.5 \times 10^{-1}$	$1.0 \times 10^{-3} k_1 k_2 t$ J

* * * * *

TABLE III—ACCESSIBLE EMISSION LIMITS FOR COLLATERAL RADIATION FROM LASER PRODUCTS

1. *Accessible emission limits* for collateral radiation having wavelengths greater than 250 nanometers but less than or equal to 13,000 nanometers are identical to the accessible emission limits of Class I laser radiation, as determined from Tables I-A and II-A in this paragraph:

i. In the wavelength range of less than or equal to 400 nanometers, for all emission durations;

ii. In the wavelength range of greater than 400 nanometers, for all emission durations less than or equal to 1×10^3 seconds and, when applicable under paragraph (f)(8) of this section, for all emission durations.

* * * * *

(e) * * *

(3) * * *

(i) The radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 80 millimeters (except for scanned laser radiation) and within a circular solid angle of acceptance of 1×10^{-3} steradian with collimating optics of 5 diopters or less.

(ii) The irradiance (W cm^{-2}) or radiant exposure (J cm^{-2}) equivalent to the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and, for irradiance, within a circular solid angle of acceptance of 1×10 cm^{-3} steradian with collimating optics of 5 diopters or less, divided by the area of the aperture stop (cm^{-2}).

(iii) The radiance (W cm^{-2} sr^{-1}) or integrated radiance (J cm^{-2} sr^{-1}) equivalent to the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and within a circular solid angle of acceptance of 1×10^{-5} steradian with collimating optics of 5 diopters or less, divided by that solid angle (sr) and by the area of the aperture stop (cm^2).

(4) *Measurement parameters for scanned laser radiation.* Accessible emission levels of scanned laser radiation shall be based upon the measurement of radiation detectable through a stationary circular aperture stop having a 7-millimeter diameter and within the circular solid angle of acceptance with collimating optics applicable under paragraph (e)(3) of this section, or the equivalent. The direction of the solid angle of acceptance shall change as needed to maximize detectable radiation, with an angular speed of up to 5 radians/second.

(f) * * *

(3) *Remote control connector.* Each laser system classified as a Class III or IV laser product shall incorporate a readily available remote control connector having an electrical potential difference of no greater than 130 root-mean-square volts between the terminals of the remote control connector. When the terminals of the connector are not electrically joined, human access to all laser and collateral radiation from the laser product in excess of the accessible emission limits of Class I and Table III of paragraph (d) of this section shall be prevented.

* * * * *

(5) * * *

(i) Each laser system classified as a Class II laser product, except Class II laser products that do not exceed the accessible emission limits of Class I for any emission duration less than or equal to 1×10^{-3} seconds, shall incorporate an emission indicator that provides a visible or audible signal during emission of accessible laser radiation in excess of the accessible emission limits of Class I.

* * * * *

(6) *Beam attenuator.* Each laser system classified as a Class II, III, or IV laser product, except Class II laser products that do not exceed the accessible emission limits of Class I for any emission duration less than or equal to 1×10^3 seconds, shall be provided with one or more permanently attached means, other than laser energy source switch(es), electrical supply main connectors, or the key-actuated master control, capable of preventing access by any part of the human body to all laser and collateral radiation in excess of the accessible emission limits of Class I and Table III.

* * * * *

(8) *Viewing optics.* All viewing optics, viewports, and display screens incorporated into a laser product, regardless of its class, shall at all times limit the levels of laser and collateral radiation accessible to the human eye by means of such viewing optics, viewports, or display screens to less than the accessible emission limits of Class I and Table III of paragraph (d) of this section. For any shutter or variable attenuator incorporated into such viewing optics, viewports, or display screens, a means shall be provided:

(i) To prevent access by the human eye to laser and collateral radiation in excess of the accessible emission limits of Class I and Table III of paragraph (d) of this section whenever the shutter is opened or the attenuator varied.

(ii) To preclude, upon failure of such means as required in paragraph (f)(8)(i) of this section, opening the shutter or varying the attenuator when access by the human eye is possible to laser or collateral radiation in excess of the accessible emission limits

of Class I and Table III of paragraph (d) of this section.

* * * * *

(g) * * *

(1) *Class II designation and warning.* (i) Each Class II laser product which does not exceed the accessible emission limits of Class I for any emission duration less than or equal to 1×10^{3} seconds, shall have affixed a label bearing the following wording: "Class IIa Laser Product—Avoid Long-Term Viewing of Direct Laser Radiation."

(ii) Each Class II laser product other than those described in paragraph (g)(1)(i) of this section shall have affixed a label bearing the warning logotype A (Figure 1 in this paragraph) and including the following wording:

[Position 1 on the logotype]

"LASER RADIATION—DO NOT STARE INTO BEAM"; and

[Position 3 on the logotype]

"CLASS II LASER PRODUCT".

* * * * *

(2) *Class III designation and warning.* (i) Each laser product classified in Class III solely because of the emission of accessible laser radiation for emission durations greater than 3.8×10^{-4} second and in the wavelength range of greater than 400 nanometers but less than or equal to 710 nanometers with an irradiance of less than or equal to 2.5×10^{-3} W cm^{-2} and with a radiant power of less than or equal to 5.0×10^{-3} W shall have affixed a label bearing the warning logotype A (Figure 1 of paragraph (g)(1) of this section) and including the following wording:

[Position 1 on the logotype]

"LASER RADIATION—DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS"; and,

[Position 3 on the logotype]

"CLASS IIIa LASER PRODUCT".

* * * * *

(4) *Aperture label.* Each laser product, except medical laser products and Class II laser products that do not exceed the accessible emission limits of Class I for any emission duration less than or equal to 1×10^{-3} seconds, shall have affixed, in close proximity to each aperture through which is emitted accessible laser or collateral radiation in excess of the accessible emission limits of Class I and Table III of paragraph (d) of this section, a label(s) bearing the following wording as applicable:

* * * * *

(6) * * *

(i) * * *

(*a*) In excess of the accessible emission limits of Class I for emission durations greater than 0.25 second and in the wavelength range greater than 400 nanometers but less than or equal to 710 nanometers; and,

* * * * *

(ii) * * *

(*b*) In excess of either an irradiance of 2.5×10^{-3} W cm^{-2} or a radiant power of 5.0×10^{-3} W for emission durations greater than 3.8×10^{-4} second for wavelengths greater than 400 nanometers but less than or equal to 710 nanometers; and,

* * * * *

(iii) * * *

(*b*) In excess of either an irradiance of 2.5×10^{-3} W cm^{-2} or a radiant power of 5.0×10^{-3} W for emission durations greater than 3.8×10^{-4} second for wavelengths greater than 400 nanometers but less than or equal to 710 nanometers; or,

* * * * *

(7) * * *

(i) * * *

(*a*) In excess of the accessible emission limits of Class I for emission durations greater than 0.25 second and in the wavelength range greater than 400 nanometers by less than or equal to 710 nanometers; and,

* * * * *

(ii) * * *

(*b*) In excess of neither an irradiance of 2.5×10^{-3} W cm^{-2} nor a radiant power of 5.0×10^{-3} W for emission durations greater than 3.8×10^{-4} second for wavelengths greater than 400 nanometers but less than or equal to 710 nanometers; and,

* * * * *

(iii) * * *

(*b*) In excess of either an irradiance of 2.5×10^{-3} W cm^{-2} or a radiant power of 5.0×10^{-3} W for emission durations greater than 3.8×10^{-4} second for wavelengths greater than 400 nanometers but less than or equal to 710 nanometers; or,

* * * * *

(8) * * *

(i) Less than or equal to 400 nanometers or greater than 710 nanometers, the word "invisible" shall appropriately precede the word "radiation"; or,

(ii) In a range specified in paragraph (g)(8)(i) of this section and also within the range of greater than 400 nanometers but less than or equal to 710 nanometers, the words "visible and invisible" or "visible and/or invisible" shall appropriately precede the word "radiation."

* * * * *

(10) *Label specifications.* Labels required by this section and § 1040.11 shall be permanently affixed to, or inscribed on, the laser product, legible, and clearly visible during operation, maintenance, or service, as appropriate. If the size, configuration, design, or function of the laser product would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, the Director, Bureau of Radiological Health, on the Director's own initiative or upon written application by the manufacturer, may approve alternate means of providing such label(s) or alternate wording for such label(s) as applicable.

(h) * * *

(2) * * *

(i) In all catalogs, specification sheets, and descriptive brochures pertaining to each laser product, a legible reproduction (color optional) of the class designation and warning required by paragraph (g) of this section to be affixed to that product, including the information required for positions 1, 2, and 3 of the applicable logotype (Figure 1 or 2 of paragraph (g)(1) and (2)(ii) of this section).

(ii) To servicing dealers and distributors and to others upon request at a cost not to exceed the cost of preparation and distribution, adequate instructions for service adjustments and service procedures for each laser product model, including clear warnings and precautions to be taken to avoid possible exposure to laser and collateral radiation in excess of the accessible emission limits in Tables I-A, I-B, I-C and III of paragraph (d) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and § 1040.11; and, in all such service instructions, a listing of those controls and procedures that could be utilized by persons other than the manufacturer or his agents to increase accessible emission levels of radiation and a clear description of the location of displaceable portions of the protective housing that could allow human access to laser or collateral radiation in excess of the accessible emission limits in Tables I-A, I-B, I-C, and III of paragraph (d) of this section. The instructions shall include protective

procedures for service personnel, and legible reproductions (color optional) of required labels and hazard warnings.

* * * * *

2. In § 1040.11, by revising paragraph (b)(1) to read as follows:

§ 1040.11 Specific purpose laser products.

* * * * *

(b) * * *

(1) Shall not permit human access to laser radiation in the wavelength range of greater than 400 nanometers but less than or equal to 710 nanometers with a radiant power that exceeds 5.0×10^{-3} W for any emission duration greater than 3.8×10^{-4} second; and,

* * * * *

Effective date. This regulation shall be effective December 8, 1978, except for § 1040.10(h)(2) (i) and (ii) which will be effective January 29, 1979.

(Sec. 358, 82 Stat. 1177-1179 (42 U.S.C. 263f).)

Dated: November 17, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-33137 Filed 11-27-78; 8:45 am]

[4710-08-M]

Title 22—Foreign Relations

CHAPTER I—DEPARTMENT OF STATE

[Dept. Reg. 108.762]

PART 3a—ACCEPTANCE OF EMPLOYMENT FROM FOREIGN GOVERNMENTS BY MEMBERS OF THE UNIFORMED SERVICES

Final Rule

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: This rule establishes regulations governing the procedures for approving civil employment by a foreign government of retired and reserve members of the uniformed services (Army, Navy, etc.) and commissioned Corps of the Public Health Service and the National Oceanic and Atmospheric Administration. The regulations implement section 509 of Pub. L. 95-105 (37 U.S.C. 801 note).

EFFECTIVE DATE: November 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Capt. John E. Burgess, United States Navy, Office of International Security Operations, Bureau of Politico-Military Affairs, Department of State, Washington, D.C 20520, phone 202-632-8688.

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking was published in the FEDERAL REGISTER on May 31, 1978 (43 FR 23593) inviting interested persons to submit comments regarding the proposed regulations. No comments were received.

The title of the new Part 3a has been changed from "Acceptance of Employment from Foreign Governments by Retired and Reserve Officers" to "Acceptance of Employment from Foreign Governments by Members of the Uniformed Services." This change reflects more accurately and generally the category of persons to whom the regulation applies. In addition, the words "no authority", which were inadvertently omitted from the text of § 3a.2(b) in the notice of proposed rulemaking, have been added. With these exceptions, the text published in the notice of proposed rulemaking is adopted without change.

ADOPTION OF AMENDMENT

Chapter I of 22 CFR is amended by adding a new Part 3a as set forth below.

Dated: November 18, 1978.

WARREN CHRISTOPHER,
Deputy Secretary of State.

Sec.

3a.1 Definitions.
3a.2 Requirement for approval of foreign government employment.
3a.3 Authority to approve or disapprove proposed foreign government employment.
3a.4 Procedure for requesting approval.
3a.5 Basis for approval or disapproval.
3a.6 Notification of approval.
3a.7 Notification of disapproval and reconsideration.
3a.8 Change in status.

AUTHORITY: Sec. 509, 91 Stat. 859 (37 U.S.C. 801 Note); Sec. 4, as amended, 63 Stat. 111 (22 U.S.C. 2658).

§ 3a.1 Definitions.

For purposes of this part—

(a) "Applicant" means any person who requests approval under this part to accept any civil employment (and compensation therefor) from a foreign government and who is: (1) Any retired member of the uniformed services;

(2) Any member of a Reserve component of the Armed Forces; or

(3) Any member of the commissioned Reserve Corps of the Public Health Service.

The term "applicant" also includes persons described in subparagraph (1), (2), or (3), who have already accepted foreign government employment and are requesting approval under this part to continue such employment.

(b) "Uniformed services" means the Armed Forces, the commissioned Regular and Reserve Corps of the Public Health Service, and the commissioned corps of the National Oceanic and Atmospheric Administration.

(c) "Armed Forces" means the Army, Navy, Air Force, Marine Corps, and Coast guard.

(d) "Secretary concerned" means: (1) The Secretary of the Army, with respect to retired members of the Army and members of the Army Reserve;

(2) The Secretary of the Navy, with respect to retired members of the Navy and the Marine Corps, members of the Navy and Marine Corps Reserves, and retired members of the Coast Guard and members of the Coast Guard Reserve when the Coast Guard is operating as a service in the Navy;

(3) The Secretary of the Air Force, with respect to retired members of the Air Force and members of the Air Force Reserve;

(4) The Secretary of Transportation, with respect to retired members of the Coast Guard and members of the Coast Guard Reserve when the Coast Guard is not operating as a service in the Navy;

(5) The Secretary of Commerce, with respect to retired members of the commissioned corps of the National Oceanic and Atmospheric Administration; and

(6) The Secretary of Health, Education, and Welfare, with respect to retired members of the commissioned Regular Corps of the Public Health Service and members of the commissioned Reserve Corps of the Public Health Service.

§ 3a.2 Requirement for approval of foreign government employment.

(a) The United States Constitution (Article I, Section 9, clause 8) prohibits the acceptance of civil employment with a foreign government by an officer of the United States without the consent of Congress. Congress has consented to the acceptance of civil employment (and compensation therefor) by any person described in § 3a.1(b) subject to the approval of the Secretary concerned and the Secretary of State (37 U.S.C. 801 Note). Civil employment with a foreign government may not be accepted without such approval by any person so described.

(b) The Secretary of State has no authority to approve employment with a foreign government by any officer of the United States other than a person described in § 3a.1(a). The acceptance of employment with a foreign government by any other officer of the United States remains subject

to the constitutional prohibition described in paragraph (a) of this section.

(c) Any person described in § 3a.1(a) who accepts employment with a foreign government without the approval required by this section or otherwise obtaining the consent of Congress is subject to forfeiture of retired pay to the extent of his or her compensation from the foreign government, according to the Comptroller General of the United States (44 Comp. Gen. 139 (1964)). This forfeiture is in addition to any other penalty which may be imposed under law or regulation.[1]

§ 3a.3 Authority to approve or disapprove proposed foreign government employment.

The Director, Bureau of Politico-Military Affairs, is authorized to approve or disapprove any request by an applicant for approval under this part to accept civil employment (and compensation therefor) from a foreign government. The Director may delegate this authority within the Bureau of Politico-Military Affairs, Department of State.

§ 3a.4 Procedure for requesting approval.

(a) An applicant must submit a request for approval of foreign government employment to the Secretary concerned, whose approval is also required by law for the applicant's acceptance of civil employment from a foreign government. The request must contain information concerning the applicant's status, the nature of the proposed employment in as much detail as possible, the identity of and relationship to the foreign government concerned, and other matters as may be required by the Secretary concerned.

(b) Requests approved by the Secretary concerned will be referred to the Director, Bureau of Politico-Military Affairs, for approval. Requests received by the Director, Bureau of Politico-Military Affairs, directly from an applicant will be initially forwarded to the Secretary concerned, or his designee, for approval of disapproval.

§ 3a.5 Basis for approval or disapproval.

Decisions by the Director, Bureau of Politico-Military Affairs, under this part shall be based on whether the applicant's proposed employment with a foreign government would adversely affect the foreign relations of the United States, in light of the applicant's official status as a retiree or reservist.

[1] Approval under this Part does not constitute an exception to the provisions of the Immigration and Nationality Act concerning loss of United States citizenship, for example, by becoming a citizen of or taking an oath of allegiance to another country. See 8 U.S.C. 1481 et seq.

§ 3a.6 Notification of approval.

The Director, Bureau of Politico-Military Affairs, will notify the Secretary concerned when an applicant's proposed foreign government employment is approved. Notification of approval to the applicant will be made by the Secretary concerned or his designee.

§ 3a.7 Notification of disapproval and reconsideration.

(a) The Director, Bureau of Politico-Military Affairs, will notify the applicant directly when an applicant's proposed foreign employment is disapproved, and will inform the Secretary concerned.

(b) Each notification of disapproval under this section must include a statement of the reasons for the disapproval, with as much specificity as security and foreign policy considerations permit, together with a notice of the applicant's right to seek reconsideration of the disapproval under paragraph (c) of this section.

(c) Within 60 days after receipt of the notice of disapproval, an applicant whose request has been disapproved may submit a request for reconsideration by the Director, Bureau of Politico-Military Affairs. A request for reconsideration should provide information relevant to the reasons set forth in the notice of disapproval.

(d) The disapproval of a request by the Director, Bureau of Politico-Military Affairs, will be final, unless a timely request for reconsideration is received. In the event of a request for reconsideration, the Director, Bureau of Politico-Military Affairs, will make a final decision after reviewing the record of the request. A final decision after reconsideration to approve the applicant's proposed employment with a foreign government will be communicated to the Secretary concerned as provided in § 3a.6. A final decision after reconsideration to disapprove the applicant's proposed employment with a foreign government will be communicated directly to the applicant as provided in paragraph (a) of this section and the Secretary concerned will be informed. The Director's authority to make a final decision after reconsideration may not be redelegated.

§ 3a.8 Change in status.

In the event that an applicant's foreign government employment approved under this part is to be materially changed, either by a substantial change in duties from those described in the request upon which the original approval was based, or by a change of employer, the applicant must obtain further approval in accordance with this part for such changed employment.

[FR Doc. 78-33341 Filed 11-27-78; 8:45 am]

[4410-01-M]

Title 28—Judicial Administration

CHAPTER I—DEPARTMENT OF JUSTICE

[Order No. 809-78]

PART 0—ORGANIZATION OF THE DEPARTMENT OF JUSTICE

Subpart M—Land and Natural Resources Division

ASSIGNMENT OF RESPONSIBILITY UNDER SECTION 201(f) OF THE SURFACE MINING CONTROL AND RECLAMATION ACT OF 1977

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: Section 201(f) of the Surface Mining Control and Reclamation Act of 1977, 91 Stat. 450, provides that no federal employee performing any function under the Act may hold any direct or indirect financial interest in surface or underground coal mining, and it directs the Secretary of the Interior to promulgate regulations enforcing it. Under regulations promulgated at 30 CFR Part 706, 42 FR 56060 (October 20, 1977), the head of each Executive Department performing any function under the Act is required to implement a system of disclosure of employee financial interests in cooperation with the Director, Office of Surface Mining Control and Reclamation, Department of the Interior. This order designates the Assistant Attorney General, Land and Natural Resources Division, to carry out the responsibilities of the Department of Justice under these regulations.

EFFECTIVE DATE: November 20, 1978.

FOR FURTHER INFORMATION CONTACT:

Lois J. Schiffer, Land and Natural Resources Division, Department of Justice, Washington, D.C. 20530, 202-633-2704.

By virtue of the authority vested in me by 5 U.S.C. 301 and 28 U.S.C. 509, 510, § 0.65 of Subpart M of Part 0 of Chapter I of Title 28, Code of Federal Regulations, is amended by adding a new paragraph (h) to read as follows:

§ 0.65 General functions.

* * * * *

(h) Performance of the Department's functions under § 706.5 of the

regulations for the prevention of conflict of interests promulgated by the Secretary of the Interior under the authority of the Surface Mining Control and Reclamation Act of 1977, section 201(f), 91 Stat. 450, and contained in 30 CFR Part 706.

Dated: November 20, 1978.

GRIFFIN B. BELL,
Attorney General.

[FR Doc. 78-33273 Filed 11-27-78; 8:45 am]

[4410-01-M]

[Order No. 810-78]

PART 0—ORGANIZATION OF THE DEPARTMENT OF JUSTICE

Subpart O—Office of Management and Finance

RESPONSIBILITY FOR AUDIOVISUAL ACTIVITIES

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: This order expressly assigns the Department-wide responsibility for the management of audiovisual programs to the Assistant Attorney General for Administration. His functions include the issuance of policies and procedures for audiovisual programs, the design of a recordkeeping and reporting system, and the approval or disapproval of production and equipment requests. The purpose of the order is to clarify the authority of the Assistant Attorney General for Administration to centralize audiovisual program management and to prevent duplication and waste.

EFFECTIVE DATE: November 20, 1978.

FOR FURTHER INFORMATION CONTACT:

Harry Fair, Acting Director, Administrative Programs Management Staff, Office of Management and Finance, Department of Justice, Washington, D.C. 20530, 202-633-2728.

By virtue of the authority vested in me by 28 U.S.C. 509, 510, and 5 U.S.C. 301, § 0.75(j) of Subpart O of Part 0 of Chapter I of Title 28, Code of Federal Regulations, is revised to read as follows:

§ 0.75 Policy functions.

* * * * *

(j) Plan, direct, and administer Department-wide policies, procedures, and regulations concerning records, reports, procurement, printing, graphics, audiovisual activities (including the approval or disapproval of production and equipment requests), forms management, supply management, motor vehicles, real and personal property, space assignment and utilization, and all other administrative services functions.

Dated: November 20, 1978.

GRIFFIN B. BELL,
Attorney General.

[FR Doc. 78-33274 Filed 11-27-78; 8:45 am]

[3510-16-M]

Title 37—Patents, Trademarks, and Copyrights

CHAPTER I—PATENT AND TRADEMARK OFFICE, DEPARTMENT OF COMMERCE

PART 4—FORMS FOR TRADEMARK CASES

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The Patent and Trademark Office adopts revisions to the suggested forms for use in trademark cases. These revisions are intended to improve suggested forms which had been found to be confusing or susceptible to misinterpretation and provide a new suggested form to eliminate the need for the user to combine two forms.

DATES: Effective date: January 1, 1979.

FOR FURTHER INFORMATION CONTACT:

Miss Katharine I. Hancock by telephone at (703) 557-5380, or by mail marked to her attention and addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of May 3, 1977 (42 FR 22378) there was published a Patent and Trademark Office proposal to revise certain existing forms and provide one new form for trademark cases. Comments were received from six persons. Two persons suggested that the the word "swears," proposed at the beginning of verifications and affidavits, was not appropriate and that language relating to oath should be confined to the jurat. This suggestion has been adopted. It was suggested by two persons that double signatures be eliminated from the forms for opposition and petition to cancel, and this suggestion has been adopted. Also, after further consideration with the object of eliminating confusion, inconsistency and error from the forms, some additional changes to forms set out in the proposal, and to forms 4.7, 4.9, 4.11 and 4.23 which were not included in the proposal, are being adopted.

Changes which have not been published for comment do not represent any change in practice but are editorial in nature and do not impose a burden on anyone; further opportunity for comment is therefore deemed not necessary.

The ways in which the changes being adopted vary from the published proposal are summarized as follows:

The words "hereby swears" proposed at the beginning of verifications and affidavits are replaced by the word "states." This change appears in forms 4.1, 4.5, 4.6, 4.13, 4.14, 4.15, 4.16, 4.16 (Combined 8 & 15), 4.17 and 4.18.

In forms 4.1, 4.1a 4.7, 4.8, 4.9 and 4.10, where goods or services are set forth, the terms "(Common, usual or ordinary name of (goods or services))" and "(Insert illustrative examples of the goods or services)" are deleted and the term "the following (goods or services):" is inserted instead, although the format of form 4.8 makes it necessary to use the variation "Name the goods or services."

In forms 4.1 and 4.1a, the term "trade style" is deleted and "business trade name" put in its place in indentifying an individual applicant in order to conform more closely to the language of the statute. The wording "including street, city and State" is deleted from the address lines. The same changes have been made, where appropriate, in forms 4.17 and 4.18.

In form 4.1a, last clause, the word "herein" is deleted as unclear; the word "further" and the last occurrence of the word "that" are deleted as unnecessary.

In form 4.5, "firm" is changed to "partnership" as a more definite term for the entity for which the form is designed; "member of firm" is changed to "partner;" and the wording "including street, city and State" in the address, as well as the wording and space for domicile, are deleted.

In form 4.6, the proposed change of the word "affidavit" to "application" in the verification is not adopted; instead, the word "affidavit" is changed to "instrument" because the paper being executed contains both an application and an affidavit (verification) and the term "instrument" will encompass both. The wording "including street, city and State" in the address is deleted.

In forms 4.8 and 4.10, footnote (5) is replaced by new footnote (16) in order to clarify instructions for setting forth the manner of use of the mark; as a result, present footnote numbers (16), (17) and (18) in companion forms 4.9 and 4.11 are changed to numbers (17), (18) and (19), respectively.

In form 4.8, last sentence, the words "declaration from form" are inserted

before "4.1a" in order to make it clear that form 4.1a is a declaration form.

In form 4.9, in the heading, the words "(If known)" under Class No. are replaced by "(A, for Goods; B, for Services)" in view of the fact that those are the only classes for certification marks. The term "(or form 4.7)" is placed after "footnote (5)" to accommodate either goods or services. For the sake of clarity, footnote (17) which explains certification has been reworded slightly.

In form 4.10 the phrase "Use form 4.1" is changed to "Use body of form 4.1, 4.7 or 4.8" in order to be more clear and to accomodate services and collective mark situations; under "Notes," reference is made to form 4.8 in addition to form 4.1 for the same reason.

In form 4.13, the statement in the verification "that the applicant for renewal owns the above identified registration" is deleted as it constitutes repetition.

In forms 4.13 and 4.16, where goods are listed, the words "or services" and "or 'all the services' " are added, where appropriate, to accommodate services as well as goods.

In forms 4.13, 4.14, 4.15 and 4.16 (Combined 8 & 15), in the Note relating to designation of a domestic representative, for purposes of clarity the word "made" is changed to "submitted with this form" and the word "prior" is added before "unrevoked."

In forms 4.13, 4.17 and 4.18, in the caption under the line where the signer's name is to appear, the words "a juristic" are added after the phrase "to sign for," and in the body of forms 4.17 and 4.18, the word "juristic" is added after the phrase "to sign for the." The purpose of these changes is to make clear who is an authorized signer and to provide uniformity with other forms.

In form 4.14, footnote (3) is deleted. The footnote relates to services but this form is not applicable to services because registration of service marks was not available under the acts to which the form pertains. Footnote numbers (4) and (5) are changed to numbers (3) and (4), respectively. Immediately above the signature, the notation footnote (3) (inadvertently omitted) is inserted.

In forms 4.14 and 4.16, in the clause for listing goods or services, the word "recited" is replaced by "stated," to conform to the language of the statute.

Proposed new form 16(a) has been redesignated as form 16 (Combined 8 & 15), in order to coordinate properly with the numbering system used for the forms.

The following changes are made in new form 16 (Combined 8 & 15): after "footnote (5)" in the body of the form, "recited" is replaced by "stated" to conform to the language of the statute; under the space for listing goods, wording is added to accommodate services as well as goods; before "footnote (4)" in the body of the form the wording "or the date of publication under section 12(c) of the act" (inadvertently omitted) is inserted; and after the phrase "that such mark is still in use" the wording "in (3) ———— (Type of commerce) commerce" (inadvertently omitted) is inserted.

Forms 4.17 (Opposition) and 4.18 (Petition to cancel) are made single signature forms by deletion of the provision for signature at the end of the body of the form, leaving a signature only at the end of the verification. This accords with forms for applications, which also require only a single signature at the end of the verification or declaration. In the verification of forms 4.17 and 4.18, the words "the foregoing" (two occurrences) are replaced by the word "this," and the words "and signed" which follow the words "has read" are deleted.

In the parenthetical sentence relating to grounds of damage, the word "he" is changed to "opposer" or "petitioner" in each form, respectively.

In form 4.21, first sentence, "he" is replaced by "said assignor."

In forms 4.21 and 4.22, third paragraph, the letter "s" is deleted from the word "rights." At the end of footnote (2) the wording "changing the word 'applicant' to 'assignee' " is added.

The words "he," "himself" and "his" have been replaced by "he/she," "himself/herself," "his/her" or "it/he/she," as appropriate, in forms 4.1, 4.1a, 4.5, 4.6, 4.13, 4.17, 4.18, 4.21 and 4.22, to give choice of gender.

In form 4.23 (Certificate of mailing), the first line at the bottom is labeled "Print or Type Name of Person Signing Certificate" and the second line is labeled "Signature of Person Signing Certificate," in order to make it clear that in addition to a person's signature, such person's name is to be set out legibly in typing or printing; under the third line, the words "of Signature" are added after "Date" to distinguish the date of signature clearly from the date of deposit which is to be set forth in the body of the form. In the heading of the form, the words "of mailing" are added after "Certificate" for the sake of clarity.

Accordingly, pursuant to the authority contained in section 41 of the act of July 5, 1946, as amended, 37 CFR Part 4 is amended as follows:

1. By revising § 4.1 to read as follows:

§ 4.1 Trademark application by an individual; Principal Register with oath.

Mark ————————————

(Identify the mark)

Class No. ————————————

(If known)

TO THE COMMISSIONER OF PATENTS AND TRADEMARKS:

.....

(Name of applicant, and business trade name, if any)

.....

(Business address)

.....

(Residence address)

.....

(Citizenship of applicant)

The above identified applicant has adopted and is using the trademark shown in the accompanying drawing (1) for the following goods:

and requests that said mark be registered in the United States Patent and Trademark Office on the Principal Register established by the Act of July 5, 1946.

The trademark was first used on the goods (2) on ————(Date); was first used in ———— (Type of commerce) commerce (3) on ————(Date); and is now in use in such commerce.

(4)

The mark is used by applying it to (5) ———— and five specimens showing the mark as actually used are presented herewith.

(6)

State of ————
County of ———— } ss.

————————————

(Name of applicant)

states that he/she believes himself/herself to be the owner of the trademark sought to be registered; to the best of his/her knowledge and belief no other person, firm, corporation or association has the right to use said mark in commerce, either in the identical form or in such near resemblance thereto as to be likely, when applied to the goods of such other person, to cause confusion, or to cause mistake, or to deceive; and the facts set forth in this application are true.

————————————

(Signature of applicant)

JURAT:

Subscribed and sworn to before me, this —— day of ————, ——.

* ————————————

Notary Public

REPRESENTATION

(See form 4.2 and Note (7) below.)

NOTES

(1) If registration is sought for a word or numeral mark not depicted in any special form, the drawing may be the mark typed in capital letters on letter-size bond paper; otherwise, the drawing shall comply with section 2.52.

*The person who signs the jurat must be authorized to administer oaths by the law of the jurisdiction where executed, and the seal or stamp of the notary, or other evidence of authority in the jurisdiction of execution, must be affixed.

(2) If more than one item in a class is set forth and the dates given for that class apply to only one of the items listed, insert the name of the item to which the dates apply.

(3) Type of commerce should be specified as "interstate," "territorial," "foreign," or other type of commerce which may lawfully be regulated by Congress. Foreign applicants relying upon use must specify commerce which Congress may regulate, using wording such as commerce with the United States or commerce between the United States and a foreign country.

(4) If the mark is other than a coined, arbitrary or fanciful mark, and the mark is believed to have acquired a secondary meaning, insert whichever of the following paragraphs is applicable:

(a) The mark has become distinctive of applicant's goods as a result of substantially exclusive and continuous use in ———— (Type of commerce) commerce for the five years next preceding the date of filing of this application.

(b) The mark has become distinctive of applicant's goods as evidenced by the showing submitted separately.

(5) Insert the manner or method of using the mark with the goods, i.e., "the goods," "the containers for the goods," "displays associated with the goods," "tags or labels affixed to the goods," or other method which may be in use.

(6) The required fee of $35.00 for each class must be submitted.

(7) If the applicant is not domiciled in the United States, a domestic representative must be designated. See form 4.4.

2. By revising Section 4.1a to read as follows:

Section 4.1a Trademark application by an individual; Principal Register with declaration.

Mark ————————

(Identify the mark)

Class No. ————————

(If known)

TO THE COMMISSIONER OF PATENTS AND TRADEMARKS:

————————

(Name of applicant, and business trade name, if any)

————————

(Business address)

————————

(Residence address)

————————

(Citizenship of applicant)

The above identified applicant has adopted and is using the trademark shown in the accompanying drawing (1) for the following goods:

————————

and requests that said mark be registered in the United States Patent and Trademark Office on the Principal Register established by the Act of July 5, 1946.

The trademark was first used on the goods (2) on ———— (Date) was first used in ———— (Type of commerce) commerce (3) on ———— (Date) and is now in use in such commerce.

(4)

The mark is used by applying it to (5) ———— and five specimens showing the mark as actually used are presented herewith.

(6)

————————

(Name of applicant)

being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any registration resulting therefrom, declares: That he/she believes himself/herself to be the owner of the trademark sought to be registered; that to the best of his/her knowledge and belief no other person, firm, corporation or association has the right to use said mark in commerce, either in the identical form or in such near resemblance thereto as may be likely, when applied to the goods of such other person, to cause confusion, or to cause mistake, or to deceive; that the facts set forth in this application are true; and that all statements made of his/her own knowledge are true and all statements made on information and belief are believed to be true.

————————

(Signature of applicant)

————————

(Date)

REPRESENTATION

(See form 4.2 and Note (7) under form 4.1.)

NOTES

For Notes referred to in this form but not set out here, see same numbered Notes under form 4.1.

3. By revising Section 4.2 to read as follows:

Section 4.2 Power of attorney at law (which may accompany application).*

Applicant hereby appoints (8) ————, ———— (Address) an attorney at law or attorneys at law, to prosecute this application to register, to transact all business in the Patent and Trademark Office in connection therewith, and to receive the certificate of registration.

NOTE.—(8) An individual attorney at law or individual attorneys at law must be named here. If the name of a law firm is given, it will be regarded merely as a designation of address for correspondence.

4. By revising Section 4.5 to read as follows:

Section 4.5 Trademark application by a partnership; Principal Register.

Mark ————————

(Identify the mark)

Class No. ————————

(If known)

TO THE COMMISSIONER OF PATENTS AND TRADEMARKS:

————————

(Name of partnership)

————————

(Names of partners)

————————

(Business address of partnership)

————————

(Citizenship of partners)

(Body of application is same as in form 4.1.)

State of ————}
County of ————} ss.

————————

(Name of partner) states that he/she is a partner of applicant partnership; he/she believes said partnership to be the owner of the trademark sought to be registered; to the best of his/her knowledge and belief no other person, firm, corporation or association has the right to use said mark in commerce, either in the identical form or in such near resemblance thereto as to be likely, when applied to the goods of such other person, to cause confusion, or to cause mistake, or to deceive; and the facts set forth in this application are true.

————————

(Signature of partner)

JURAT:

Subscribed and sworn to before me, this —— day of ————, ——.

* ————————

Notary Public

REPRESENTATION

(See form 4.2 and Note (7) under form 4.1.)

5. By revising Section 4.6 to read as follows:

Section 4.6 Trademark application by a corporation; Principal Register.

Mark ————————

(Identify the mark)

Class No. ————————

(If known)

TO THE COMMISSIONER OF PATENTS AND TRADEMARKS:

————————

(Corporate name and State or country of incorporation) (10)

————————

(Business address)

(Body of application is same as in form 4.1.)

State of ————}
County of ————} ss.

————————

(Name of officer of corporation) states that he/she is ———— (Official title) of applicant corporation and is authorized to execute this instrument on behalf of said corporation; he/she believes said corporation to be the owner of the trademark sought to be registered; to the best of his/her knowledge and belief no other person, firm, corporation or association has the right to use said mark in commerce, either in the identical form or in such near resemblance thereto as to be likely, when applied to the goods of such other person, to cause

————

*An attorney at law is not required to file a power of attorney; an attorney at law may represent a trademark applicant on the basis of being an attorney at law without presenting a power of attorney.

*The person who signs the jurat must be authorized to administer oaths by the law of the jurisdiction where executed, and the seal or stamp of the notary, or other evidence of authority in the jurisdiction of execution, must be affixed.

confusion, or to cause mistake, or to deceive; and the facts set forth in this application are true.

_____
(Name of corporation)
By _____
(Signature of officer of corporation, and official title of officer)

JURAT:
Subscribed and sworn to before me, this —— day of ————, ——.
_____*
Notary Public

REPRESENTATION

(See form 4.2 and Note (7) under form 4.1.)

NOTE.—(10) If applicant is an association or other collective group, the word "association" or other appropriate designation should be substituted for "corporation" when referring to applicant.

6. By revising Section 4.7 to read as follows:

Section 4.7 Service mark application; Principal Register.

Mark _____
(Identify the mark)
Class No. _____
(If known)

TO THE COMMISSIONER OF PATENTS AND TRADEMARKS:

(Insert appropriate identification of applicant in accordance with form 4.1, 4.5, or 4.6.)

The above identified applicant has adopted and is using the service mark shown in the accompanying drawing (11) for the following services: ————————, and requests that said mark be registered in the United States Patent and Trademark Office on the Principal Register established by the act of July 5, 1946.

The service mark was first used in connection with the services (2) on ———————— (Date); was first used in connection with the services rendered in (3) ———————— (Type of commerce) commerce on ———————— (Date); and is now in use in such commerce. (4)

The mark is used by _____

_____
(State method of using the mark in connection with the services)
and five (12) ———————— showing the mark as actually used are presented herewith.

(Insert appropriate verification of declaration from form 4.1, 4.1a, 4.5 or 4.6, changing the word "trademark" to "service mark" and the word "goods" to "services.")

REPRESENTATION

(See form 4.2 and Note (7) under form 4.1.)

NOTES

For Notes referred to in this from but not set out here, see same numbered Notes under form 4.1.

(11) See Note (1) under form 4.1, and if drawing is not practicable, insert description of the mark instead of reference to the drawing.

(12) Insert "specimens," or state the nature of the representation of the mark which is furnished.

7. By revising Section 4.8 to read as follows:

Section 4.8 Collective mark application (including collective membership mark); Principal Register.

Mark _____
(Identify the mark)
Class No. _____
(If known)

TO THE COMMISSIONER OF PATENTS AND TRADEMARKS:

(Insert identification of applicant in accordance with form 4.6.)

The above identified applicant has adopted and is exercising legitimate control over the use of the collective mark shown in the accompanying drawing (1) for (13) ———————— (Name the goods or services) to indicate (14) ————————, and requests that said mark be registered in the United States Patent and Trademark Office on the Principal Register established by the act of July 5, 1946.

The collective mark was first used on the (2) ———————— (Insert "goods" or "services") (15) by members of applicant on ———————— (Date); was first used by said members in (3) ———————— (Type of commerce) commerce on ———————— (Date); and is now in use in such commerce. (4)

The mark is used by applying it to (16) ———————— and five specimens of the mark as actually used are presented herewith.

(Insert verification from form 4.6 or declaration from form 4.1a, changing the wording as necessary to agree with applicant's legal entity.)

REPRESENTATION

(See form 4.2 and Note (7) under form 4.1.)

NOTES

For notes referred to in this form but not set out here, see same numbered Notes under form 4.1.

(13) If the application is for a membership mark, omit the word "for" and the space for the name of the goods or services.

(14) If the application is for a membership mark, insert "membership in applicant organization," or similar appropriate statement. If not for a membership mark, omit the words "to indicate" and the following space.

(15) If the application is for a membership mark, the phrase "on the goods or services" should be omitted.

(16) For goods, see Note (5); for services, see form 4.7; for membership, insert the manner or method of using the mark to indicate membership, such as membership cards, wall plaques, or other method which may be in use.

8. By revising Section 4.9 to read as follows:

Section 4.9 Certification mark application; Principal Register.

Mark _____
(Identify the mark)
Class No. _____
(A, for Goods; B, for Services)

TO THE COMMISSIONER OF PATENTS AND TRADEMARKS:

(Insert appropriate identification of applicant in accordance with form 4.1, 4.5 or 4.6.)

The above identified applicant has adopted and is exercising legitimate control over the use of the certification mark shown in the accompanying drawing (1) for the following goods or services:

_____

and requests that said mark be registered in the United States Patent and Trademark Office on the Principal Register established by the act of July 5, 1946.

The certification mark, as used by persons authorized by applicant, certifies (17) ————————; said mark was first used under the authority of applicant on ———————— (Date); was first used in (3) ———————— (Type of commerce) commerce on ———————— (Date); and is now in use in such commerce. (4)

The mark is used by applying it to (5) (or see form 4.7) ————, and five specimens showing the mark as actually used are presented herewith.

Applicant is not engaged in the production or marketing of any goods or services to which the mark is applied.

(Insert appropriate verification or declaration from form 4.1, 4.1a, 4.5 or 4.6 and add after the word "association" the words "other than those authorized by applicant.")

REPRESENTATION

(See form 4.2 and Note (7) under form 4.1.)

NOTES

For Notes referred to in this form but not set out here, see same numbered Notes under form 4.1.

(17) Insert an appropriate statement as to what the mark certifies, relating to regional origin, or to material, mode of manufacture, quality, accuracy or other characteristic of the goods or services, or that the work or labor on the goods or in rendering the services was performed by members of applicant.

9. By revising Section 4.10 to read as follows:

Section 4.10 Application based on concurrent use; Principal Register.

Mark _____
(Identify the mark)
Class No. _____
(If known)

TO THE COMMISSIONER OF PATENTS AND TRADEMARKS:

(Insert appropriate identification of applicant in accordance with form 4.1, 4.5 or 4.6.)

Use body of form 4.1, 4.7 or 4.8, and add at the end of the first paragraph: "for the area comprising ———————— (List the States for which registration is sought)"; and add as final paragraph of application:

The following exception(s) to applicant's right to exclusive use are:

By ————, doing business at ————————, who is using the mark ———————— (Identify the mark and Reg. No. or Ser. No., if any) for the following goods (or services): ———————— in the States of ———————— by applying the mark to (16) ———— from ———————— (Earliest known date of such use) to the present.

(Insert appropriate verification of declaration from form 4.1, 4.1a, 4.5 or 4.6 and add after the word "association" the words "other than specified in the application.")

*The person who signs the jurat must be authorized to administer oaths by the law of the jurisdiction where executed, and the seal or stamp of the notary, or other evidence of authority in the jurisdiction of execution, must be affixed.

REPRESENTATION

(See form 4.2 and Note (7) under form 4.1.)

NOTES

For Notes referred to in this form but not set out here, see same numbered Notes under forms 4.1 and 4.8.

10. By revising Section 4.11 to read as follows:

Section 4.11 Application to register on Supplemental Register.

Mark ———————————

(Identify the mark)

Class No. ———————————

(If known)

TO THE COMMISSIONER OF PATENTS AND TRADEMARKS:

(Insert appropriate identification of applicant in accordance with form 4.1, 4.5 or 4.6.)

For the body of an application for a trademark registration (18), yse form 4.1, 4.5 or 4.6, whichever is appropriate, changing the word "Principal" to "Supplemental," and adding a final paragraph to the application as follows:

"The mark sought to be registered has been in lawful use in ———— (Type of commerce) commerce in connection with the goods for the year preceding the date of filing of this application." (19)

(Insert appropriate verification or declaration from form 4.1, 4.1a, 4.5 or 4.6.)

REPRESENTATION

(See form 4.2 and Note (7) under form 4.1.)

NOTES

(18) For the body of service mark, collective mark or certification mark applications on the Supplemental Register, use form 4.7, 4.8 or 4.9, whichever is applicable, with the change and addition indicated in this form.

(19) If the mark has not been in use for the year next preceding the filing date, and registration in the United States is required as a basis for obtaining foreign protection of the mark, substitute the following statement for the last sentence: The mark sought to be registered is now in use in ———— (Type of commerce) commerce and domestic registration is required as a basis for foreign protection of the mark.

In this instance applicant will be required to make a showing that U.S. registration is required as a basis for foreign protection of the mark.

11. By revising Section 4.13 to read as follows:

Section 4.13 Application for renewal.

Mark ———————————

(Identify the mark)

Reg. No. ———————————

Class No. ———————————

TO THE COMMISSIONER OF PATENTS AND TRADEMARKS:

(Insert appropriate identification of applicant for renewal in accordance with form 4.1, 4.5 or 4.6.)(1)

The above identified applicant for renewal requests that the above identified registration, granted to ———— (Name of original registrant) on ———— (Date of Issuance); which applicant for renewal now owns, as shown by records in the Patent and Trademark Office, be renewed in accordance with the provisions of section 9 of the act of July 5, 1946.

The mark shown in said registration is still in use in (2) ———— (Type of commerce) commerce on each of the following goods (3) recited in the registration: ————, (List the goods or services or insert the words "all the goods" or "all the services"), the attached specimen (or facsimile) showing the mark as currently used. (4)

(5)

State of ————
} ss.
County of ————

———————————

(Name of renewal applicant or of person authorized to sign for a juristic renewal applicant) states that to the best of his/her knowledge and belief the facts set forth in this application are true.

———————————

(Signature of renewal applicant; if renewal applicant is a corporation or other juristic organization, give the official title of the person who signs for renewal applicant)

(JURAT) (Use Jurat from form 4.1.)

REPRESENTATION

(See form 4.2 and Note (6) below.)

NOTES

(1) Applicant for renewal must be the present owner of the registration.

(2) Type of commerce should be specified as "interstate," "foreign," "territorial," or other type of commerce which may lawfully be regulated by Congress. Foreign registrants must specify commerce which Congress may regulate, using wording such as commerce with the United States or commerce between the United States and a foreign country.

(3) If a service mark registration, state "in connection with each of the following services * * *".

(4) If the mark is not in use in commerce at the time of filing the application for renewal, but there is no intention to abandon the mark, facts must be recited to show that the nonuse is due to special circumstances. A specimen (or facsimile) illustrating use, or facts as to nonuse, must be submitted for each class sought to be renewed.

(5) The required fee for renewal sought prior to expiration is $25.00 for each class; and for delayed renewal filed within three months after expiration, an additional $5.00 for each class. If renewal is sought for less than the total number of classes in the registration, the classes for which renewal is sought should be specified.

(6) If applicant for renewal is not domiciled in the United States, a domestic representative must be designated. See form 4.4. If a designation is not submitted with this form, a prior unrevoked designation will meet the requirement if such is already in the registration file.

12. By revising Section 4.14 to read as follows:

Section 4.14 Affidavit for publication under section 12(c).

Mark ———————————

(Identify the mark)

Reg. No. ———————————

Date of Issue ———————————

To: ———————————

(Name of original registrant)

State of ————
} ss.
County of ————

———————————

(Name of registrant or of person authorized to sign for a juristic registrant) states that (1) ———— (Name of registrant) owns the above identified registration, as shown by records in the Patent and Trademark Office; that said registration is now in force; that the mark shown therein is in use in (2) ———— (Type of commerce) commerce on each of the following goods stated in the registration:

———— (List the goods or insert the words "all the goods") and that the benefits of the act of July 5, 1946, are hereby claimed for said registration.

(3)

———————————

(Signature; if a corporation or other juristic organization, give the official title of the person who signs.)

(JURAT) (Use jurat from form 4.1.)

REPRESENTATION

(See form 4.2 and Note (4) below.)

NOTES

(1) The present owner of the registration must file the affidavit as registrant.

(2) Type of commerce should be specified as "interstate," "territorial," "foreign," or other type of commerce which may lawfully be regulated by Congress. Foreign registrants must specify commerce which Congress may regulate, using wording such as commerce with the United States or commerce between the United States and a foreign country.

(3) The required fee of $10.00 must be submitted.

(4) If registrant is not domiciled in the United States, a domestic representative must be designated. See form 4.4. If a designation is not submitted with this form, a prior unrevoked designation will meet the requirement if such is already in the registration file.

13. By revising Section 4.15 to read as follows:

Section 4.15 Affidavit required by section 8.

Mark ———————————

(Identify the mark)

Reg. No. ———————————

Class No. ———————————

State of ————
} ss.
County of ————

———————————

(Name of registrant or of person authorized to sign for a juristic registrant) states that (1) ———— (Name of registrant) owns the above identified registration issued ———— (Date) (2), as shown by records in the Patent and Trademark Office; and that the mark shown therein is still in use (3) as evidenced by (4) ————.

(5)

———————————

(Signature; if a corporation or other juristic organization, give the official title of the person who signs.)

(JURAT) (Use jurat from form 4.1.)

REPRESENTATION

(See form 4.2 and Note (6) below.)

NOTES

The affidavit of which this form is an illustration must be filed within the sixth year after the date of registration under the act of 1946 or after the date of publication under section 12(c) of said act.

(1) The present owner of the registration must file the affidavit as registrant.

(2) If the registration issued under a prior act and has been published under section 12(c), add: "and published under section 12(c) on ———— (Date)".

(3) If the mark is not in use at the time of filing the affidavit, but there is no intention to abandon the mark, facts must be recited to show that the nonuse is due to special circumstances.

(4) Insert "the specimen included showing the mark as currently used," or recite facts as to sales or advertising which will show that the mark is in current use. Specimen illustrating use, or facts as to use or nonuse, are required for each class for which action is sought.

(5) The required fee of $10.00 must be submitted for each class for which action is sought, and if action is sought for less than the total number of classes in the registration, the classes for which action is sought should be specified.

(6) If registrant is not domiciled in the United States, a domestic representative must be designated. See form 4.4. If a designation in not submitted with this form, a prior unrevoked designation will meet the requirement if such is already in the registration file.

14. By revising Section 4.16 to read as follows:

Section 4.16 Affidavit under section 15.

Mark ————————
(Identify the mark)
Reg. No. ————————
Class No. ————————
State of ————— }
County of ————— } ss.

———————
(Name of registrant or of person authorized to sign for a juristic registrant) states that (1) ———— (Name of registrant) owns the above identified registration issued ———— (Date) (2), as shown by records in the Patent and Trademark Office; that the mark shown therein has been in continuous use in (3) ———— (Type of commerce) commerce for five consecutive years from (4) ———— (Date) to the present, on each of the following goods (5) stated in the registration:

———————
(List the goods or services or insert the words "all the goods" or "all the services"); that such mark is still in use in (3) ———— (Type of commerce) commerce; that there has been no final decision adverse to registrant's claim of ownership of such mark for such goods or services, or to registrant's right to register the same or to keep the same on the register, and that there is no proceeding involving said rights pending and not disposed of either in the Patent and Trademark Office or in the courts.

———————
(Signature; if a corporation or other juristic organization, give the official title of the person who signs.)

(JURAT) (Use jurat from form 4.1.)

REPRESENTATION

(See form 4.2.)

NOTES

(1) The present owner of the registration must file the affidavit as registrant.

(2) If the registration issued under a prior act and has been published under section 12(c), add: "and published under section 12(c) on ————(Date)."

(3) Type of commerce must be specified as "interstate," "territorial," "foreign," or such other commerce as may lawfully be regulated by Congress. Foreign registrants must specify commerce which Congress may regulate, using wording such as commerce with the United States or commerce between the United States and a foreign country.

(4) The date should be the beginning of a five year period of continuous use, all of which five year period falls after the date of registration under the act of 1946 or after the date of publication under section 12(c). A date which would produce a period of continuous use which is longer than five years may be stated provided the period indicated includes five years of continuous use after registration under the act of 1946 or publication under section 12(c)

(5) If a service mark registration, state: "in connection with each of the following services."

15. By adding a new Section 4.16 (Combined 8 & 15) to read as follows:

Section 4.16 (Combined 8 & 15) Combined affidavit under Sections 8 and 15.

Mark ————————
(Identify the mark)
Reg. No. ————————
Class No. ————————
State of ————— }
County of ————— } ss.

———————
(Name of registrant or of person authorized to sign for a juristic registrant) states that (1) ———— (Name of registrant) owns the above identified registration issued ———— (Date) (2), as shown by records in the Patent and Trademark Office; that the mark shown therein has been in continuous use in (3) ———— (Type of commerce) commerce for five consecutive years from the date of the registration or the date of publication under section 12(c) (4) to the present, on each of the following goods (5) stated in the registration:

———————
(List the goods or services or insert the words "all the goods" or "all the services"); that such mark is still in use in (3) ———— (Type of commerce) commerce; that such mark is still in use as evidenced by (6) ———— ; that there has been no final decision adverse to registrant's claim of ownership of such mark for such goods or services, or to registrant's right to register the same or to keep the same on the register, and that there is no proceeding involving said rights pending and not disposed of either in the Patent and Trademark Office or in the courts.

(7)

———————
(Signature; if a corporation or other juristic organization, give the official title of the person who signs.)

(JURAT) (Use jurat from form 4.1.)

REPRESENTATION

(See form 4.2 and note (8) below.)

NOTES

This combined form should not be used with the section 8 portion of the affidavit is based on nonuse.

(1) The present owner of the registration must file the affidavit as registrant.

(2) If the registration issued under a prior act and has been published under section 12(c), add: "and published under section 12(c) on ———— (Date)."

(3) Type of commerce must be specified as "interstate," "territorial," "foreign," or such other commerce as may lawfully be regulated by Congress. Foreign registrants must specify commerce which Congress may regulate, using wording such as commerce with the United States or commerce between the United States and a foreign country.

(4) This form is only appropriate when the five year period of continuous use which is required for section 15 is also the first five years after registration or after publication under section 12(c) which is required for section 8.

(5) If a service mark registration, state: "in connection with each of the following services."

(6) Insert "the specimen included showing the mark as currently used," or recite facts as to sales or advertising which will show that the mark is in current use.

(7) The required fee of $10.00 for section 8 must be submitted for each class for which action is sought, and if action is sought for less than the total number of classes in the registration, the classes for which action is sought should be specified.

(8) If registrant is not domiciled in the United States, a domestic representative must be designated for section 8. See form 4.4. If a designation is not submitted with this form, a prior unrevoked designation will meet the requirement if such is already in the registration file.

16. By revising Section 4.17 to read as follows: Section 4.17 Opposition in the United States Patent and Trademark Office.

In the matter of application Serial No. ————. Published in the Official Gazette on ———— (Date)

———————
(Name of opposer)
v.

———————
(Name of applicant)

Opposition No. ———— (To be inserted by Patent and Trademark Office) ———— (Name of opposer), a(n)(1) ———— (Legal entity of opposer), located and doing business at ———— (Address), believes that it/he/she will be damaged by registration of the mark shown in the above identified application, and hereby opposes the same.

As grounds of opposition, it is alleged that:

(Numbered paragraphs should state the grounds and recite facts tending to show why opposer believes opposer will be damaged.)

(2)

State of ———— }
County of ———— } ss.

———————————

(Name of opposer or of person authorized to sign for a juristic opposer) states that he/she is the opposer named in this opposition, or is the person authorized to sign for the juristic opposer named in this opposition; that he/she has read the opposition and knows the contents thereof; and that the allegations are true, except as to the matters stated therein to be upon information and belief, and as to those matters he/she believes them to be true.

———————————

(Signature of opposer; if opposer is a corporation or other juristic organization, give the official title of the person who signs for opposer.)

(JURAT) (Use Jurat from form 4.1)

REPRESENTATION

(See form 4.2 and Note (7) under from 4.1 For opposers who are foreigners, is is customary to regard a power of attorney as the equivalent of a domestic representative.)

NOTES

(1) If an individual, state: "an individual," or "an individual trading as ————," if there is a business trade name. If a partnership, state: "a partnership composed of ———— (Names of partners)." If a corporation, association, or other organization, state "a corporation (or specify other type of organization) organized and existing under the laws of ———— (State or country)."

(2) The required fee of $25.00 must be submitted for each class to be opposed, and if opposition is sought for less than the total number of classes, the classes to be opposed should be specified.

17. By revising Section 4.18 to read as follows:

Section 4.18 Petition to cancel a registration in the United States Patent and Trademark Office.

In the matter of Registration No. ————. Date of Issue ————.

———————————

(Name of petitioner)

v.

———————————

(Name of registrant)

Cancellation No. ———— (To be inserted by Patent and Trademark Office)

———— (Name of petitioner), a(n)(1) ———— (Legal entity of petitioner), located and doing business at ———— (Address), believes that it/he/she is or will be damaged by the above identified registration, and hereby petitions to cancel the same.

As grounds therefor, it is alleged that:

(Numbered paragraphs should state the grounds and recite facts tending to show why petitioner believes that petitioner is or will be damaged.)

(2)

State of ———— }
County of ———— } ss.

———————————

(Name of petitioner or of person authorized to sign for a juristic petitioner) states that he/she is the petitioner named in this petition to cancel, or is the person authorized to sign for the juristic petitioner named in this petition to cancel; that he/she has read the petition to cancel and knows the contents thereof; and that the allegations are true, except as to the matters stated therein to be upon information and belief, and as to those matters he/she believes them to be true.

———————————

(Signature of petitioner to cancel; if petitioner is a corporation or other juristic organization, give the official title of the person who signs for petitioner.)

(JURAT) (Use jurat from form 4.1.)

REPRESENTATION

(See form 4.2 and Note (7) under form 4.1. For petitioners who are foreigners, it is customary to regard a power of attorney as the equivalent of a domestic representative.)

NOTES

(1) If an individual, states: "an individual," or "an individual trading as ————," if there is a business trade name. If a partnership, state: "a partnership composed of ———— (Names of partners)." If a corporation, association, or other organization, state "a corporation (or specify other type of organization) organized and existing under the laws of ———— (State or country)."

(2) The required fee of $25.00 must be submitted for each class sought to be cancelled, and if cancellation is sought for less than the total number of classes, the classes sought to be cancelled should be specified.

18. By revising Section 4.21 to read as follows: Section 4.21 Assignment of application.

Whereas ———— (Name of assignor), of ———— (Address), has adopted and is using a mark for which said assignor has filed application in the United States Patent and Trademark Office for registration, Serial No. ————; and

Whereas ———— (Name of assignee), of (1) ———— (Address), is desirous of acquiring said mark;

Now, therefore, for good and valuable consideration, receipt of which is hereby acknowledged, said ———— (Name of Assignor) does hereby assign unto the said ———— (Name of assignee) all right, title and interest in and to the said mark, together with the good will of the business symbolized by the mark, and the above identified application for registration of said mark.

(2)

The Commissioner of Patents and Trademarks is requested to issue the certificate of registration to said assignee.

———————————

(Signature of assignor; if assignor is a corporation or other juristic organization, give the official title of the person who signs for assignor.)

State of ———— }
County of ———— } ss.

On this —— day of ————, ——, before me appeared ————, the person who signed this instrument, who acknowledged that he/she signed it as a free act on his/her own behalf (or on behalf of the identified corporation or other juristic entity with authority to do so).

————————————*

Notary Public

NOTES

(1) If the postal address of the assignee is not given either in the instrument or in an accompanying paper, registration to the assignee may be delayed.

(2) If assignee is not domiciled in the United States, a domestic representative must be designated. See form 4.4, changing the word "applicant" to "assignee."

19. By revising Section 4.22 to read as follows:

Section 4.22 Assignment of registration.

Whereas ———— (Name of assignor), of ———— (Address), has adopted, used and is using a mark which is registered in the United States Patent and Trademark Office, Registration No. ————, dated ————; and

Whereas ———— (Name of assignor), of ———— (Address), is desirous of acquiring said mark and the registration thereof;

Now, therefore, for good and valuable consideration, receipt of which is hereby acknowledged, said ———— (Name of assignor) does hereby assign unto the said ———— (Name of assignee) all right, title and interest in and to the said mark, together with the good will of the business symbolized by the mark, and the above identified registration thereof.

(2)

———————————

(Signature of assignor; if assignor is a corporation or other juristic organization, give the official title of the person who signs for assignor.)

State of ———— }
County of ———— } ss.

On this —— day of ————, ——, before me appeared ————, the person who signed this instrument, who acknowledged that he/she signed it as a free act on his/her own behalf (or on behalf of the identified corporation or other juristic entity with authority to do so).

————————————*

Notary Public

NOTES

(1) If the postal address of the assignee is not given either in the instrument of in an

———————————

*(The wording of the acknowledgement may vary from this illustration but should be wording acceptable under the law of the jurisdiction where executed; the person who signs the acknowledgement must be authorized to do so by the law of the jurisdiction where executed, and the seal or stamp of the notary, or other evidence of authority in the jurisdiction of execution, must be affixed.)

accompanying paper, recording may be delayed pending receipt of such address.

(2) If assignee is not domiciled in the United States, a domestic representative must be designated. See form 4.4, changing the word "applicant" to "assignee."

20. By revising Section 4.23 to read as follows:

Section 4.23 A suggested format for the certificate of mailing under 37 CFR 1.8(a) to be included with the correspondence.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on ——————— (Date of Deposit).

Print or Type Name of Person Signing Certificate

Signature of Person Signing Certificate

Date of Signature

The Patent and Trademark Office has determined that these rule changes have no potential major economic consequences requiring the preparation of a regulatory analysis under Executive Order 12044.

Dated: September 18, 1978.

DONALD W. BANNER,
Commissioner of Patents and Trademarks.

Approved: November 21, 1978.

JORDAN J. BARUCH,
Assistant Secretary for Science and Technology.

Dated: November 21, 1978.

[FR Doc. 78-33269 Filed 11-27-78; 8:45 am]

[6560-01-M]

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER E—PESTICIDE PROGRAMS

[FRL 1013-5; PP 8E2015/R176]

PART 180—TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

Thiabendazole

AGENCY: Office of Pesticide Programs, Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a tolerance for residues of the fungicide thiabendazole on bananas for preharvest application. The regulation was requested by Merck & Co. This rule establishes a maximum permissible level for residues of thiabendazole on bananas and banana pulp from preharvest application.

EFFECTIVE DATE: Effective on November 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Henry Jacoby, Product Manager (PM) 21, Registration Division (TS-767), Office of Pesticide Programs, EPA, 401 M Street SW., Washington, D.C. 20460, 202-426-2456.

SUPPLEMENTARY INFORMATION: On April 28, 1978, notice was given (43 FR 18246) that Merck & Co., Inc., P.O. Box 2000, Rahway, N.J. 07065, had filed a pesticide petition (PP 8E2015) with the EPA. Since the petition was for tolerances of residues of a pesticide on imported bananas, it was reclassified as an "E" petition and was examined under Section 408(e) of the Federal Food, Drug, and Cosmetic Act.

The petition proposed that 40 CFR 180.242 be amended to establish a tolerance for residues of the fungicide thiabendazole (2-(4-thiazolyl)ben-zimidazole) in or on the raw agricultural commodity bananas at 3 parts per million (ppm), of which no more than 0.4 ppm of residues shall be present in the pulp after the peel is removed and discarded, resulting from both preharvest and postharvest applications. No comments were received in response to this notice of filing.

Since the proposed tolerances are the same as those presently established for postharvest application to bananas, there will be no change in the dietary exposure to thiabendazole.

The scientific data considered in support of the tolerance included an acute oral toxicity test (LD_{50}) showing an LD_{50} of 3.3 grams (g)/kilogram (kg) of body weight (bw); two-year rat and dog feeding studies with a no-observable-effect level (NOEL) of 10 and 50 milligrams mg/kg bw/day, respectively; a five-generation mouse reproduction study with an NOEL of 30 mg/kg bw/day (the highest dose used); a rat three-generation reproduction study with an NOEL of 20 mg/kg bw/day; a rabbit teratology study (negative at 800 mg/kg bw/day) (highest dose); a rat teratology study with a NOEL of 80 mg/kg bw/day; subacute studies on rats, sheep, and other farm animals; and a 24-week study in humans with no observable effects noted at a dosage of 250 mg/person/day.

Based on a rat study, the NOEL is 10 mg/kg bw/day. This results in an acceptable daily intake (ADI) of 0.1 mg/kg bw/day and a maximum permissible intake (MPI) of 6 mg/day for a 60-kg man. Existing and proposed tolerances result in a theoretical maximal residue contribution of about 1 mg/day. Tolerances have previously been established for residues of thiabendazole in or on a variety of raw agricultural commodities, ranging from 10 ppm to 0.1 ppm. An adequate analytical method (spectrophotofluorometry) is available to enforce the tolerances established by this regulation. A tolerance for residues of thiabendazole in or on sugar beets is currently pending (PP 6F1860).

The existing meat and milk tolerances are adequate to cover any residues resulting from the proposed use as delineated in 40 CFR 180.6(a)(2). There are no desirable data lacking from the petition, nor are there any actions currently pending against continued registration of the pesticide, nor are any other considerations involved in establishing the proposed tolerances. It has been determined that the tolerances established by amending 40 CFR 180.242 will protect the public health, and it is concluded, therefore, that the tolerances be established as set forth below.

Any person adversely affected by this regulation may, on or before December 28, 1978, file written objections with the Hearing Clerk, EPA, Room M-3708, 401 M Street SW., Washington, D.C. 20460. Such objections should be submitted and should specify both the provisions of the regulation deemed to be objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought.

Effective on November 28, 1978, Part 180 is amended as set forth below.

(Sec. 408(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(d)(2)).)

Dated: November 17, 1978.

JAMES M. CONLON,
Acting Deputy Assistant Administrator for Pesticide Programs.

Part 180, Subpart C, § 180.242 is amended by revising the items "Bananas" and "Bananas, pulp" in the table in paragraph (a) to read as follows:

§ 180.242 Thiabendazole; tolerances for residues.

(a) * * *

Commodity:	*Parts per million*
* * * * *	
Bananas (PRE-H and POST-H)	3
Bananas, pulp (PRE-H and POST-H)	0.4
* * * * *	

[FR Doc. 78-33097 Filed 11-27-78; 8:45 am]

[6560-01-M]

[FRL 1013-6; OPP—300016A]

PART 180—TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

Exemptions from Requirement of a Tolerance for Certain Inert Ingredients in Pesticide Formulations

AGENCY: Office of Pesticide Programs, Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes exemptions from the requirement of a tolerance for two new inert (or occasionally active) ingredients in pesticide formulations and changes the use pattern of a third. The regulation was requested by various firms. This rule permits the use of two inert ingredients in pesticide formulations and expands the use pattern of a third to include wheat.

EFFECTIVE DATE: Effective on November 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. David L. Ritter, Hazard Evaluation Division (TS-769), Office of Pesticide Programs, EPA, 401 M Street, SW, Washington DC (202/426-2680).

SUPPLEMENTARY INFORMATION: On September 21, 1978, the EPA published a notice of proposed rulemaking in the FEDERAL REGISTER (43 FR 42769) to amend 40 CFR 180.1001 by exempting two pesticide chemicals which are additional inert (or occasionally active) ingredients in pesticide formulations from tolerance requirements and by expanding the use pattern of a third inert ingredient under provisions of Section 408(e) of the Federal Food, Drug, and Cosmetic Act. No comments or requests for referral to an advisory committee were received by the Agency with regard to this notice. It has been concluded that the amendment will protect the public health and, therefore, that the amendment to the regulations should be adopted as proposed.

Any person adversely affected by this regulation may, on or before December 28, 1978, file written objections with the Hearing Clerk, EPA, Room M-3708, 401 M St., SW, Washington DC 20460. Such objections should be submitted in quintuplicate and should specify both the provisions of the regulation deemed to be objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issue for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought.

Effective on November 28, 1978, Part 180, Subpart D, § 180.1001 is amended as set forth below.

Dated: November 17, 1978.

JAMES M. CONLON,
Deputy Assistant Administrator for Pesticide Programs.

(Sec. 408(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(e)))

Part 180, Subpart D, § 180.1001 is amended by alphabetically inserting new items in the tables in paragraphs (c), (d), and (e) and by revising "isophorone * * *" in paragraph (d), as follows:

1. Section 180.1001 is amended by alphabetically inserting the items "Carrageenan * * *" in the tables in paragraphs (c) and (e) and "Dipropylene glycol dibenzoate * * *" in the table in paragraph (d) to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * * * *

(c) * * *

Inert ingredients	Limits	Uses
* * * * * * *		
Carrageenan, conforming to 21 CFR 172.620.	Minimum molecular weight: 100,000...	Thickener.
* * * * * * *		

(d) * * *

Inert ingredients	Limits	Uses
* * * * * * *		
Dipropylene glycol dibenzoate.	For seed treatment use only.....	Solvent, cosolvent.
* * * * * * *		

(e) * * *

Inert ingredients	Limits	Uses
* * * * * * *		
Carrageenan, conforming to 21 CFR 172.620.	Minimum molecular weight: 100,000...	Thickener.

2. Section 180.1001(d) is amended by revising the item "Isophorone * * *" in the table to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * * * *

(d) * * *

Inert ingredients	Limits	Uses
* * * * * * *		
Isophorone	.....	Solvent and cosolvent for formulations used before crop emerges from soil, for postemergence herbicide use on rice and wheat before crop begins to head, and for postemergence use on beets (sugar beets, and table beets).
* * * * * * *		

[FR Doc. 78-33096 Filed 11-27-78; 8:45 am]

[1505-01-M]

Title 41—Public Contracts and Property Management

CHAPTER 14—DEPARTMENT OF THE INTERIOR

PART 14-19—TRANSPORTATION

Ocean Transportation on Privately Owned United States Flag Vessels

Correction

In FR Doc. 78-31336, appearing on page 51635, in the issue for Monday, November 6, 1978, below the "SUMMARY" paragraph, add the following effective date paragraph: "EFFECTIVE DATE: December 6, 1978".

[6820-25-M]

CHAPTER 101—FEDERAL PROPERTY MANAGEMENT REGULATIONS

SUBCHAPTER F—ADP AND TELECOMMUNICATIONS

[FPMR Amdt. F-35]

PART 101-36—ADP MANAGEMENT

ADP Standards

AGENCY: General Services Administration, Automated Data and Telecommunications Service.

ACTION: Final rule.

SUMMARY: This regulation specifies mandatory standard terminology for Federal agencies in ADP acquisitions relating to recorded magnetic tape cartridges for information interchange, computer output microforms, and the transmittal form for describing computer tape file properties. Use of the standards information implements approved National Bureau of Standards Federal Information Processing Standards Publications (FIPS PUBS).

EFFECTIVE DATE: November 28, 1978.

FOR FURTHER INFORMATION CONTACT:

L. Perlman, Office of Policy and Planning, telephone 202-566-0834.

The table of contents for Part 101-36 is amended to add the following entries:

Sec.

101-36.1304-18 FIPS PUB 52, Recorded Magnetic Tape Cartridge for Information Interchange, 4-Track, 6.30 mm (0.250 in), 63 BPMM (1600 BPI) Phase Encoded.

101-36.1304-19 FIPS PUB 54, Computer Output Microform (COM) Formats and Reduction Ratios, 16 mm and 105 mm.

101-36.1305-4 FIPS PUB 53, Transmittal Form for Describing Computer Magnetic Tape File Properties.

Subpart 101-36.13—Implementation of Federal Information Processing and Federal Telecommunication Standards Into Solicitation Documents

1. Sections 101-36.1304-18 and 101-36.1304-19 are added as follows:

§ 101-36.1304-18 FIPS PUB 52, Recorded Magnetic Tape Cartridge for Information Interchange, 4-Track, 6.30 mm (0.250 in), 63 BPMM (1600 BPI) Phase Encoded.

(a) FIPS PUB 52 specifies the recorded characteristics for a 6.30 mm (0.250 in) wide magnetic tape cartridge with either one, two, or four serial data tracks in order to provide for data interchange between information processing systems, communication systems, and associated equipment at a recording density of 63 bits per millimeter (1600 bits per inch) using phase encoding recording techniques. This standard is one of a series of Federal standards implementing the Federal Standard Code for Information Interchange (FIPS PUB 1) on magnetic tape media. (With one exception as cited in FIPS PUB 52, technical specifications of the standard are contained in American National Standard X3.56-1977, Recorded Magnetic Tape Cartridge for Information Interchange, 4-Track, 0.250 in (6.30 mm), 1600 BPI (63 BPMM), Phase Encoded.)

(b) The standard terminology for use in solicitation documents is:

All magnetic tape cartridge recording and reproducing equipment which results from this solicitation and employs 6.30 millimeter (0.250 inch) wide magnetic tape with one, two, or four independent serial data tracks at recording densities of 63 bits per millimeter (1600 bit per inch) using phase encoding techniques, including associated software, shall provide the capability to accept and generate recorded magnetic tape cartridges in the code and format as specified in FIPS PUB 1 and FIPS PUB 52.

§ 101-36.1304-19 FIPS PUB 54, Computer Output Microform (COM) Formats and Reduction Ratios, 16 mm and 105 mm.

(a) FIPS PUB 54 specifies the image arrangement, size, and reduction for 16 mm and 105 mm microforms generated by computer output microfilmers. It is limited to systems using business-oriented fonts similar to line printer output. The standard does not cover engineering drawings or microphotocomposition using complex graphics or graphic arts fonts and formats, nor does it cover special systems using two-step reduction techniques. (Technical specifications of the standard are included with FIPS PUB 12.)

(b) The standard terminology for use in solicitation documents is:

All applicable equipment or services that may result from this solicitation that produce computer generated microforms using plain type faces must be in compliance with FIPS PUB 54.

2. Section 101-36.1305-4 is added as follows:

§ 101-36.1305-4 FIPS PUB 53, Transmittal Form for Describing Computer Magnetic Tape File Properties.

(a) FIPS PUB 53 provided for the use of Standard Form 277, Computer Magnetic Tape File Properties, together with the instructions for providing the necessary information on the form. The form is to be used by Federal agencies to document the physical properties and characteristics of a recorded magnetic tape file needed by the receiving agency to process the tape. (Technical specifications of the standard are contained in FIPS PUB 53.)

(b) The standard terminology for use in solicitation documents is:

All magnetic tape used to transmit coded information to the Federal Government as a result of this solicitation must include completed Standard Forms 277 describing magnetic tape file properties as set forth in FIPS PUB 53.

(Sec. 205(c), 63 Stat. 390; (40 U.S.C. 486(c)).)

Dated: November 8, 1978.

JAY SOLOMON,
Administrator of General Services.

[FR Doc. 78-33228 Filed 11-27-78; 8:45 am]

[4110-02-M]

Title 45—Public Welfare

CHAPTER I—OFFICE OF EDUCATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PART 137—EDUCATIONAL INFORMATION CENTERS PROGRAM

AGENCY: Office of Education, HEW.

ACTION: Final regulations.

SUMMARY: These final regulations will govern the administration of the Educational Information Centers Program as authorized by the Education

Amendments of 1976. Under this program grants are made to States that have submitted an acceptable plan to pay a portion of the cost of planning, establishing, and operating Educational Information Centers. The Centers provide educational information, talent search, guidance, counseling, and referral services to persons residing in the area served by the Center.

EFFECTIVE DATE: These regulations are expected to take effect 45 days after they are transmitted to Congress. Regulations are usually transmitted to Congress several days before they are published in the FEDERAL REGISTER. The effective date is changed by statute if Congress disapproves the regulations or takes certain adjournments. If you want to know the effective date of these regulations, call or write the Office of Education contact person.

FOR FURTHER INFORMATION CONTACT:

Velma L. Monteiro, Division of Student Services and Veterans Programs, Room 3514, ROB 3, U.S. Office of Education, 400 Maryland Avenue, SW., Washington, D.C. 20202, telephone: 202-245-2511.

SUPPLEMENTARY INFORMATION: The Educational Information Centers Program is a State plan program under which the Commissioner provides States with funds to plan, establish, and operate Educational Information Centers. Centers will provide educational information, guidance, counseling and referral services to all individuals in a State. Only the State agency or institution designated by the Governor may submit the State plan. Any individual interested in additional information about a State's participation in this program should write or call the Office of Education contact person.

A Notice of Intent to Issue Regulations was published in the FEDERAL REGISTER on November 29, 1976 (41 FR 52414-52415). The Notice set forth those issues on which the Office of Education sought direction in developing the proposed regulations. The comments received in response to the Notice of Intent were considered in the development of the proposed regulations.

A Notice of Proposed Rulemaking was published in the FEDERAL REGISTER on January 12, 1978 (43 FR 1896-1898). Public hearings were held in St. Louis, Missouri; Los Angeles, California; Tallahassee, Florida; and Washington, D.C. In addition, interested persons were given 30 days in which to submit written comments, suggestions, or objections.

The written and oral comments received in response to specific sections of the Notice of Proposed Rulemaking and the response of the Office of Education to these comments follow.

§ 137.1(a) PURPOSE AND SCOPE—GENERAL PROVISIONS

Comment. One commenter expressed concern about the purpose of the program. This commenter felt that the purpose of the program was reasonable but totally unrealistic because of the low appropriation level.

Response. The regulations that govern the implementation of the program have been modified to allow States to submit (1) a plan for developing a plan; (2) a comprehensive strategy for implementing a plan or (3) a plan that combines planning and implementing. However, the program requirements are mandated by statute and cannot be eliminated because of a small appropriation.

§ 137.2 DEFINITIONS

Comment. Several commenters pointed out that the definition of Educational Information Centers did not make sense with regard to the area to be served. Specifically, the Notice of Proposed Rulemaking included the "geographical area now greater than that which will afford all persons * * *".

Response. This error has been corrected. The confusion is the result of a typographical error. The word *now* was mistyped for *no*.

Comment. Several commenters questioned whether reasonable geographic distance, reasonable access, and reasonable time would be defined in the final regulations or whether the States would be responsible for developing their own definitions.

Response. No additional terms have been defined in the regulations. States vary a great deal in geography, population density, and services currently available for the dissemination of educational information. Since no standard definition for these terms would be fairly and equally applicable to all States, the Commissioner will allow each State to define these terms for itself.

§ 137.3(a) ALLOTMENT OF FUNDS

Comment. Several commenters suggested changes in the allotment formula to better accommodate rural and sparsely populated areas.

Response. No change has been made in the regulations because the allotment formula is specified in the statute.

§ 137.3(b) ALLOTMENT OF FUNDS

Comment. One commenter suggested that when the appropriation for a fiscal year is insufficient to permit the award of the $50,000 minimum, the allocation should be based on the population of the participating States with a minimum allocation of $25,000 to each State submitting an approved plan.

Response. No change has been made in the regulations. Because each State will have many similar basic costs regardless of its size, the States that participate in the program will share equally when the appropriation is insufficient to permit the award of the $50,000 minimum.

§ 137.4(a) EDUCATIONAL INFORMATION CENTERS PROGRAM REQUIREMENTS

Comment. Several commenters expressed concern that private and public agencies and organizations may receive grants and contracts from the States only when the agencies and organizations are acting in combination with an institution of higher education.

Response. No change has been made in the regulations. The regulations do not require agencies and organizations to act in combination with an institution of higher education. Only local educational agencies must act in combination with institutions of higher education in order to receive a contract or grant from the State.

Comment. One commenter suggested that the regulations be modified to permit an area vocational school to be considered an institution of higher education rather than a local educational agency so that it may be eligible for State grants without the need to work in combination with an institution of higher education.

Response. No change in this definition can be made by regulations. This program is subject to the statutory definition of an institution of higher education as defined in Sections 1201(a) and 491(b) of the Higher Education Act.

Comment. Several commenters expressed concern that a State government might retain the major part of its allotment to pay for the administration of and planning for the project rather than using most of its allotment to deliver services to clients.

Response. The regulations have been modified to allow States: (1) to plan for developing a plan; (2) to submit a comprehensive strategy for implementing the plan; or (3) to both plan and implement a comprehensive strategy. Costs, therefore, for planning, establishing, and operating the program are allowable within an approved work plan. Costs for planning activities in addition to or beyond those specified in the approved State plan are unallowable.

Comment. Several commenters urged that non-institutional educational centers have a chance to receive funding to continue their existing operations and thus avoid duplication of

services. In addition, the commenters suggested that business and industry, proprietary schools, and secondary school adult education programs can plan a major role in offering services and training.

Response. No change has been made in the regulations. Section 137.4(a) permits States to fund non-institutional educational centers. Section 137.4(c), which refers to postsecondary education and training, does not limit the referrals of persons to institutions of higher education only. The intent of the program is that each center will refer individuals to all available and appropriate sources of services and training: agencies, organizations, and institutions—whether private, profit, or non-profit—as well as institutions of higher education.

§ 137.4(c) EDUCATIONAL INFORMATION CENTERS PROGRAM REQUIREMENTS

Comment. Several commenters expressed concern that the direct services offered by the Educational Information Centers would conflict with other Governmental agencies and with private businesses providing these same services.

Response. No change has been made in the regulations. The regulations do not require the Centers to provide direct services. Rather, it is the intent of the regulations to have the Centers provide information and *referral* services. Referrals are to be made to any public or private agency and organization, any public, private or proprietary school, or to any individual that can adequately help the client.

Comment. One commenter suggested that § 137.4(c)(v) be amended to read: "Guidance and counseling services by *professionally trained personnel* designed to assist * * *"

Response. No change has been made in the regulations. Each State will decide for itself the type of guidance and counseling services it will provide through the Center or Centers.

Comment. One commenter questioned whether the Educational Information Centers needed to provide all of the services described in § 137.4(c)(i-vi) or just some of them.

Response. No change has been made in the regulations. The statute that governs the Educational Information Centers Program requires all of the services described in § 137.4(c) of the regulations.

§ 137.5 STATE PLAN REQUIREMENTS—INITIAL YEAR

Comment. Many commenters expressed concern over the requirements for the State plan for the initial year of funding. Because of the limited level of funding, several commenters suggested that these requirements for initial year funding be geared heavily toward planning, surveying, and organizing for a Statewide network. States, therefore, could better coordinate with those agencies, organizations, and institutions that are currently providing services similar to those to be provided through this program. Another suggestion was that the regulations be relaxed to allow those States that are not ready to implement this program to plan for the development of a plan. Finally, other commenters suggested that the regulations allow States to both plan and establish Educational Information Centers in the initial year of funding.

Response. The regulations have been revised to allow for the flexibility suggested by the commenters regarding State plan requirements for the initial year of funding. Specifically, § 137.5(a)(4), (5), (7), (8), and (9) have been revised to permit States to submit a plan that includes a plan for the development of those items requested in § 137.5(a)(4), (5), (7), (8), and (9). They will have the prerogative to choose to submit either the completed material or a plan for the development of the material, or both.

Comment. One commenter recommended that members of the business community, such as representatives of proprietary schools, have the right to veto a State plan and policy for establishing and operating Educational Information Centers.

Response. No change has been made in the regulations. There is no statutory authority for such a veto. Moreover, to allow a veto by one section of the community would have unfair impact on all others involved with the development of the plan.

Comment. One commenter expressed concern that, except for § 137.5(a)(1), (2), (4) and (b)(3), this section is unnecessarily prescriptive and should not be judged as "essential to carry out the provisions of the legislation."

Response. No change has been made in this part of the regulations. The requirements for initial year State plans are consistent with the legislation from which these regulations are derived.

§ 137.5(a)(1) AND (2) STATE PLAN REQUIREMENTS—INITIAL YEAR

Comment. Several commenters named an agency or institution within their State that, they believed, should be named by the Governor to develop and administer the State Plan.

Response. No change has been made in the regulations because the Governor of each State has the sole authority and responsibility for choosing the agency or institution to develop the plan. Recommendations, therefore, should be directed to each Governor.

§ 137.5(a)(3) AND (b)(4) STATE PLAN REQUIREMENTS—INITIAL YEAR

Comment. Many commenters named various groups that should be heavily involved in the development of the State plan. Each commenter wanted his or her group to play a more significant role in the development of the plan.

Response. No change has been made in the regulations to require that specific groups be included in the development of the State plan. Preferably, each State will involve a variety of groups, agencies, institutions, and individuals in the development of its plan so that a full strategy for the State will be developed.

§ 137.5(a)(6) STATE PLAN REQUIREMENTS—INITIAL YEAR

Comment. Several commenters expressed concern that their respective programs were not listed under § 137.5(a)(6)(i), "* * * such as occupational and career information systems, * * *".

Response. No change has been made in the regulations. The types of programs cited are illustrative of the programs that could be coordinated with the Educational Information Centers Program and are not meant to be exhaustive.

§ 137.5(b)(1)(i) STATE PLAN REQUIREMENTS—INITIAL YEAR

Comment. One commenter expressed concern that the State legal officer had to submit a certification as part of the State plan. The commenter stated that this procedure is both unnecessary and burdensome.

Response. The Office of Education concurs. Sections 137.5(b)(1) (i) and (ii), therefore, have been deleted from these regulations.

§ 137.5(b) STATE PLAN REQUIREMENTS—INITIAL YEAR

Comment. One commenter suggested that another assurance be required of the States. That assurance should require States to provide services to the low-income and academically disadvantaged.

Response. No change has been made in the regulations. The regulations require that Centers provide the necessary information and referral services to all individuals in the State. Therefore, services are to be provided to low-income and academically disadvantaged persons within a reasonable distance of the Center.

§ 137.6 STATE PLAN AMENDMENTS

Comment. One commenter expressed concern that this section appears to be designed to aid the Office of Education in maintaining its program personnel rather than to help

address realistically the need of States to update their plans periodically and to report routinely progress in the achievement of objectives. This commenter felt that the need for States to update plans could be easily accomplished through more simple and flexible procedures and requirements.

Response. No change has been made in the regulations. The legislation from which these regulations are derived requires the Commissioner to use the latest available actual data, including data on previous participation, to assess State plans and to make allocations to the States. The State plan amendments section of the regulations, therefore, is consistent with the law.

§ 137.8(b) REPORTS

Comment. Several commenters suggested that the annual performance reporting requirements be revised to accommodate those States that will be involved with planning and surveying during their initial year in the program.

Response. The Office of Education concurs, and § 137.8(b) has been revised accordingly.

§ 137.9 ALLOWABLE COSTS—MATCHING

Comment. Several commenters suggested that § 137.9(b) be revised to include a statement that the matching 33⅓ percent may be in cash or in kind.

Response. The Office of Education concurs. Section 137.9(b) has been revised accordingly.

(Catalog of Federal Domestic Assistance Program No. 13.585; Educational Information Centers Program.)

Dated: September 28, 1978.

ERNEST L. BOYER,
U.S. Commissioner of Education.

Approved: November 11, 1978.

HALE CHAMPION,
Acting Secretary of Health, Education, and Welfare.

Chapter I of Title 45 of the Code of Federal Regulations is amended by adding a new part, Part 137, to read as follows:

Sec.
137.1 Purpose and scope—general provisions.
137.2 Definitions.
137.3 Allotment of funds.
137.4 Educational Information Centers Program requirements.
137.5 State plan requirements—initial year.
137.6 State plan amendments.
137.7 Approval of the State plan.
137.8 Reports.
137.9 Allowable costs—matching requirement.

AUTHORITY: Sec. 418A, 418B, Title IV of the Higher Education Act of 1965 as added by sec. 125 of Title I, Pub. L. 94-482, 90 Stat. 2096-2098 (20 U.S.C. 1070d-2—1070d-3), unless otherwise noted.

§ 137.1 Purpose and scope—general provisions.

The purpose of the Educational Information Centers Program is to provide educational information, guidance, counseling, and referral services to all individuals in a State through Centers. These Centers would be located within a reasonable distance of all residents in the State, including those individuals residing in rural areas. The Commissioner will award to each State that submits an approved State plan a grant to pay the Federal share of the cost of planning, establishing, and operating the Centers.

(b) Assistance provided under this part is subject to the provisions in Subchapter A of this chapter relating to fiscal, administrative, and other matters (General Provisions for Office of Education Programs—45 CFR Part 100b).

(20 U.S.C. 1070d-2—1070d-3.)

§ 137.2 Definitions.

For the purpose of this part:

"Educational Information Center" or "Center" means an institution or agency, or combination of institutions or agencies, organized to provide educational information, guidance, counseling, and referral services for a geographical area. That area may not be greater than that which will afford all persons within the area reasonable access to the services of the Center.

(20 U.S.C. 107d0-2.)

"State" means, in addition to the several States of the Union, the Commonwealth of Puerto Rico, the District of Columbia, Guam, American Samoa, the Virgin Islands, the Trust Territory of the Pacific Islands, and the Northern Mariana Islands.

(20 U.S.C. 1141(b); 1088(a).)

§ 137.3 Allotment of funds.

(a) For each fiscal year, the Commissioner will allocate funds to each State that has submitted an approved plan. That amount will bear the same ratio to the appropriation as the population of that State bears to the total population of all States submitting an approved State plan. However, subject to the availability of funds, no State submitting an approved plan shall receive less than $50,000.

(b) If the appropriation for a fiscal year is insufficient to permit the award of the $50,000 minimum, the appropriation will be divided equally among each of the participating States.

(c) In making allocations under this section, the Commissioner will use the latest available census data.

(20 U.S.C. 1070d-2(b).)

§ 137.4 Educational Information Centers Program requirements.

(a) Each State receiving funds may make grants and contracts to plan, establish, and operate Centers. However, it may enter into these grants and contracts only with (1) institutions of higher education as defined in sections 1201(a) and 491(b) of the Higher Education Act of 1965; (2) combinations of such institutions as defined in section 1201(j) of that Act; (3) public and private agencies; and (4) local educational agencies as defined in section 1201(g) of that Act that are acting in combination with an institution of higher education.

(b) Each State must establish a sufficient number of Centers so that there is a Center within a reasonable geographic distance of all residents of the State.

(c) Each Center must provide the following services:

(1) Information and talent search services. These services must be designed to seek out persons who could benefit from postsecondary education or training if it were not for cultural or financial barriers, physical handicaps, deficiencies in secondary education, or lack of information about available programs or financial assistance. They must also be designed to encourage those persons to participate in full-time or part-time postsecondary education or training;

(2) Information and referral services with regard to:

(i) Available postsecondary educational and training programs;

(ii) Available Federal, State, and other financial assistance;

(iii) The procedures and requirements for applying for the educational and training programs and the financial assistance;

(iv) Job placement;

(v) Gaining admission to postsecondary educational institutions offering education programs designed to prepare persons for careers or for retraining, continuing education, or upgrading of skills;

(vi) Competency-based learning opportunities. These opportunities include testing existing competencies for the purpose of certification, awarding of credit, or advanced placement in postsecondary education programs;

(vii) Guidance and counseling services designed to assist persons in identifying postsecondary educational or training opportunities that are appropriate to their needs and to their individual career plans. These opportunities may include part-time opportunities for persons who are employed; and

(viii) Remedial or tutorial services designed to prepare persons for postsecondary educational opportunities

or training programs. These services may be provided to persons enrolled in postsecondary educational institutions within the area served by the Center.

(d) Services may be provided by a Center directly or under an agreement with agencies and institutions located in the area served by the Center.

(20 U.S.C. 107d0-2; 1141(a)(g)(j); 1088(b).)

§ 137.5 State plan requirements—initial year.

(a) Any State desiring to receive its allotment for the first year of its participation in the program must submit a State plan to the Commissioner. The plan must comply with the forms and instructions that will be furnished for this purpose. The State plan must include:

(1) The name of the State agency or institution that will be responsible for administering and implementing the State plan;

(2) The name of the official, within that agency or institution, designated by the Governor as responsible for submitting the State plan and to whom communications concerning the plan shall be directed;

(3) A description of the involvement of individuals, public and private agencies, organizations and institutions in the development of the State plan. This description shall include a list of those agencies, organizations, institutions and individuals;

(4) A schedule for establishing or expanding the Centers, within a reasonable period of time, so as to make their services available to all residents of the State; or, a plan for developing the schedule;

(5) A comprehensive plan for providing the required program activities; or, a plan for developing the comprehensive plan. The comprehensive plan must include:

(i) Specific goals and objectives,

(ii) The development of various educational information systems, and,

(iii) The manner in which the State will monitor the accuracy and timeliness of the information being disseminated;

(6) A plan for:

(i) Surveying the State to identify those organizations and agencies that already provide comparable information, referral and guidance services, such as occupational and career information systems, and

(ii) Coordinating the activities of the Centers with the activities of those agencies and organizations;

(7) The policies and procedures to be used in selecting the location of each Center; or, a plan for developing the policies and procedures;

(8) The criteria that will be followed by the State in selecting the recipients of grants or contracts as permitted by section 137.4(a); or, a plan for developing the criteria;

(9) The monitoring process to be used to assure that adequate progress is being made toward achieving the goals of the program; or, a plan for developing the monitoring process;

(10) A budget itemizing the approximate amount of funds from Federal and non-Federal sources that will be needed during the first year for:

(i) Developing and administering the State plan for that year; and/or

(ii) Establishing or expanding and operating the Centers for that year.

(11) The activities to be funded if the State's allotment is less than the amount the State indicated it needed in subparagraph (10) of this paragraph; and

(12) The source and amount of the State, local, and/or private funds that will be used to meet the non-Federal share.

(b) The State plan must also include the following assurances:

(1) An assurance that the State has provided for fiscal control and fund accounting procedures that are necessary to assure proper disbursement of and accounting for Federal funds paid the State. These procedures include the monitoring of funds paid by the State to agencies, organizations and/or institutions to carry out the activities under section 137.4;

(2) An assurance that State, local and/or private funds will be provided to meet the non-Federal share of the cost of planning, establishing and operating the Centers; and

(3) An assurance that, in the development of the State plan, the State has consulted with a variety of public and private agencies, organizations, institutions, and individuals, including potential consumers.

(20 U.S.C. 1070d-3.)

§ 137.6 State plan amendments.

(a) The State plan must be amended annually to reflect any change in the information submitted under § 137.5. The State plan amendment must be submitted at the time and in the format prescribed by the Commissioner and must contain the following information:

(1) The revisions in the State plan and their relationship to the State's comprehensive plan for establishing or expanding and operating the Centers. The amendment shall contain any changes in the locations of the Centers and in the services provided;

(2) The activities are to be carried out in planning, establishing, and operating the Centers for that year;

(3) The progress the State has made during the award period toward accomplishing the goals and objectives of its State plan;

(4) The problems the State encountered that prevented it from meeting its goals and objectives;

(5) The location of Centers currently operating;

(6) The program activities and services being provided through each Center;

(7) A budget itemizing the approximate amount of funds from Federal and non-Federal sources that will be needed during the next program year for:

(i) Updating and administering the State plan for the next program year;

(ii) Establishing or expanding and operating the Centers; and

(8) The source and amount of the State, local, and/or private funds that will be used to meet the non-Federal share of the cost of planning, establishing, and operating Centers for that year.

(b) The annual State plan amendment shall also contain the assurances required under § 137.5(b).

(c) Those States that, for their initial year, submitted a plan to plan for the development of items required by § 137.5(a) (4), (5), (7), (8), and (9) must submit those completed items with their first State plan amendment.

(20 U.S.C. 1070d-3.)

§ 137.7 Approval of the State plan.

(a) The Commissioner will approve each State plan that meets the requirements of § 137.5 and will notify the applicant of the granting, conditioning, or withholding of approval in each case.

(b) The Commissioner will approve each annual State plan amendment that meets the requirements set forth in § 137.6

(20 U.S.C. 1070d-3.)

§ 137.8 Reports.

The State shall prepare and submit to the Commissioner the following reports within 90 days after the close of the grant period:

(a) An annual financial report for the grant period that sets forth:

(1) The total outlays and unpaid obligations;

(2) The amount and source of the State's matching funds;

(3) The amount of funds from all sources that were spent for administrative purposes; and

(4) The amount of unobligated funds, allotted under this part, that will remain at the end of the grant period; and

(b) An annual performance report that contains:

(1) A list of grants and contracts made during that year, including:

(i) The name of the grantee or contractor;

(ii) A description of services provided under the grant or contract;

(iii) The locations where services were provided; and

(iv) The amount of funds, from all sources, involved;

(2) A report on the number of individuals served by the program and the services provided them; and

(3) If the State has not provided services to clients, a narrative report of the progress that the State has made during the award period toward the development of its comprehensive strategy.

(20 U.S.C. 1070d-2.)

§ 137.9 Allowable costs—matching requirement.

(a) The Commissioner will pay up to 66⅔ percent of the costs reasonably related to planning, establishing, and operating Educational Information Centers.

(b) The State must provide 33⅓ percent of those costs. Its share may be met with State, local or private funds and may be met in cash or in kind.

(20 U.S.C. 1070d-2.)

[FR Doc. 78-32856 Filed 11-27-78; 8:45 am]

[7035-01-M]

Title 49—Transportation

CHAPTER X—INTERSTATE COMMERCE COMMISSION

SUBCHAPTER A—GENERAL RULES AND REGULATIONS

[S.O. No. 1347]

PART 1033—CAR SERVICE

Hillsdale County Railway Co. Inc. Authorized To Operate Over Tracks Abandoned by Penn Central Transportation Co.

AGENCY: Interstate Commerce Commission.

ACTION: Emergency Order, Service Order No. 1347.

SUMMARY: The Hillsdale County Railway Company Inc. is authorized to operate between Pleasant Lake, Indiana, and Steubenville, Indiana, over tracks abandoned by Penn Central Transportation Company. Hillsdale County Railway has purchased this railroad property from the trustees of Penn Central Transportation Company and the Fort Wayne and Jackson Railroad Company.

DATES: Effective 11:59 p.m., November 21, 1978. Expires 11:59 p.m., May 15, 1979.

FOR FURTHER INFORMATION CONTACT:

Charles C. Robinson, Chief, Utilization and Distribution Branch, Interstate Commerce Commission, Washington, D.C. 20423, telephone 202-275-7840, Telex 89-2742.

SUPPLEMENTARY INFORMATION: The Order is printed in full below.

Decided November 20, 1978.

The Hillsdale County Railway Company Inc. (HCRC) operates 59 miles of line in Branch and Hillsdale Counties, Michigan, and Steuben County, Indiana, connecting with the Consolidated Rail Corporation (CR) at Quincy, Michigan. There are no other connections with CR or other railroads. To provide another connection with the general rail network the HCRC purchased from the trustees of the former Penn Central Transportation Company, 2.93 miles of railroad between Pleasant Lake, Indiana, the end of the present HCRC, and a connection with the Norfolk and Western Railway Company (NW) at Steubenville, Indiana. Access to the NW will enable the HCRC to provide shippers served by its lines with additional routings and improved car supplies. An application seeking permanent authority to acquire and operate these tracks will be filed with the Commission.

It is the opinion of the Commission that an emergency exists requiring the operation by HCRC over tracks formerly operated by PC in the interest of the public; that notice and public procedure are impracticable and contrary to the public interest; and that good cause exists for making this order effective upon less than thirty days' notice.

It is ordered,

§ 1033.1347 Service Order No. 1347.

(a) *Hillsdale County Railway Company Inc. authorized to operate over tracks abandoned by Penn Central Transportation Company.* The Hillsdale County Railway Company Inc. (HCRC) is authorized to operate over tracks abandoned by Penn Central Transportation Company (PC) between former PC milepost 35.7 at Pleasant Lake, Indiana, and former PC milepost 32.77 at Steubenville, Indiana, a distance of approximately 2.93 miles.

(b) *Application.* The provisions of this order shall apply to intrastate, interstate and foreign traffic.

(c) *Rates applicable.* Operations over these tracks by HCRC shall not commence until tariffs to, from and via Steubenville become effective.

(d) Nothing herein shall be considered as a prejudgement of the application of the HCRC seeking authority to operate over these tracks.

(e) *Effective date.* This order shall become effective at 11:59 p.m., November 21, 1978.

(f) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., May 15, 1979, unless otherwise modified, changed or suspended by order of this Commission.

(49 U.S.C. 1(10-17).)

This order shall be served upon the Association of American Railroads, Car Service Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms of that agreement and upon the American Short Line Railroad Association. Notice of this order shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing a copy with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, Members Joel E. Burns, Robert S. Turkington and John R. Michael.

H. G. Homme, Jr.,
Secretary.

[FR Doc. 78-33189 Filed 11-27-78; 8:45 am]

[7035-01-M]

[S.O. No. 1348]

PART 1033—CAR SERVICE

Chicago & North Western Transporation Co. Authorized To Operate Over Tracks of Chicago, Milwaukee, St. Paul & Pacific Railroad Co.

AGENCY: Interstate Commerce Commission.

ACTION: Emergency Order, Service Order No. 1348.

SUMMARY: The line of the Chicago and North Western Transportation Company (CNW) between James Valley Junction, South Dakota, and Redfield, South Dakota, has deteriorated and is no longer operable thus isolating that portion of the CNW north of Redfield from the remainder of the system. The Chicago, Milwaukee, St. Paul and Pacific Railroad Company (MILW) has consented to use of its parallel line by the CNW between Wolsey, South Dakota, and Aberdeen, South Dakota. Use of this MILW line by the CNW will enable the CNW to continue service to shippers on its line north of Redfield. Service Order No. 1348 authorizes the use of these MILW tracks by the CNW pending disposition by the Commission of the application of the CNW seeking permanent authority to operate over this line.

DATES: Effective 12:01 a.m., November 22, 1978. Expires 11:59 p.m., May 15, 1979.

FOR FURTHER INFORMATION CONTACT:

Charles C. Robinson, Chief, Utilization and Distribution Branch, Interstate Commerce Commission, Washington, D.C. 20423, telephone 202-275-7840, Telex 89-2742.

SUPPLEMENTARY INFORMATION: The Order is printed in full below.

Decided November 20, 1978.

The line of the Chicago and North Western Transportation Company (CNW) between James Valley Junction, South Dakota, and Aberdeen, South Dakota, has deteriorated and is no longer suitable for the movement of loaded cars having a gross weight in excess of 210,000 pounds. An alternate route is available via the Chicago, Milwaukee, St. Paul and Pacific Railroad Company (MILW). The CNW has requested and the MILW has consented to use of the parallel line of the MILW between a connection with the CNW at Wolsey, South Dakota, and another connection between these lines at Aberdeen, a distance of approximately 70.6 miles.

It is the opinion of the Commission that an emergency exists requiring operation of CNW trains over these tracks of the MILW in the interest of the public; that notice and public procedure are impracticable and contrary to the public interest; and that good cause exists for making this order effective upon less than thirty days' notice.

It is ordered,

§ 1033.1348 Service Order No. 1348.

(a) *Chicago and North Western transportation Company authorized to operate over tracks of Chicago, Milwaukee, St. Paul and Pacific Railroad Company.* The Chicago and North Western Transportation Company (CNW) is authorized to operate over tracks of the Chicago, Milwaukee, St. Paul and Pacific Railroad Company (MILW) between MILW milepost 705.0 at Wolsey, South Dakota, and MILW milepost 775.6 at Aberdeen, South Dakota, a distance of approximately 70.6 miles.

(b) *Application.* The provisions of this order shall apply to intrastate, interstate and foreign traffic.

(c) *Rates applicable.* Inasmuch as this operation by the CNW over tracks of the MILW is deemed to be due to carrier's disability, the rates applicable to traffic moved by the CNW over the tracks of the MILW shall be the rates which were applicable on the shipments at the time of shipment as originally routed.

(d) Nothing in this order shall be deemed to prejudge the decisions of the Commission in the applications of the CNW seeking permanent authority to operate over these tracks of the MILW.

(e) *Effective date.* This order shall become effective at 12:01 a.m., November 22, 1978.

(f) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., May 15, 1979, unless otherwise modified, changed, or suspended by order of this Commission.

(49 U.S.C. 1(10-17).)

This order shall be served upon the Association of American Railroads, Car Service Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms of that agreement and upon the American Short Line Railroad Association. Notice of this order shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing a copy with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members Joel E. Burns, Robert S. Turkington and John R. Michael.

H. G. HOMME, Jr.,
Secretary.

[FR Doc. 78-33190 Filed 11-27-78; 8:45 am]

[4310-55-M]

Title 50—Wildlife and Fisheries

CHAPTER 1—FISH AND WILDLIFE SERVICE, DEPARTMENT OF THE INTERIOR

PART 33—SPORT FISHING

National Wildlife Refuges in Nevada

AGENCY: Fish and Wildlife Service.

ACTION: Special regulations.

SUMMARY: The Director has determined that the opening to fishing of certain National Wildlife Refuges in Nevada is compatible with the objectives for which these areas were established, will utilize a renewable natural resource, and will provide additional recreational opportunity to the public. This document established special regulations effective for the upcoming fishing season.

DATES: January 1, 1979, through December 31, 1979.

ADDRESS: Contact the Refuge Manager at the address and/or telephone number listed below in the body of the special regulations.

FOR FURTHER INFORMATION CONTACT:

William D. Sweeney, Area Manager, U.S. Fish and Wildlife Service, 2800 Cottage Way, Room E-2740, Sacramento, California 95825, telephone: FTS 468-4664, Commercial (916) 484-4664.

SUPPLEMENTARY INFORMATION: Fishing is permitted on the National Wildlife Refuges indicated below in accordance with 50 CFR, Part 33, and the following Special Regulations. Portions of refuges which are open to fishing are designated by signs and/or delineated on maps available at refuge headquarters. No vehicle travel is permitted except on maintained roads and trails designated open to public use. Fishing shall be in accordance with all applicable State regulations subject to the following conditions:

§ 33.5 Special regulations; sport fishing; for individual wildlife refuge areas.

Charles Sheldon Antelope Range, (Headquarters: P.O. Box 111, Lakeview, Oregon 97630, (503) 947-2366).

Ruby Lake National Wildlife Refuge, Ruby Valley, Nevada 89833, (702) 779-2237.

Special Condition: Utilization of personal flotation devices will be permitted only in those portions of Unit 21 and only during only those periods as designated by signs. Boats, canoes, and all other types of watercraft are prohibited.

Stillwater National Wildlife Refuge, P.O. Box 1236, Fallon, Nevada, 89406, (702) 423-5128.

Special Condition: Refuge closed to fishing during the migratory waterfowl hunting season.

Pahranagat National Wildlife Refuge, (Headquarters: 1500 North Decatur Blvd., Las Vegas, Nevada 89108, (702) 878-9617).

Special Condition: Only that portion of Upper Pahranagat Lake between the south dam and the cross dike, approximately one mile north is open to fishing as posted.

The provisions of these special regulations supplement the regulations which govern fishing on wildlife refuge areas generally, which are set forth in Title 50, Code of Federal Regulations, Part 33. The public is invited to offer suggestions and comments at any time.

NOTE.—The Fish and Wildlife Service has determined that this document does not contain a major proposal requiring preparation of an Economic Impact Statement under Executive Order 11949 and OMB Circular A-107.

The primary author of this document is Lynn C. Howard, Sacramento Area Office, Telephone FTS 468-4664, Commercial (916) 484-4664.

Dated: November 20, 1978.

PATRICK O'HALLORAN,
Area Manager—California-Nevada, U.S. Fish and Wildlife Service.

[FR Doc. 78-33277 Filed 11-27-78; 8:45 am]

[4310-55-M]

PART 33—SPORT FISHING

National Wildlife Refuges in California

AGENCY: Fish and Wildlife Service.

ACTION: Special regulations.

SUMMARY: The Director has determined that the opening to fishing of certain National Wildlife Refuges in California is compatible with the objectives for which these areas were established, will utilize a renewable natural resource, and will provide additional recreational opportunity to the public. This document established special regulations effective for the upcoming fishing season.

DATES: January 1, 1979, through December 31, 1979.

ADDRESS: Contact the Refuge Manager at the address and/or telephone number listed below in the body of the special regulations.

FOR FURTHER INFORMATION CONTACT:

William D. Sweeney, Area Manager, U.S. Fish and Wildlife Service, 2800 Cottage Way, Room E-2740, Sacramento, California 95825, telephone: FTS 468-4664, Commercial (916) 484-4664.

SUPPLEMENTARY INFORMATION: Fishing is permitted on the National Wildlife Refuges indicated below in accordance with 50 CFR, Part 33, and the following Special Regulations. Portions of refuges which are open to fishing are designated by signs and/or delineated on maps available at refuge headquarters. No vehicle travel is permitted except on maintained roads and trails designated open to public use. Fishing shall be in accordance with all applicable State regulations subject to the following conditions:

§ 33.5 Special regulations; sport fishing; for individual wildlife refuge areas.

Colusa National Wildlife Refuge, (Headquarters: Sacramento National Wildlife Refuge, Route 1, Box 311, Willows, California 95988, (916) 934-4090.

Special Condition: The taking of frogs is permitted in the public fishing area. The refuge is closed to sport fishing and taking of frogs during the migratory waterfowl hunting season. No campfires or firearms permitted.

Delevan National Wildlife Refuge, (Headquarters: Sacramento National Wildlife Refuge, Route 1, Box 311, Willows, California 95988, (916) 934-4090.

Special Condition: The taking of frogs is permitted in the public fishing area. The refuge is closed to sport fishing and the taking of frogs during the migratory waterfowl hunting season. No campfires or firearms permitted.

Modoc National Wildlife Refuge, (Headquarters: Sheldon-Hart Mountain-Modoc National Wildlife Refuges, P.O. Box 111, Lakeview, Oregon 97630, (503) 947-3315.

Special Conditions: (1) The refuge is closed to fishing during the waterfowl hunting season.

(2) The taking of frogs on refuge lands is prohibited.

Sacramento National Wildlife Refuge, Route 1, Box 311, Willows, California 95988, (916) 934-4090.

Special Condition: The taking of frogs is permitted in the public fishing area. The refuge is closed to sport fishing and the taking of frogs during the migratory waterfowl hunting season. No campfires or firearms permitted.

Salton Sea National Wildlife Refuge, P.O. Box 247, Calipatria, California 92233, (714) 348-2323.

Special Condition: Fishing is permitted only on that portion of the refuge which is inundated by the Salton Sea and other refuge lands posted with public fishing signs.

San Luis National Wildlife Refuge, P.O. Box 2176, Los Banos, California 93635, (209) 826-3508.

Special Conditions: (1) Fishing permitted from sunrise to one hour after sunset.

(2) The refuge is closed to sport fishing during the migratory waterfowl hunting season.

(3) Use of boats is prohibited.

The provisions of these special regulations supplement the regulations which govern fishing on wildlife refuge areas generally, which are set forth in Title 50, Code of Federal Regulations, Part 33. The public is invited to offer suggestions and comments at any time.

NOTE.—The Fish and Wildlife Service has determined that this document does not contain a major proposal requiring preparation of an Economic Impact Statement under Executive Order 11949 and OMB Circular A-107.

The primary author of this document is Lynn C. Howard, Sacramento Area Office, Telephone FTS 468-4664, Commercial (916) 484-4664.

Dated: November 20, 1978.

PATRICK O'HALLORAN,
Area Manager—California-Nevada, U.S. Fish and Wildlife Serivce.

[FR Doc. 78-33278 Filed 11-27-78; 8:45 am]

[3510-22-M]

CHAPTER VI—FISHERY CONSERVATION AND MANAGEMENT, NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION, DEPARTMENT OF COMMERCE

PART 651—ATLANTIC GROUNDFISH (COD, HADDOCK, AND YELLOWTAIL FLOUNDER)

Corrections of Notice of Closures and Catch Limit Adjustments

AGENCY: National Oceanic and Atmospheric Administration/Commerce.

ACTION: Correction to trip limitations and closure notice.

SUMMARY: On November 15, 1978, a notice containing a table (Appendix B—Catch Limitations) appeared in the FEDERAL REGISTER (43 FR 53040). This table summarized the catch limitations for U.S. fishermen participating in the Atlantic groundfish fishery. That table contained several errors. A corrected table appears herein.

EFFECTIVE DATE: November 22, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. William G. Gordon, Regional Director, Northeast Region, National Marine Fisheries Service, 14 Elm Street, Gloucester, Mass. 01930, telephone 617-281-3600.

SUPPLEMENTARY INFORMATION: The table summarizing trip limitations and vessel class closures which appeared in the FEDERAL REGISTER on November 15, 1978 (43 FR 53040) contained several errors. Consequently, that table is withdrawn, and the attached table is substituted for it.

The general public has already been advised of the correct landing limitations and vessel class closures, which will become effective on November 22, 1978.

(16 U.S.C. 1801 et seq.)

Signed at Washington, D.C., on this the 22d day of November 1978.

WINFRED H. MEIBOHM,
Acting Executive Director, National Marine Fisheries Service.

Strike 50 CFR Part 651, Appendix B, substitute the following 50 CFR Part 651 Appendix B.

[3510-22-C]

COD (pounds/week)

Vessel Class	Gulf of Maine		Georges Bank and South	
	limits	overruns	limits	overruns
0-60 GRT	2,500	1,500	4,900	3,500
61-125 GRT	2,500	1,500	4,900	1,500
Over 125 GRT	Close Nov. 19		7,000	1,500
Fixed gear	5,000	0	13,000	0

HADDOCK (pounds/week)

Vessel Class	Gulf of Maine		Georges Bank and South	
	limits	overruns	limits	overruns
0-60 GRT	Close Nov. 19		Close Nov. 19	
61-125 GRT	Close Nov. 19		3,500	1,500
Over 125 GRT	Close Nov. 19		Close Nov. 19	
Fixed gear	8,000	0	8,000	0

YELLOWTAIL FLOUNDER*

Vessel Class	West of 69° West	East of 69° West
0-60 GRT	5,000	
61-125	5,000	
Over 125	5,000	

*

Pounds per week or trip, whichever time period is longer. A vessel may land no more than 5,000 pounds, even if it fished on both sides of the 69° W. line. No overruns are allowed.

[FR Doc. 78-33344 Filed 11-27-78; 8:45 am]

proposed rules

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.

[6720-01-M]

FEDERAL HOME LOAN BANK BOARD

[12 CFR Part 563]

[No. 78-642]

FEDERAL SAVINGS AND LOAN INSURANCE CORPORATION

Proposed Amendments Regarding Forward Commitments To Purchase Securities

NOVEMBER 22, 1978.

AGENCY: Federal Home Loan Bank Board.

ACTION: Proposed rule.

SUMMARY: The Federal Home Loan Bank Board proposes to regulate forward commitments by FSLIC-insured institutions to purchase certain securities. Regulatory action is needed because some institutions are incurring losses by engaging in forward commitments in a speculative manner and are keeping inadequate records of such transactions. The new regulation would limit the dollar amount of outstanding forward commitments, require certain records to be maintained, prohibit so-called "overtrading", specify the accounting treatment of commitment fees, and provide for immediate accounting of profit or loss if forward commitments are disposed of prior to settlement.

DATE: Comments must be received on or before January 15, 1979.

ADDRESS: Send comments to the Office of the Secretary, Federal Home Loan Bank Board, 1700 G Street NW., Washington, D.C. 20552. Comments available for public inspection at this address.

FOR FURTHER INFORMATION, CONTACT:

Harry W. Quillian, Associate General Counsel, Federal Home Loan Bank Board, 202-377-6440, at the above address.

SUPPLEMENTARY INFORMATION: The Bank Board, as operating head of the Federal Savings and Loan Insurance Corporation, is mandated by Congress to require FSLIC-insured institutions to follow safe and sound practices, consistent with economical home financing and the purposes of the National Housing Act, as amended. In recent months, the Bank Board's examiners have reported instances of some institutions engaging speculatively in forward commitments to purchase securities, resulting in commitments in excess of their internal funding capacity, with consequent losses or liability for failure to honor the commitments. It also appears that there may be instances of undisclosed and unreported transactions involving an unsafe level of forward commitments by other FSLIC-insured institutions. The proposed regulations are principally intended to assist the Bank Board in fulfilling its responsibilities regarding such unsafe financial transactions by limiting the dollar amounts of forward commitments to amounts which can be funded in the normal course of business, prohibiting so-called "overtrading" or "overmarketing", specifying the accounting treatment of commitment fees, and requiring maintenance of sufficient records to enable the Bank Board's examiners to scrutinize forward commitments of FSLIC-insured institutions.

The proposed regulations would not require that the names and current limits of authority of an institution's personnel authorized to engage in forward commitments for it be disclosed, but the Bank Board believes that institutions should follow the normal business practice of disclosing this information to a seller or prospective seller to the institution of securities under a forward commitment.

Paragraph (e)(4) of the proposed regulation would require recognition of any decline in market value during the period of a standby commitment. It would require that an association in booking a purchase charge the amount of such a decline against current income with a corresponding credit to unearned discount.

The Bank Board believes that the limitations and requirements hereby proposed are reasonable and appropriate to ensure safe and sound operation of insured institutions engaging in forward commitment transactions. It therefore strongly encourages insured institutions engaging in such transactions to do so only in compliance with these proposed regulations, pending final action on them.

Accordingly, the Board proposes to add a new § 563.17-3 to the rules and regulations for Insurance of Accounts (12 CFR 563.17-3) to read as set forth below.

§ 563.17-3 Forward commitments.

(a) *Definitions*—(1) *Forward commitment.* A contract, oral or written, to purchase securities at a date more than 30 days after the date of the contract; such a commitment is a *standby commitment* if sale is optional with the seller and a *firm commitment* if both seller and purchaser are obligated to perform on the agreed date.

(2) *Securities.* Mortgage loans and assets which are legal investments for a Federal savings and loan association under § 545.9 of this chapter (except mortgage-futures transactions made in accordance with § 545.29), and any additional similar assets of a State-chartered insured institution.

(3) *Commitment fee.* Any consideration received either directly or indirectly by an insured institution for a forward commitment.

(b) *Authorized personnel.* The minutes of the board of directors of the insured institution shall set out the names, duties, responsibilities, and current limits of authority of the insured institution's personnel authorized to engage in forward commitments for the institution.

(c) *Limitations.* An insured institution's outstanding forward commitments may not exceed the lesser of (1) total repayments of principal on its outstanding mortgage loans during the twelve-month period ending at the close of the preceding month or (2) its documented capacity to fund all commitments. An insured institution shall not sell a forward commitment or security at a price above actual market value under agreement to purchase another forward commitment or security at a price above actual market value.

(d) *Disposal prior to settlement.* All profit or loss related to disposal or modification of a forward commitment prior to settlement shall be recognized on the institution's books at the time of disposal or modification.

(e) *Recordkeeping requirements.* An institution engaging in forward commitments shall establish and maintain the following:

(1) A current register of all outstanding forward commitments;

(2) Documentation of the institution's ability to fund all outstanding forward commitments in compliance with paragraph (c) of this section, stating specifically the actual or projected source of funds to be used in the funding; and

(3) A record of each forward commitment, including type (firm or standby), commitment date, amount, rate, price to be paid at settlement, market price at date of commitment, settlement date, commitment fees received, date and manner of disposal, sales price and market value at disposal if disposition is made on or prior to settlement date other than through funding, and seller's identity and confirmation.

(4) Purchases under standby commitments shall be recorded at the lower of cost or market value at the date of settlement.

(f) *Commitment fees received:* Any fee received for a forward commitment shall be deducted from the purchase price of the securities as recorded by an insured institution, except that a fee received in cash for a commitment may be recognized as income over the life of the commitment, but in no event more rapidly than permitted by generally accepted accounting principles, if (1) the commitment term is longer than 30 days and (2) the commited purchase price is not in excess of the market price at the date of commitment. Fees received in connection with a commitment to purchase securities on a date less than 30 days after the date of commitment shall be deferred over a period of at least ten years.

(Secs. 402, 403, 407, 48 Stat. 1256, 1257, 1260, as amended (12 U.S.C. 1725, 1726, 1730). Reorg. Plan No. 3 of 1947, 12 FR 4981, 3 CFR, 1943-48 Comp. p. 1071.)

By the Federal Home Loan Bank Board.

J. J. FINN,
Secretary.

[FR Doc. 78-33343 Filed 11-27-78; 8:45 am]

[4110-07-M]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Social Security Administration

[20 CFR Part 404]

[Reg. No. 4]

FEDERAL OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE

Records of Earnings

AGENCY: Social Security Administration, HEW.

ACTION: Proposed rulemaking.

SUMMARY: The Department of Health, Education, and Welfare (HEW) proposes to revise the regulations on earnings records to make them clearer and easier for the public to use. The Social Security Administration (SSA) keeps records of the earnings of persons who work in employment or self-employment covered under social security. The regulations deal mainly with the rules for correcting errors in these records. All the rules have been reorganized and rewritten in simpler, clearer language. There are no changes in policy.

DATES: Your comments will be considered if we receive them no later than January 29, 1979.

ADDRESSES: Send your written comments to: Social Security Administration, Department of Health, Education, and Welfare, P.O. Box 1585, Baltimore, Md. 21203.

Copies of all comments we receive can be seen at the Washington Inquiries Section, Office of Information, Social Security Administration, Department of Health, Education, and Welfare, North Building, Room 5131, 330 Independent Avenue, SW, Washington, D.C. 20201.

FOR FURTHER INFORMATION CONTACT:

James MacDonald, Room 4234, West High Rise Building, 6401 Security Boulevard, Baltimore, Md. 21235, 301-594-7336.

SUPPLEMENTARY INFORMATION: These regulations, which carry out section 205(c) of the Social Security Act, are being revised as part of HEW's "Operation Common Sense". Operation Common Sense is a Department-wide initiative to review, simplify and reduce HEW's regulations.

The regulations on earnings records are in Subpart I of Part 404 in Title 20 of the Code of Federal Regulations. This subpart is an important part of the regulations issued for SSA's retirement, survivors', and disability program. SSA keeps a record of the earnings of all persons who work in employment or self-employment covered under social security. SSA uses these records of earnings to determine whether benefits are payable based on a person's earnings and the amount of those benefits. The regulations in this subpart deal mainly with the rules for correcting errors in the earnings records. In addition, the regulations explain the circumstances under which SSA's record of a person's earnings is conclusive evidence of earnings for social security purposes. The regulations also explain how to obtain a statement of earnings and how to request correction of the earnings record.

In rewriting this subpart we have made the following changes:

(1) We have simplified the title of the subpart.

(2) We have simplified in proposed § 404.802 those definitions currently used in the regulations. Also, we have added some new definitions to cover other terms that are frequently used.

(3) We have clarified in proposed § 404.810 the rule that a request to SSA for a statement of earnings must be in writing. The revised section also tells the public what information the request must contain, to help us locate the record of earnings, and that the request may be made at any social security office.

(4) We have clarified and combined in proposed § 404.820 the rules about filing a request for correction of an earnings record. We have clarified the rule that a request to correct an earnings record must be filed within the time limit for correcting the year in question unless an exception to the time limie applies. The proposed section (1) states the rule concerning who may sign a request for correction of a person's record of earnings, (2) explains where to file a request and what determines the date of filing, and (3) states the requirements for withdrawing a request and cancelling a withdrawal. Some of the rules about requests in the proposed section are the same rules that apply to applications for social security benefits. In the interest of shortening the regulations, these rules are not described in full in this section. Instead they are shown by reference to the appropriate sections on applications in Subpart G (as published with notice of proposed rulemaking in the FEDERAL REGISTER on September 1, 1978. See Vol. 43, No. 171, pages 39266 to 39274).

(5) We have moved to proposed § 404.822 all the rules about correcting records of earnings after the time limit ends. We have included in this section the rules about correcting an earnings records after the time limit ends based on an investigation that began before the time limit ended. We have clarified the current regulations to show that we will not make a downward (and therefore a normally adverse) correction of the earnings record in these cases unless we carried out the investigation as promptly as circumstances permitted.

(6) We have clarified what is meant by the statutory term "absence of an entry". Proposed § 404.822(e)(5) states that we may add wages paid to an employee by an employer for a period if no part of those wages are entered on SSA's record of the employee's earnings for that period. Wages previously entered on the record for the employee paid by that employer for that period, but later removed, are not considered entries.

(7) We have deleted current § 404.811 which states in detail the information that should be furnished with a request to revise an earnings record. In its place we have included a much shorter statement specifying the minimum information we need and indicating that any available evidence

can be included with the request (see proposed § 404.820(b)).

(8) We have deleted much of current § 404.812. The rule in current § 404.812 about who makes determinations of whether covered wages were paid for work in the employ of the United States is included in proposed § 404.823.

(Catalog of Federal Domestic Assistance Program Nos. 13.802 Social Security-Disability Insurance; 13.803 Social Security-Retirement Insurance; 13.804 Social Security Special Benefits for Persons Aged 72 and Over; 13.805 Social Security-Survivors' Insurance.)

Dated: October 19, 1978.

STANFORD G. ROSS,
Commissioner of Social Security.

Approved: November 17, 1978.

HALE CHAMPION,
Acting Secretary of Health, Education, and Welfare.

Subpart I of Part 404 of Chapter III of Title 20 of the Code of Federal Regulations is revised to read as follows:

Subpart I—Records of Earnings

GENERAL PROVISIONS

Sec.
404.801 Introduction.
404.802 Definitions.
404.803 Conclusiveness of the record of your earnings.

OBTAINING EARNINGS INFORMATION

404.810 How to obtain a statement of the record of your earnings.

CORRECTING THE EARNINGS RECORD

404.820 Filing a request for correction of the record of your earnings.
404.821 Correction of the record of your earnings before the time limit ends.
404.822 Correction of the record of your earnings after the time limit ends.
404.823 Correction of the record of your earnings for work performed in the employ of the United States.

NOTICE OF REMOVAL OR REDUCTION OF AN ENTRY OF EARNINGS

404.830 Notice of removal or reduction of your wages.
404.831 Notice of removal or reduction of your self-employment income.

AUTHORITY: Secs. 205 and 1102 of the Social Security Act, as amended, 53 Stat. 1368, as amended, 49 Stat. 647, as amended; sec. 5, Reorg. Plan No. 1 of 1953, 67 Stat. 18, 631 (42 U.S.C. 405, 1302).

Subpart I—Records of Earnings

GENERAL PROVISIONS

§ 404.801 Introduction.

The Social Security Administration (SSA) keeps a record of the earnings of all persons who work in employment or self-employment covered under social security. We use these earnings records to determine entitlement to and the amount of benefits that may be payable based on a person's earnings under the retirement, survivors', disability and health insurance program. This subpart tells what is evidence of earnings, how you can find out what the record of your earnings shows, and how and under what circumstances the record of your earnings may be changed to correct errors.

§ 404.802 Definitions

For the purpose of this subpart—

"Earnings" means wages and self-employment income earned by a person based on work covered by social security. (See Subpart K for the rules about what constitutes wages and self-employment income for benefit purposes.)

"Period" means a taxable year when referring to self-employment income. When referring to wages it means a calendar quarter if the wages were reported quarterly by your employer or a calendar year if the wages were reported annually by your employer.

"Record of earnings", "earnings record", or "record" means SSA's records of the amounts of wages and the amounts of self-employment income you received and the periods in which the wages and the self-employment income were received.

"Survivor" means your spouse, divorced wife, child, or parent, who survives you. "Survivor" also includes your surviving divorced wife who may be entitled to benefits as a surviving divorced mother.

"Tax return" means, as appropriate, a tax return of wages or a tax return of self-employment income (including information returns and other written statements filed with the Commissioner of Internal Revenue under chapter 2 or 21 of the Internal Revenue Code of 1954, as amended.

"Time limit" means a period of 3 years, 3 months, and 15 days after any year in which you received earnings. The period may be extended by the Soldiers and Sailors Relief Act of 1940 because of your military service or the military service of certain relatives who survive you (50 U.S.C. App. 501 and following sections). Where the time limit ends on a Federal nonwork day, we will extend it to the next Federal work day.

"Wage report" means a statement filed by a State under section 218 of the Social Security Act or related regulations. This statement includes wage amounts for which a State is billed and wage amounts for which credits or refunds are made to a State according to an agreement under section 218 of the Act.

"We", "us", or "our" means the Social Security Administration (SSA).

"Year" means a calendar year when referring to wages and a taxable year when referring to self-employment income.

"You" or "your" means any person for whom we maintain a record of earnings.

§ 404.803 Conclusiveness of the record of your earnings.

(a) *Generally.* For social security purposes, SSA records are evidence of the amounts of your earnings and the periods in which they were received.

(b) *Before time limit ends.* Before the time limit ends for a year, SSA records are evidence, but not conclusive evidence, of the amounts and periods of your earnings in that year.

(c) *After time limit ends.* After the time limit ends for a year—

(1) If SSA records show self-employment income or wages during that year, our records are conclusive evidence of your self-employment income in that year or the wages paid to you by the employer and the periods in which they were received unless one of the exceptions in § 404.822 applies;

(2) If SSA records show no entry of wages for an employer for a period in that year, our records are conclusive evidence that no wages were paid to you by that employer in that period unless one of the exceptions in § 404.822 applies; and

(3) If SSA records show no entry of self-employment income for that year, our records are conclusive evidence that you did not receive self-employment income in that year unless the exception in § 404.822(b)(2) (i) or (iii) applies.

OBTAINING EARNINGS INFORMATION

§ 404.810 How to obtain a statement of the record of your earnings.

You or your legal representative or, after your death, your survivor or the legal representative of your estate, may obtain a statement of your earnings as shown by SSA records by making a written request. The written request for a statement of your earnings may be made at any social security office. The request must be signed and contain your full name, address, social security number, and date of birth. The earnings statement will explain the right to request correction of your earnings record if you believe it is incorrect.

CORRECTING THE EARNINGS RECORDS

§ 404.820 Filing a request for correction of the record of your earnings.

(a) *When to file a request for correction.* You or your survivor must file a request for correction of the record of your earnings within the time limit for the year being questioned unless one of the exceptions in § 404.822 applies.

(b) *Contents of a request.* (1) A request for correction of an earnings

record must be in writing and must state that the record is incorrect.

(2) A request must be signed by you or your survivor or by a person who may sign an application for benefits for you or for your survivor as described in § 404.612.

(3) A request should state the period being questioned.

(4) A request should describe, or have attached to it, any available evidence which shows that the record of earnings is incorrect.

(c) *Where to file a request.* A request may be filed at any social security office of with an SSA employee who is authorized to receive a request. A request may be filed with the Veterans Administration Regional Office in the Philippines or with any U.S. Foreign Service Office.

(d) *When a request is considered filed.* A request is considered filed on the day it is received by any of our offices, by an authorized SSA employee, by the Veterans Administration Regional Office in the Philippines, or by any U.S. Foreign Service Office. If using the date we receive a mailed request disadvantages the requester, we will use the date the request was mailed to us as shown by a U.S. postmark. If the postmark is unreadable or there is no postmark, we will consider other evidence of when the request was mailed.

(e) *Withdrawal of a request for correction.* A request for correction of SSA records of your earnings may be withdrawn as described in § 404.640.

(f) *Cancellation of a request to withdraw.* A request to withdraw a request for correction of SSA records of your earnings may be cancelled as described in § 404.641.

(g) *Determinations on requests.* When we receive a request described in this section, we will make a determination to grant or deny the request. If we deny the request, this determination may be appealed under the provisions of Subpart J of this part.

§ 404.821 Correction of the record of your earnings before the time limit ends.

Before the time limit ends for any year, we will correct the record of your earnings for any year for any reason if satisfactory evidence shows SSA records are incorrect. We may correct the record as the result of a request filed under § 404.820 or we may correct it on our own.

§ 404.822 Correction of the record of your earnings after the time limit ends.

(a) *Generally.* After the time limit for any year ends, we may correct the record of your earnings for that year if satisfactory evidence shows SSA records are incorrect and any of the circumstances in paragraphs (b) through (e) of this section applies.

(b) *Correcting SSA records to agree with tax returns.* We will correct SSA records to agree with a tax return of wages or self-employment income to the extent that the amount of earnings shown in the return is correct.

(1) *Tax returns of wages.* We may correct the earnings record to agree with a tax return of wages or with a wage report of a State.

(2) *Tax returns of self-employment income.*—(i) *Return filed before the time limit ended.* We may correct the earnings record to agree with a tax return of self-employment income filed before the end of the time limit.

(ii) *Return filed after time limit ended.* We may remove or reduce, but not increase, the amount of self-employment income entered on the earnings record to agree with a tax return of self-employment income filed after the time limit ends.

(iii) *Self-employment income entered in place of erroneously entered wages.* We may enter self-employment income for any year up to an amount erroneously entered in SSA records as wages but which was later removed from the records. However, we may enter self-employment income under this paragraph only if—

(A) An amended tax return is filed before the time limit ends for the year in which the erroneously entered wages were removed; or

(B) Net earnings from self-employment, which are not already entered in the record of your earnings, were included in a tax return filed before the end of the time limit for the year in which the erroneously entered wages were removed.

(c) *Written request for correction or application for benefits filed before the time limit ends*—(1) *Written request for correction.* We may correct an earnings record if you or your survivor files a requiest for correction before the time limit for that year ends. The request must state that the earnings record for that year is incorrect. However, we may not correct the record under this paragraph after our determination on the request becomes final.

(2) *Application for benefits.* We may correct an earnings record if an application is filed for monthly benefits or for a lump-sum death payment before the time limit for that year ends. However, we may not correct the record under this paragraph after our determination on the application becomes final.

(3) See Subpart J for the rules on the finality of determinations.

(d) *Transfer of wages to or from the Railroad Retirement Board.*—(1) *Wages erroneously reported.* We may transfer to or from the records of the Railroad Retirement Board earnings which were erroneously reported to us or to the Railroad Retirement Board.

(2) *Earnings certified by Railroad Retirement Board.* We may enter earnings for railroad work under Subpart O if the earnings are certified by the Railroad Retirement Board.

(e) *Other circumstances permitting correction.*—(1) *Investigation started before time limit ends.* We may correct an earnings record if the correction is made as the result of an investigation started before, but completed after the time limit ends. An investigation is started when we take an affirmative step leading to a decision on a question about the earnings record. for example, an investigation is started when one SSA unit asks another unit to obtain additional information or evidence. We will remove or reduce earnings on the record under this paragraph only if we carried out the investigation as promptly as circumstances permitted.

(2) *Error apparent on face of records.* We may correct an earnings record to correct errors, such as mechanical or clerical errors, which can be identified and corrected without going beyond any of the pertinent SSA records.

(3) *Fraud.* We may remove any entry which was entered on the earnings record as the result of fraud.

(4) *Entries for wrong person or period.* We may correct errors in SSA records resulting from earnings being entered for the wrong person or period.

(5) *No entry of wages on SSA records.* We may enter wages paid to you by an employer for a period if no part of those wages are entered on SSA records. Wages previously entered on SSA records for that employer and that period but later removed are not entries on SSA records.

(6) *Wage payments under a statute.* We may enter and allocate wages awarded to you for a period as the result of a determination or agreement approved by a court or administrative agency that enforces Federal or State statutes protecting your right to employment or wages.

§ 404.823 Correction of the record of your earnings for work performed in the employ of the United States.

We may not correct the record of your earnings under § 404.821 or § 404.822 to remove, reduce, or enter earnings for work performed in the employ of the United States, except—

(a) To make the record agree with a tax return filed under section 3122 of the Internal Revenue code (26 U.S.C. 3122); or

(b) To make the record agree with a certification by the head of the Federal agency or instrumentality or his or her agent. A Federal instrumentality for these purposes includes a non-ap-

propriated fund activity of the armed forces or Coast Guard.

NOTICE OF REMOVAL OR REDUCTION OF AN ENTRY OF EARNINGS

§ 404.830 Notice of removal or reduction of your wages.

If we remove or reduce an amount of wages entered on the record of your earnings, we will notify you of this correction if we previously notified you of the amount of your wages for the period involved. We will notify your survivor if we previously notified you or your survivor of the amount of your earnings for the period involved.

§ 404.831 Notice of removal or reduction of your self-employment income.

If we remove or reduce an amount of self-employment income entered on the record of your earnings, we will notify you of this correction. We will notify your survivor if we previously notified you or your survivor of the amount of your earnings for the period involved.

[FR Doc. 78-33191 filed 11-27-78; 8:45 am]

[4110-03-M]

Food and Drug Administration

[21 CFR Part 337]

[Docket No. 78N-0036]

EMETIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Tentative Final Order

In FR Doc. 78-24841 in the issue of Tuesday, September 5, 1978 on page 39546 in the 3d column, in § 337.50(d), the 5th line should read, "[Precau-]-tions": "Activated charcoal will adsorb . . . ".

[4310-10-M]

ADVISORY COUNCIL ON HISTORIC PRESERVATION

[36 CFR Part 800]

PROTECTION OF HISTORIC AND CULTURAL PROPERTIES

Extension of comment period and Notice of Public Briefing

AGENCY: Advisory council on Historic Preservation.

ACTION: Extension of comment period and notice of public briefing.

SUMMARY: This document extends the comment period on proposed amendments and supplementary information to the Council's current regulations and also notifies the public of a briefing on the proposed amendments. The comment period has been extended in response to requests from members of the Council and others.

DATES: Written comments are due by December 29, 1978. The Public briefing will be held on December 11, 1978, beginning at 9:30 a.m.

ADDRESS: Comments should be addressed to Executive Director, Advisory Council on Historic Preservation, 1522 K Street, NW., Washington, D.C. 20005.

FOR FURTHER INFORMATION CONTACT:

John Fowler, Director, Office of Intergovernmental Programs and Planning, Advisory Council on Historic Preservation, 1522 K Street, NW., Washington, D.C. 20005, 202-254-3495.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER, October 30, 1978, (43 FR 50650), the Council published proposed amendments and supplementary guidelines for public comment. [NOTE.—This document was inadvertently published in the "Rules and Regulations" section of the FEDERAL REGISTER. The document should have appeared in the "Proposed Rules" section.] Interested persons were invited to submit comments on the proposed amendments and supplementary guidelines by November 29, 1978.

A number of council member agencies and interested individuals and organizations have requested an extension of the deadline for submission of comments. The Executive Director has decided it would be appropriate to extend the commenting period in order to allow sufficient time for all interested parties to submit comments. Therefore, the comment period is being extended an additional 30 days until December 29, 1978.

Additionally, the staff of the Council will conduct an informal briefing for interested agencies, organizations, and individuals on the proposed amendments and supplementary guidelines on Monday, December 11, 1978. The briefing will be held in Room 2008 of the New Executive Office Building, 17th Street and Pennsylvania Avenue, NW., Washington, D.C. beginning at 9:30 a.m. The briefing will last approximately two hours. Council staff will review the proposed amendments and supplementary guidelines and will answer questions. Persons wishing to attend the briefing and who lack Federal identification cards must notify the Council by December 8, 1978 at 202-254-3495 that they will be attending.

Dated: November 22, 1978.

ROBER R. GARVEY, Jr.,
Executive Director.

[FR Doc. 78-33316 Filed 11-27-78; 8:45 am]

[3510-16-M]

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[37 CFR Parts 1 and 3]

PATENT APPLICATION OATH OR DECLARATION REQUIREMENTS

Proposed Rulemaking

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Proposed rulemaking.

SUMMARY: Patent and Trademark Office proposes amendment of the rules of practice and also amendment of certain forms for patent cases to specify certain additional requirements of an oath or declaration for a patent application. In view of various court decisions interpreting the patent law, this proposal would clearly indicate matter which must be disclosed by applicants for the proper examination of patent applications.

DATES: Written comments by February 7, 1979. Hearing: February 7, 1979, beginning at 1:00 p.m.

ADDRESSES: Address written comments to the Commissioner of Patents and Trademarks, Washington, D.C. 20231. The hearing will be held in Room 11C-24 of Building 3, Crystal Plaza at 2021 Jefferson Davis Highway, Arlington, Virginia. Written comments and transcript of hearing will be available for public inspection in Room 11E-10 of Building 3, Crystal Plaza, at 2021 Jefferson Davis Highway, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT:

Mr. Louis O. Maassel by telephone at (703) 557-3070, or by mail marked to his attention and addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

SUPPLEMENTARY INFORMATION: The Patent and Trademark Office is considering amendments to the rules of practice and forms for patent cases (1) to require acknowledgment by the inventor in the oath or declaration of the best mode disclosure requirement of Section 112 of Title 35, United States Code and (2) to more clearly specify the requirements of an oath or declaration accompanying a continuation-in-part application.

The reasons for the change are set forth in the following discussion.

BEST MODE ACKNOWLEDGEMENT

The addition of an acknowledgment of the requirement to disclose the best mode known to the applicant at the time of filing in the oath or declaration seems desirable in view of the frequency of assertions in litigation of the failure of the patentee to have disclosed the best mode. A number of these assertions have been successful in recent years. See *Flick-Reedy Corp.* v. *Hydro-Line Manufacturing Co.*, 351 F.2d 546, 146 USPQ 694 (CA 7 1965), cert. denied, 383 U.S. 958, 148 USPQ 771 (1966); *Indiana General Corp.* v. *Krystinel Corp.*, 297 F. Supp. 427, 161 USPQ 82 (S.D.N.Y. 1969), affirmed, 421 F.2d 1033, 164 USPQ 321 (CA 2 1970); *Dale Electronics, Inc.* v. *R.C.L. Electronics, Inc.*, 488 F.2d 382, 180 USPQ 235 (CA 1 1973); *Union Carbide Corp.* v. *Borg-Warner Corp.*, 550 F. 2d 355, 193 USPQ 1 (CA 6 1977); *Reynolds Metals Co.* v. *Acorn Building Components Inc.* 548 F.2d 155, 163, 192 USPQ 737 (CA 6 1977).

The proposed changes in 37 CFR 1.65 and in the related forms and sections are not intended to add to any presently defined requirement for disclosing best mode under 35 U.S.C. 112 or the duty of disclosure under 37 CFR 1.56. The changes are not to be interpreted to create any new requirement to include an up-dated best mode of carrying out an invention, as better modes are discovered after filing an application or at the time of or after filing a continuation, divisional or continuation-in-part application. In regard to existing best mode requirements, see *Sylgab Steel & Wire Corp.* v. *Imoco-Gateway Corp.*, 357 F. Supp. 657, 178 USPQ 22 (N.D. Ill. 1973); *H. K. Porter Co., Inc.* v. *Gates Rubber Co.*, 187 USPQ 692, 708, (D. Colo. 1975).

The acknowledgment should serve as better notice and as a reminder of the best mode requirement of the statute and result in greater patent validity.

For these reasons, § 1.65 is proposed to be amended by the addition of a requirement to acknowledge the existing requirement for a disclosure of the best mode. Corresponding changes are proposed in the oath and declaration forms Part 3 of 37 CFR. Examples of the proposed changes in the continuation-in-part oath and declaration forms are set forth below. If the proposed addition of the acknowledgment of the best mode requirement language to the continuation-in-part forms is adopted, the same change will be made in the other relevant oath and declaration forms.

CONTINUATION-IN-PART OATH OR DECLARATION

Any claim in a continuation-in-part application which is directed *solely* to subject matter adequately disclosed under 35 U.S.C. 112 in the parent application is entitled to the benefit of the filing date of the parent application. However, if a claim in a continuation-in-part application recites a feature which was not disclosed or adequately supported by a proper disclosure under 35 U.S.C. 112 in the parent application, but which was first introduced or first adequately supported in the continuation-in-part application, such a claim is entitled only to the benefit of the filing date of the continuation-in-part application, *In re von Langenhoven*, 458 F.2d 132, at 136, 173 USPQ 426, at 429, (CCPA 1972) and *Chromalloy American Corp.* v. *Alloy Surfaces Co., Inc.*, 339 F. Supp. 859, at 874, 173 USPQ 295, at 306, (D. Del. 1972).

An illustration of the effects of these and other cases is as follows: An application is filed which discloses the combination AB. Within the priority year a foreign application to the combination AB is filed by applicant and later published. More than one year after the foreign publication, but still during the pendency of the parent United States application, a second United States application is filed by the same inventor which discloses and claims the combination AC and is therefore designated a continuation-in-part application.

Upon examination of the continuation-in-part application, the examiner concludes that C is in fact a known element in the art and that it would be obvious to substitute C for B in the combination AB.

A claim drawn to AC finds no support in the parent case and therefore carries an effective date only as early as the filing of the continuation-in-part application. Therefore, any publication, public use or sale in this country of AB more than one year prior to the filing of the continuation-in-part application, or the grant of a foreign patent or inventor's certificate based on a foreign application filed more than twelve months prior to and issued before the filing of the continuation-in-part application, is prior art under 35 U.S.C. 103 by reason of the provisions of 35 U.S.C. 102 (b) or (d) and, together with a showing that C is old, may provide basis for rejection of a claim to AC for obviousness.

By way of further illustration, if the claims of a continuation-in-part application "read on" such published, publicly used or sold or patented subject matter (e.g., as in a genus-species relationship) a rejection under 35 U.S.C. 102 would be proper. Cases of interest in this regard are *In re Steenbock*, 83 F. 2d 912, 30 USPQ 45 (CCPA 1936); *In re Ruscetta*, 255 F. 2d 687, 118 USPQ 101 (CCPA 1958); *In re Hafner*, 410 F. 2d 1403, 161 USPQ 783 (CCPA 1969); *In re Lukach*, 442 F. 2d 967, 169 USPQ 795 (CCPA 1971); and *Ex parte Hageman*, 179 USPQ 747 (Bd. App. 1971).

In addition, knowledge, use or patenting by another before the applicant's invention of additional subject matter claimed in the continuation-in-part application would also constitute prior art although such activity may not necessarily be known to the applicant.

In view of the above, § 1.65 is proposed to be amended by the addition of a subsection (d) which would require the applicant in a continuation-in-part application, which both discloses and claims subject matter in addition to that disclosed in the prior copending application, to make an oath or declaration as of the filing date of the continuation-in-part application. Corresponding changes are proposed in the oath and declaration forms 3.18 and 3.18a for continuation-in-part applications in Part 3 of 37 CFR.

It is recognized that all of the information called for in the proposed oath and declaration would not be required in some cases, such as where there is additional disclosure in the continuation-in-part application but where all claims are directed to the common subject matter disclosed in the parent application. In such case, proposed § 1.65(d) does not require the new statements in the proposed forms and the applicant may modify the forms, if desired, for use in such case. However, the use of the proposed forms in these cases would act as a safeguard for applicant. For example, if applicant later amended his claims to recite some of the additional disclosure, a new oath or declaration would be required. Similarly, the examiner might disagree with applicant's conclusion that additional subject matter is not being claimed in the continuation-in-part application. For this reason and the possibility that confusion might be generated by multiple forms, no specific forms are proposed for use in the case where all of the claims in the continuation-in-part application may be entitled to the filing date of the parent application.

Where activity has occurred in connection with an invention, but is not believed to constitute prior art within the meaning of Section 102 of Title 35, United States Code (such as a prior public use or sale of an experimental nature more than one year before the date of the application), such activity may be referred to in the CIP oath or declaration with any qualifications about its prior art status deemed warranted, or it need not be mentioned in the oath or declaration at all. If such activity is not mentioned in the CIP oath or declaration but may be material to the examination under 37 CFR 1.56, it, of course, must be called to the Office's attention in a separate paper.

Section 1.65 is also proposed to be amended in a manner to refer to both genders.

Notice is hereby given that, pursuant to the authority contained in Section 6 of the Act of July 19, 1952 as amended (66 Stat. 793; 85 Stat. 364; 88 Stat. 1949; 35 U.S.C. 6), the Patent and Trademark Office proposes to amend Title 37 of the Code of Federal Regulations by amending §§ 1.65, 3.18 and 3.18(a).

The Patent and Trademark Office has determined that these rule changes have no potential major economic consequences requiring the preparation of a regulatory analysis under Executive Order 12044.

The proposed forms are examples of forms which would meet the requirements of proposed §1.65(d). The forms could be modified by applicant to handle specific situations.

In the texts of the following proposed amendments to §1.65, additions are indicated by arrows and deletions are indicated by brackets. The changes to §3.18 and 3.18(a) are not noted in this manner because of numerous changes in wording. It is proposed to amend 37 CFR Chapter I, as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

1. By amending § 1.65 by revising paragraph (a) and adding a new paragraph (d) to read as follows:

§1.65 Oath or declaration.

(a)(1) The applicant, if the inventor, must state that [he] ► the applicant ◄ verily believes himself ► or herself ◄ to be the original and first inventor or discoverer of the process, machine, manufacture, composition of matter, or improvement thereof, for which [he solicits] a patent ► is solicited ◄ ; that [he] ► the applicant ◄ does not know and does not believe that the same was ever known or used in the United States before [his] ► the applicant's ◄ invention or discovery thereof, and shall state of what country [he] ► the applicant ◄ is a citizen and where [he] ► the applicant ◄ resides and whether [he] ► the applicant ◄ is a sole or joint inventor of the invention claimed in [his] ► the ◄ application. In every original application the applicant must distinctly state that to the best of [his] ► the applicant's ◄ knowledge and belief the invention has not been in public use or on sale in the United States more than one year prior to [his] ► the ◄ application or patented or described in any printed publication in any country before [his] ► the applicant's ◄ invention or more than one year prior to [his] ► the ◄ application, or patented or made the subject of an inventor's certificate in any foreign country prior to the date of [his] ► the ◄ application on an application filed by [himself] ► the applicant ◄ or [his] ► the applicant's ◄ legal representatives or assigns more than twelve months prior to the application in this country. ► The applicant must acknowledge the requirement of section 112 of Title 35 United States Code to disclose the best mode contemplated by the inventor of carrying out the invention. ◄ [He] ► The applicant ◄ must ► also ◄ acknowledge [a] ► the ◄ duty to disclose information [he] ► the applicant ◄ is aware of which is material to the examination of the application. [He] ► The applicant ◄ shall state whether or not any application for patent or inventor's certificate on the same invention has been filed in any foreign country, either by [himself] ► the applicant ◄, or [his] ► the applicant's ◄ legal representatives or assigns. If any such application has been filed, the applicant shall name the country in which the earliest such application was filed, and shall give the day, month, and year of its filing; [he] ► the applicant ◄ shall also identify by country and by day, month, and year of filing, every such foreign application filed more than twelve months before the filing of the application in this country.

(2) This statement (i) must be subscribed to by the applicant, and (ii) must either (*a*) be sworn to (or affirmed) as provided in § 1.66, or (*b*) include the personal declaration of the applicant as prescribed in § 1.68. See § 1.153 for design cases and § 1.162 for plant cases.

* * * * *

► (d) An applicant in a countinuation-in-part application, filed under the conditions specified in 35 U.S.C. 120, which discloses and claims subject matter in addition to that disclosed in the prior copending application, must identify the prior copending application and make an oath or declaration which includes (1) the statements required by paragraph (a) of this section, or a list of the exceptions to the statements, as to the common subject matter and (2) the statements required by paragraph (a) of this section as to the non-common subject matter. The statements must be made in reference to the filing date of the continuation-in-part application in both cases (1) and (2).◄

PART 3—FORMS FOR PATENT CASES

2. By revising § 3.18 to read as follows:

§ 3.18 Oath in copending application containing additional subject matter.

(This form of oath may be used with an application disclosing additional subject matter to that disclosed in a prior copending application of the same inventor.)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I depose and say that I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the invention entitled:———— described and claimed in the attached specification.

That I acknowledge the requirement of section 112 of Title 35 United States Code to disclose the best mode contemplated by me for carrying out my invention and also acknowledge my duty to disclose information of which I am aware which is material to the examination of this application.

This application discloses subject matter in addition to that disclosed in my or our earlier filed pending application(s), Serial No. ———, filed ————.

As to the subject matter of this application which is common to said earlier application, I do not know and do not believe that the same was ever known or used in the United States of America before my or our invention thereof, or patented or described in any printed publication in any country before my or our invention thereof or more than one year prior to this application, except as follows: ———— that the same was not in public use or on sale in the United States of America more than one year prior to this application, except as follows: ————, that said common subject matter has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months prior to this application, except as follows: ————; that as to applications for patent or inventor's certificate on said common subject matter filed in any country foreign to the United States of America prior to this application by me or my legal representatives or assigns,

[-] no such applications have been filed

[-] such applications have been filed, the filing date and country in which the earliest such application was filed is ————, and that the filing date and country of filing of every other such foreign application filed more than twelve months prior to the filing of this application is as follows: ————.

As to the additional subject matter of this application which is not common to said earlier application, I do not know and do not believe that the same was ever known or used in the United States of America before my or our invention thereof, or patented or described in any printed publication in any country before my or our invention thereof or more than one year prior to this application, that the same was not in public use or on sale in the United States of America more than one year prior to the date of this application, and that said non-common subject matter has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months prior to the date of this application; that as to applications for patent or inventor's certificate on said non-common subject matter filed in any country foreign to the United States of America

prior to this application by me or my legal representatives or assigns,

[-] no such applications have been filed

[-] such applications have been filed, the filing date and country in which the earliest such application was filed is ————, and that the filing dates and country of filing of every other such foreign application filed more than twelve months prior to the filing of this application is as follows:————.

I hereby appoint the following attorney(s) and/or agents to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: ———— Registration Number ———— Telephone No. ————.

Address all correspondence to ————.

Inventor's full name————————

Inventor's signature————————

Date ————————

Residence ————————

Citizenship ————————

Post Office Address ————————

Inventor's full name————————

Inventor's signature————————

Date ————————

Residence ————————

Citizenship ————————

Post Office Address ————————

————————ss:

Sworn to and subscribed before me this —— day of ————, 19——.

.....

(Signature of notary or officer)

.....

(Official character)

3. By revising § 3.18a to read as follows:

§ 3.18a Declaration in copending application containing additional subject matter.

(§§ 1.65 and 1.68 provide for a declaration in lieu of an oath in certain instances.)

(This form of declaration may be used with an application disclosing additional subject matter to that disclosed in a prior copending application of the same inventor.)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I hereby declare that I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the invention entitled: ———— described and claimed in the attached specification.

That I acknowledge the requirement of section 112 of Title 35 United States Code to disclose the best mode contemplated by me for carrying out my invention and also acknowledge my duty to disclose information of which I am aware which is material to the examination of this application.

This application discloses subject matter in addition to that disclosed in my or our earlier filed pending application(s), Serial No. ————, filed ————.

As to the subject matter of this application which is common to said earlier application, I do not know and do not believe that the same was ever known or used in the United States of America before my or our invention thereof, or patented or described in any printed publication in an country before my or our invention thereof or more than one year prior to this application, except as follows: ————, that the same was not in public use or on sale in the United States of America more than one year prior to this application, except as follows: ————, that said common subject matter has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months prior to this application, except as follows: ————; that as to applications for patent or inventor's certificate on said common subject matter filed in any country foreign to the United States of America prior to this application by me or my legal representatives or assigns,

[ ] no such applications have been filed

[ ] such applications have been filed, the filing date and country in which the earliest such application was filed to is ————, and that the filing date and country of filing of every other such foreign application filed more than twelve months prior to the filing of this application is as follows: ————.

As to the additional subject matter of this application which is not common to said earlier application, I do not know and do not believe that the same was ever known or used in the United States of America before my or our invention thereof or patented or described in any printed publication in any country before my or our invention thereof or more than one year prior to this application, that the same was not in public use or on sale in the United States of America more than one year prior to the date of this application, and that said non-common subject matter has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve monthe prior to the date of this application; that as to applications for patent or inventor's certificate on said non-common subject matter filed in any country foreign to the United States of America prior to this application by me or my legal representatives or assigns,

[ ] no such applications have been filed,

[ ] such applications have been filed, the filing date and country in which the earliest such application was filed is ————, and that the filing dates and country of filing of every other such foreign application filed more than twelve months prior to the filing of this application is as follows: ————.

I hereby appoint the following attorney(s) and/or agents to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: ———— Regis. No. ———— Telephone No. ————.

Address all correspondence to ————.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Inventor's full name ———— ————

Inventor's signature ———— Date

————————————————

Residence ————————————

Citizenship ———— ————————

Post Office Address ————————

Dated: October 10, 1978.

DONALD W. BANNER,
Commissioner of Patents and Trademarks.

Approved: November 14, 1978.

JORDAN J. BARUCH,
Assistant Secretary for Science and Technology.

[FR Doc. 78-33230 Filed 11-27-78; 8:45 am]

[8320-01-M]

VETERANS ADMINISTRATION

[38 CFR Part 3]

VETERANS BENEFITS

Increased Benefits

AGENCY: Veterans Administration.

ACTION: Proposed rulemaking.

SUMMARY: The Veterans Administration is amending its regulations to implement the Veterans' Disability Compensation and Survivors' Benefits Act of 1978, enacted October 18, 1978. This law (1) increases the rates of disability compensation and dependency and indemnity compensation by approximately 7.3 percent, (2) reduces the service-connected degree of disability evaluation needed to be eligible to receive additional compensation for dependents from 50 percent to 30 percent, (3) increases the Medal of Honor pension from $100 to $200 monthly, (4) provides increased compensation for certain veterans who have suffered service-connected loss or loss of use of three extremities, (5) authorizes an increase in the rate of dependency and indemnity compensation payable to a veteran's surviving spouse who is housebound, (6) increases the compensation payable to certain veterans who have suffered service-connected loss or loss of use of an extremity and non-service-connected loss or loss of use of the paired extremity, (7) increases the clothing allowance from $203 to $218, (8) establishes a new monthly aid and attendance rate of $900 for certain veterans catastrophically disabled from service-connected disability, (9) authorizes payment of dependency and indemnity compensation rates in certain cases when the cause of the veteran's death is non-service-connected, (10) increases from $250 to $300 the burial allowance payable when the cause of a veteran's death is non-service-connected and from $800 to $1,100 (or if greater, the amount payable for the funeral and burial expenses of a

Federal employee who dies as a result of an injury sustained in the performance of duty) the burial allowance payable when the cause of a veteran's death is service-connected, (11) increases the automobile allowance from $3,300 to $3,800, and (12) exempts from taxation the amount of military retired pay equivalent to the amount of compensation or pension a former service member is found entitled to receive from date of the compensation or pension entitlement determination to date of waiver of retired pay provided waiver of retired pay is filed within 1 year after notification of Veterans Administration entitlement. In addition to changes implementing the new law, certain terms (e.g. "widow or widower" to "surviving spouse") have been changed to eliminate gender references.

DATES: Comments must be received on or before December 28, 1978. It is proposed to make the increase in the Medal of Honor pension effective January 1, 1979, and all other changes effective October 1, 1978, as these are the effective dates specified in the law, designated as Pub. L. 95-479.

ADDRESSES: Send written comments to: Administrator of Veterans Affairs (271A), Veterans Administration, 810 Vermont Avenue, NW., Washington, D.C. 20420. Comments will be available for inspection at the address shown above during normal business hours until January 8, 1979.

FOR FURTHER INFORMATION CONTACT:

T. H. Spindle, 202-389-3005.

SUPPLEMENTAL INFORMATION: The regulation changes needed to implement the various rate increases authorized by the Veterans' Disability Compensation and Survivors' Benefits Act of 1978, Pub. L. 95-479, require no explanation since the only changes made are substitution of the new rates for the old ones. The reduction in degree of service-connected disability evaluation from 50 percent to 30 percent for a veteran to be eligible to receive additional compensation for dependents is also self explanatory.

Explanatory comment is furnished for the changes implementing increased compensation for loss of three extremities, increased dependency and indemnity compensation for surviving spouses who are housebound, increased compensation for loss of paired extremities, payment of dependency and indemnity compensation rates in certain cases based on a non-service-connected cause of death, the military retired pay tax exemption, and the new aid and attendance allowance for catastrophically disabled veterans.

INCREASED COMPENSATION FOR LOSS OF THREE EXTREMITIES

Compensation in excess of the monthly amount of compensation payable for total disability ($809) is authorized under 38 U.S.C. 314 (l) through (o) for certain seriously disabled veterans. For example, under Section 314(l) a veteran who has suffered service-connected anatomical loss or loss of use of both hands is entitled to $1,005 monthly. Under Section 314(m) a veteran who has suffered service-connected anatomical loss or loss of use of two extremities at a level, or with complications, preventing natural elbow or knee action with prosthesis in place, is entitled to $1,107 monthly.

Under Section 314(p) a veteran whose service-connected disabilities exceed the requirements for a rate prescribed under Sections 314 (l) through (n) but are not severe enough to qualify for the next higher rate, may receive an intermediate rate subject to a monthly maximum of $1,408. For example, if a veteran entitled under Section 314(l) for loss of use of both hands has also suffered permanent service-connected disability independently ratable at 50 percent or more, he or she would be entitled to the intermediate rate between Section 314(l) and Section 314(m) under 38 CFR 3.350(f)(3). (The intermediate rates and intermediate rate criteria are provided by regulation. See 38 CFR 3.350(f)). The Section 314(l) rate is $1,005 and the Section 314(m) rate is $1,107. The intermediate rate between them is $1,056.

Pub. L. 95-479 amends 38 U.S.C. 314(p) to provide that a veteran who has suffered loss or loss of use of three extremities shall be entitled to the next higher rate (either statutory or intermediate) not to exceed $1,408. In applying this provision an eligible veteran will first be rated without regard to this provision and then, pursuant to this provision, will have his or her compensation rate increased to the next higher rate without any loss of entitlement under 38 U.S.C. 314(k). (Under 38 U.S.C. 314(k) special monthly compensation of $56 is payable for loss or loss of use of certain extremities and organs).

The following example illustrates application of the three extremity provision of Pub. L. 95-479.

A veteran has suffered service-connected loss or loss of use of two hands and one foot. Loss or loss of use of one hand and one foot entitles the veteran to compensation at the rate authorized by 38 U.S.C. 314(l). Loss of the other hand, which is at least 60 percent disabling affords entitlement to the next higher rate under 38 CFR 3.350(f)(3) which is the intermediate rate between 38 U.S.C. 314(l) and 314(m). Application of the three extremity provision increases the veteran's compensation to the rate provided under 38 U.S.C. 314(m).

The addition of § 3.350(f)(5) implements this change.

HOUSEBOUND RATE FOR SURVIVING SPOUSES IN RECEIPT OF DEPENDENCY AND INDEMNITY COMPENSATION

Prior to the enactment of Pub. L. 95-479 housebound benefits were provided only to veterans in receipt of disability compensation or pension. Pub. L. 95-479 amends 38 U.S.C. 411 to provide that the monthly dependency and indemnity compensation payable to a surviving spouse shall be increased by $45 if the surviving spouse is, by reason of disability, permanently housebound but does not qualify for the higher aid and attendance allowance. The housebound requirement is met when the surviving spouse is substantially confined to his or her home or if institutionalized, the ward or clinical areas.

The amendments to §§ 3.5 and 3.351 implement this benefit.

INCREASED COMPENSATION FOR LOSS OF PAIRED EXTREMITIES

Pub. L. 95-479 authorizes increased compensation of $175 monthy to certain veterans who have suffered service-connected loss or loss of use of one extremity and non-service-connected loss or loss of use of the paired extremity. To qualify for the increase the service-connected extremity loss must be rated at 40 percent or more disabling and the non-service-connected extremity loss must also be 40 percent or more disabling under the same rating criteria that would apply if the non-service-connected loss was service connected.

This increase is limited to veterans in receipt of compensation not in excess of the 90 percent rate (38 U.S.C. 314(i)) and who are also receiving special monthy compensation under 38 U.S.C. 314(k). In addition, this increase is not payable after the veteran receives any money or property in settlement of a cause of action for the non-service-connected extremity loss until the amount of the increase that would have been payable but for this provision equals the amount of money and the fair market value of any property received in settlement of the cause of action. Social Security benefits and Workmen's Compensation are not subject to recoupment under this provision.

The addition of § 3.384 implements the paired extremity provision.

PAYMENT OF DIC RATES BASED ON NON-SERVICE-CONNECTED CAUSE OF DEATH

Dependency and indemnity compensation (DIC) authorized by chapter 13, of title 38, United States Code, is a

monthly payment made by the Veterans Administration based on a service-connected cause of death to deceased veteran's surviving spouse or children and parents. The rates of DIC payable to a veteran's surviving spouse and children are greater than the rates of death pension payable to the surviving spouse and children of a veteran who dies of non-service-connected causes. In addition, unlike death pension, DIC is paid to a surviving spouse and children without regard to their income or net worth.

Pub. L. 95-479 provides that the surviving spouse and children of certain veterans who die from non-service-connected causes may receive DIC rates in the same manner as if cause of death is service connected. No benefits, however, are payable if the cause of the veteran's death is due to his or her own willful misconduct. For a spouse or child to receive benefits in the same manner as if cause of death is service connected the veteran must have been receiving (or but for the receipt of military retired pay was entitled to receive) compensation at time of death for service-connected disablement that either was continuously rated totally disabling for a period of 10 or more years immediately preceding death, or was continously rated totally disabling from date or discharge from active duty until death for a minimum period of 5 years. Both schedular and unemployability ratings meet the total disability rating requirment. A surviving spouse must have been married to the veteran for not less than 2 years immediately preceding the veteran's death to qualify for benefits in the same manner as if the veteran's death is service connected.

No benefits are payable to a surviving spouse or child after the surviving spouse or child receives any money or property in settlement of a cause of action for the veteran's death until after the amount of the benefit that would be payable but for this provision equals the amount of money and the fair market value of any property received in settlement of the cause of action. Social Security benefits and Workmen's Compensation are not subject to recoupment under this provision since offsets are limited to recoveries from judicial proceedings or settlements of causes of action for damages.

The addition of § 3.22 and amendment of § 3.54 implement this new benefit.

Retired Pay Taxation Exemption

Veterans Administration compensation and pension is not subject to taxation. Military retired pay based on longevity is taxable.

Many persons entitled to military retired pay are also entitled to Veterans Administration compensation as a result of service-connected disability. The law does not permit concurrent payment of these benefits. A military retiree must, therefore, waive an equivalent portion of retired pay to receive Veterans Administration compensation (or all of his or her retired pay if the amount of compensation payable exceeds the amount of military retired pay payable).

When the Veterans Administration receives a claim from a person in receipt of military retired pay, benefits are not awarded until the date waiver of retired pay is effective. Considering the time to develop the claim and receive and process the waiver, several months can elapse between the date a person is first potentially entitled to Veterans Administration benefits and the date Veterans Administration benefits are actually received by the claimant.

The Internal Revenue Service had at one time taken the position that a person could not exclude from taxable military retired pay income the amount of Veterans Administration benefits that would have been paid but for the delay in receipt of a waiver from date of entitlement until date waiver is effective. Pub. L. 95-479 now permits this exclusion from taxable income provided waiver is filed within 1 year from date of Veterans Administration entitlement notification.

The Veterans Administration has no jurisdiction over tax law and, therefore, no Veterans Administration regulation changes are necessary to implement this provision of Pub. L. 95-479.

High Level of Care Aid and Attendance Allowance

Pub. L. 95-479 provides that if a veteran entitled to the regular aid and attendance allowance under 38 U.S.C. 314(r) is in need of a higher level of care and the Veterans Administration finds that but for the provision of such care the veteran would require hospitalization, nursing home care, or other residential institutional care, the veteran shall receive $900 per month allowance in lieu of the regular aid and attendance allowance. Under this provision, a need for a higher level of care would be considered a need for personal health care services provided on a daily basis in the veteran's home by a person who either is licensed to provide such services or who the Veterans Administration finds is providing such services under the regular supervision of a licensed health care professional.

The factors considered in determining whether a disabled veteran is in the need or regular aid and attendance under current law are specified in 38 CFR 3.352(a). They include, among others, the inability to dress or undress oneself; keep ordinarily clean and presentable; feed oneself; attend to the wants of nature; or to protect oneself from the hazards or dangers incident to one's daily environment. Individuals providing assistance to a veteran for these necessities ordinarily need not possess any specific health care skills.

It is recognized, however, that the health care needs of certain of the more seriously disabled veterans are such that higher levels of skill are required of those giving them aid and attendance, and that, in such cases, the costs of necessary aid and attendance are extraordinarily high. Therefore, the higher aid and attendance allowance will be paid to those whose need for such assistance extends beyond that for which the current rate is adequate. It is intended that entitlement to the higher rate be limited to those who, in addition to meeting the requirements for aid and attendance under 38 CFR 3.352(a), have a demonstrable need for and regularly receive the services of a licensed health care professional (such as a doctor of medicine or osteopathy, a registered or licensed practical nurse, or a physical thereapist) or an individual performing skilled health care services under the regular supervision of a licensed professional, and who, but for the assistance of such person, would be institutionalized.

Examples of qualifying skilled health care services for this purpose include, but are not limited to, physical therapy, administration of injections, placement of indwelling catheters, and the changing of sterile dressing, or like function which are required on a regular basis and which require professional health care training or the regular supervision of a trained health care professional to perform. The need for such care is to be determined by a physician employed by the Veterans Administration, or in areas where no such physician is available, after examination by a physician retained under a contract or fee arrangement.

Ordinarily, the laws governing veterans' benefits are liberally construed but in this instance it is the expressed will of Congress that this provision be strictly construed by the Veterans Administration and that the higher allowance be granted only when the need is clearly established and the amount of services required by the veteran each day is substantial.

The amendment of §§ 3.350 and 3.552 implements the new high level of care aid and attendance allowance.

Additional Comment Information

Interested persons are invited to submit written comments, suggestions, or objections regarding the proposal to

the Administrator of Veterans' Affairs (271A), Veterans Administration, 810 Vermont Avenue, NW., Washington, DC 20420. All written comments received will be available for public inspection at the above address only between the hours of 8 am and 4:30 pm Monday through Friday (except holidays) until January 8, 1979. Any person visiting Central Office for the purpose of inspecting any such comments will be received by the Central Office Veterans Services Unit in room 132. Such visitors to any VA field station will be informed that the records are available for inspection only in Central Office and furnished the address and the above room number.

Approved: November 20, 1978.

By direction of the Administrator.

JOHN J. LEFFLER,
Associate Deputy Administrator.

§ 3.3 [Amended]

1. Section 3.3 is amended by deleting the words "widow, widower" and inserting "surviving spouse" in the first and second sentences of paragraph (d)(3).

2. Section 3.4 is amended as follows:

(a) By deleting the words, "widow, widower" and inserting "surviving spouse".

(1) In the first sentence of paragraph (a);

(2) In the introductory portion of paragraph (c) preceding subparagraph (1).

(b) By revising paragraph (b)(2) to read as follows:

§ 3.4 Compensation.

* * * * *

(b) *Disability compensation.* * * *

(2) An additional amount of compensation may be payable for a spouse, child, and/or dependent parent where a veteran is entitled to compensation based on disability evaluated as 30 percentum of more disabling. (38 U.S.C. 315)

* * * * *

3. In § 3.5, paragraph (a), the introductory portion of paragraph (b) preceding subparagraph (1) and paragraphs (d) and (e) are revised to read as follows:

§ 3.5 Dependency and indemnity compensation.

(a) *"Dependency and indemnity compensation."* This term means a monthly payment made by the Veterans' Administration to a surviving spouse, child, or parent:

(1) Because of a service-connected death occurring after December 31, 1956, or

(2) Pursuant to the election of a surviving spouse, child, or parent, in the case of such a death occurring before January 1, 1957. (38 U.S.C. 101 (14))

(b) *Entitlement.* Basic entitlement for a surviving spouse, child or children, and parent or parents of veteran exists, if:

* * * * *

(d) *Group life insurance.* No dependency and indemnity compensation or death compensation shall be paid to any surviving spouse, child or parent based on the death of a commissioned offier of the Public Health Service, the Coast and Geodetic Survey, the Environmental Science Services Administration, or the National Oceanic and Atomspheric Administration occurring on or after May 1, 1957, if any amounts are payable under the Federal Employees' Group Life Insurance Act of 1954 (Pub. L. 598, 83d Cong., as amended) based on the same death. (Sec. 501(c)(2), Pub. L. 881, 84th Cong. (70 Stat. 857), as amended by Sec. 13(u), Pub. L. 85-857; (72 Stat. 1266); Sec. 5, Pub. L. 91-621 (84 Stat. 1863))

(e) *Surviving spouse's rate.* (1) The monthly rate of dependency and indemnity compensation for a surviving spouse is based on the "pay grade" of the veteran. This rate is subject to increase as provided in paragraph (e)(3) and (4) of this section. (38 U.S.C. 411(a))

(2) The Secretary of the concerned service department will certify the "pay grade" of the veteran and the certification will be binding on the Veterans Administration. (38 U.S.C. 421)

(3) If there is a surviving spouse with one or more children under the age of 18 (including a child not in the surviving spouse's actual or constructive custody and a child who is in active military, air, or naval service), the total amount payable shall be increased by the amount set forth in 38 U.S.C. 411(b) for each child.

(4) If the surviving spouse is determined to be in need of aid and attendance under the criteria in § 3.352 or is a patient in a nursing home, the total amount payable shall be increased by the amount set forth in 38 U.S.C. 411(c). If the surviving spouse does not qualify for the aid and attendance allowance but is housebound under the criteria in § 3.351(f), the total amount payable shall be increased by the amount set forth in 38 U.S.C. 411(d).

4. Section 3.20 is revised to read follows:

§ 3.20 Surviving spouse's benefit for month of veteran's death.

Where the veteran died on or after December 1, 1962, the rate of death pension, death compensation or dependency and indemnity compensation otherwise payable for the surviving spouse for the month in which the death occurred shall be not less than the amount of pension or compensation which would have been payable to or for the veteran for that month but for his or her death. (38 U.S.C. 3110)

5. Section 3.22 and a cross reference are added to read as follows:

§ 3.22 Benefits payable as if cause of death is service connected.

(a) *Entitlement criteria.* Benefits authorized by chapter 13 of title 38, United States Code shall be paid to a deceased veteran's surviving spouse (See § 3.54(c)(2)) or children in the same manner as if the cause of the veteran's death is service connected when the following conditions are met:

(1) The veteran's death was not caused by his or her own willful misconduct; and

(2) The veteran was in receipt of (or but for the receipt of military retired pay was entitled to receive) compensation at time of death for service-connected disablement that either:

(i) Was continuously rated totally disabling by a schedular or unemployability rating for a period of 10 or more years immediately preceding death; or

(ii) Was continuously rated totally disabling by a schedular or unemployability rating from the date of the veteran's discharge or release from active duty for a period of not less than 5 years immediately preceding death.

(b) *Effect of judgment or settlement.* If a surviving spouse or child eligible for benefits under paragraph (a) of this section receives any money or property pursuant to a judicial proceeding based upon, or a settlement or compromise of, any cause of action or other right or recovery for damages for the death of the veteran, benefits payable under paragraph (a) of this section shall not be paid for any month following the month in which such money or property is received until the amount of benefits that would otherwise have been payable under paragraph (a) of this section equals the amount of money received or the fair market value of the property received.

(c) *Relationship to survivor benefit plan.* For the purpose of 10 U.S.C. 1448(d) and 1450(c) eligibility for benefits under paragraph (a) of this section shall be deemed eligible for dependency and indemnity compensation under 38 U.S.C. 411(a). (38 U.S.C. 410(b))

CROSS REFERENCE: Marriage dates. See § 3.54.

6. Section 3.54 is amended as follows:

(a) By deleting the words "widow's or widower's" and inserting "surviving spouse's" in the first sentence of paragraph (d).

(b) By deleting "widow or widower" and inserting "surviving spouse" in paragraph (e).

(c) By revising the introductory portion of paragraph (b) preceding subparagraph (1) and paragraph (c) to read as follows:

§ 3.54 Marriage dates.

* * * * *

(b) *Compensation.* Death compensation may be paid to a surviving spouse who, with respect to date of marriage, could have qualified as a surviving spouse for death compensation under any law administered by the Veterans Administration in effect on December 31, 1957, or who was married to the veteran:

* * * * *

(c) *Dependency and indemnity compensation.* (1) Dependency and indemnity compensation payable under 38 U.S.C. 410(a) may be paid to the surviving spouse of a veteran who died on or after January 1, 1957, who was married to the veteran:

(i) Before the expiration of 15 years after the termination of the period of service in which the injury or disease causing the death of the veteran was incurred or aggravated, or

(ii) For 1 year or more, or

(iii) For any period of time if a child was born of the marriage, or was born to them before the marriage. (38 U.S.C. 404)

(2) In order for a surviving spouse to be entitled to benefits under chapter 13 of title 38, United States Code, in the same manner as if the cause of death is service connected, the marriage to the veteran shall have been for a period of not less than 2 years immediately preceding the date of the veteran's death. (See § 3.22) The birth of a child does not change this requirement. (38 U.S.C. 410(b))

7. In § 3.55, the introductory portion of paragraph (a) preceding subparagraph (1) and paragraphs (b), (c) and (d) are revised as follows:

§ 3.55 Terminated marital relationships.

(a) Remarriage of a surviving spouse or marriage of a child shall not bar the furnishing of benefits to such surviving spouse or to or on account of such child, if the marriage

* * * * *

(b) On and after January 1, 1971, remarriage of a surviving spouse shall not bar the furnishing of benefits to such surviving spouse if the marriage

(1) Has been terminated by death, or

(2) Has been dissolved by a court with basic authority to render divorce decrees unless the Veterans Administration determines that the divorce was secured through fraud by the surviving spouse or by collusion.

(c) On and after January 1, 1971, the fact that a surviving spouse has lived with another person and has held herself (himself) out openly to the public as the spouse of such other person shall not bar the furnishing of benefits to her (him) after she (he) terminates the relationship.

(d) On and after January 1, 1971, the fact that benefits to surviving spouse may previously have been barred because her (his) conduct or a relationship into which she (he) had entered had raised an inference or presumption that she (he) had remarried or had been determined to be open and notorious adulterous cohabitation, or similar conduct, shall not bar the furnishing of benefits to such surviving spouse after she (he) terminates the conduct or relationship.

* * * * *

8. In § 3.350, paragraphs (a) (introductory portion preceding subparagraph (1)), (f)(1) (i) and (iii) and (2) (i) and (iii) and (h) are revised and paragraph (f)(5) is added so that the added and revised material reads as follows:

§ 3.350 Special monthly compensation ratings.

The rates of special monthly compensation stated in this section are those provided under 38 U.S.C. 314.

(a) *Ratings under 38 U.S.C. 314(k).* Special monthly compensation under 38 U.S.C. 314(k) is payable for each anatomical loss or loss of use of one hand, one foot, both buttocks, one or more creative organs, blindness of one eye having only light perception, deafness of both ears, having absence of air and bone conduction, or complete organic aphonia with constant inability to communicate by speech. This special compensation is payable in addition to the basic rate of compensation otherwise payable on the basis of degree of disability, provided that the combined rate of compensation does not exceed $1,005 monthly when authorized in conjunction with any of the provisions of 38 U.S.C. 314 (a) through (j) or (s). When there is entitlement under 38 U.S.C. 314 (l) through (n) or an intermediate rate under (p) such additional allowance is payable for each such anatomical loss or loss of use existing in addition to the requirements for the basic rates: *Provided,* The total does not exceed $1,408 per month. The limitations on the maximum compensation payable under this paragraph are independent of and do not preclude payment of additional compensation for dependents under 38 U.S.C. 315, or the special allowance for aid and attendance provided by 38 U.S.C. 314(r).

* * * * *

(f) *Intermediate or next higher rate; 38 U.S.C. 314(p)—(1) Extremities.* (i) Anatomical loss or loss of use of one extremity with the anatomical loss or loss of use of another extremity at a level or with complications preventing natural elbow or knee action with prosthesis in place will entitile to the rate intermediate between 38 U.S.C. 314 (l) and (m). The monthly rate is $1,056.

* * * * *

(iii) Anatomical loss or loss of use of extremity at a level preventing natural elbow or knee action with prosthesis in place with anatomical loss of another extremity so near the shoulder or hip as to prevent the use of a prosthetic appliance will entitle to the rate intermediate between 38 U.S.C. 314 (m) and (n). The monthly rate is $1,183.

(2) *Eyes, bilateral, and blindness in connection with deafness.* (i) Blindness of one eye with 5/200 visual acuity or less and blindness of the other eye having only light perception will entitle to the rate intermediate between 38 U.S.C. 314 (l) and (m). The monthly rate is $1,056.

* * * * *

(iii) Blindness of one eye having only light perception and anatomical loss, or blindness having no light perception accompanied by phthisis bulbi, evisceration or other obvious deformity or disfigurement of the eye, will entitle to a rate intermediate between 38 U.S.C. 314 (m) and (n). The monthly rate is $1,183.

* * * * *

(5) *Three extremities.* Anatomical loss or loss of use, or a combination of anatomical loss and loss of use, of three extremities shall entitle a veteran to the next higher rate without regard to whether that rate is a statutory rate or an intermediate rate. The maximum monthly payment under this provision may not exceed $1,408. (38 U.S.C. 314(p))

* * * * *

(h) *Special aid and attendance benefit in maximum monthly compensation cases; 38 U.S.C. 314(r).* A veteran receiving the maximum rate ($1,408) of special monthly compensation under any provision or combination of provisions in 38 U.S.C. 314 who is in need of regular aid and attendance or high level of care aid and attendance

is entitled to an additional allowance during periods he or she is not hospitalized at U.S. Government expense. (See § 3.552(b)(2) as to continuance following admission for hospitalization.) The regular aid and attendance allowance rate is $604; the high level of care aid and attendance allowance rate is $900 and is in lieu of the regular aid and attendance allowance. Determination of this need is subject to the criteria of § 3.352. The regular or high level of care aid and attendance allowance is payable whether or not the need for regular aid and attendance or high level of care aid and attendance was a partial basis for entitlement to the maximum $1,408 rate, or was based on an independent factual determination.

* * * * *

9. In § 3.351, paragraph (a) and the introductory portion of paragraph (c) preceding subparagraph (1) are revised and paragraph (f) is added so that the revised and added material reads as follows:

§ 3.351 Special monthly dependency and indemnity compensation, death compensation, pension and spouse's compensation ratings.

(a) *Aid and attendance; general.* Additional pension for veterans in need of regular aid and attendance is provided for Spanish-American War veterans (38 U.S.C. 512) and for veterans of the Mexican border period, world War I, World War II, the Korean conflict or the Vietnam era (38 U.S.C. 521). Additional pension for surviving spouses in need of regular aid and attendance is provided for surviving spouses of veterans of all periods of war, including those entitled to pension under the law in effect on June 30, 1960, based on service in World War I, World War II, or the Korean conflict (38 U.S.C. 544). Additional compensation is provided for a married veteran receiving compensation of the 30 percent rate or greater whose spouse is in need of regular aid and attendance. (38 U.S.C. 315(1)(I)) Additional dependency and indemnity compensation and dealth compensation for surviving spouses and for parents in need of regular aid and attendance is provided for surviving spouses and for parents of veterans of all periods of service. (38 U.S.C. 322(b); 411(c); 415(h))

* * * * *

(c) *Aid and attendance; criteria.* The veteran, spouse, surviving spouse, or parent will be considered in need of regular aid and attendance if he or she:

* * * * *

(f) *Housebound; dependency and indemnity compensation.* The monthly rate of dependency and indemnity compensation payable to a surviving spouse who does not qualify for increased dependency and indemnity compensation under 38 U.S.C. 411(c) based on need for regular aid and attendance shall be increased by the amount specified in 38 U.S.C. 411(d) if the surviving spouse is permanently housebound by reason of disability. The permanently housebound requirement is met when the surviving spouse is substantially confined as a direct result of disabilities to his or her home (ward or clinical areas, if institutionalized) or immediate premises by reason of disability or disabilities which it is reasonably certain will remain throughout the surviving spouse's lifetime. (38 U.S.C. 411(d))

10. Immediately following § 3.351, the cross references are changed to read as follows:

CROSS REFERENCES: Basic pension determinations. See § 3.314.

Criteria for permanent need for aid and attendance and "permanently bedridden." See § 3.352.

11. Section 3.352 is amended as follows:

(a) By changing the heading of the section.

(b) By changing the heading of paragraph (a).

(c) By adding paragraph (b) and redesignating paragraph (b) as paragraph (c) so that the added and redesignated material reads as follows:

§ 3.352 Criteria for permanent need for aid and attendance and "permanently bedridden."

(a) *Basic criteria for regular aid and attendance and permanently bedridden.* * * *

(b) *Basic criteria for the high level of care aid and attendance allowance.* (1) A veteran is entitled to the high level of care aid and attendance allowance authorized by § 3.350(h) in lieu of the regular aid and attendance allowance when all of the following conditions are met:

(i) The veteran is entitled to the compensation authorized under 38 U.S.C. 314(o), or the maximum rate of compensation authorized under 38 U.S.C. 314(p).

(ii) The veteran meets the requirements for entitlement to the regular aid and attendance allowance in paragraph (a) of this section.

(iii) The veteran needs a "higher level of care" (as defined in paragraph (b)(2) of this section) than is required to establish entitlement to the regular aid and attendance allowance, and in the absence of the provision of such higher level of care the veteran would require hospitalization, nursing home care, or other residential institutional care.

(iv) The veteran's need for a higher level of care than is required to establish entitlement to the regular aid and attendance allowance is determined by a Veterans Administration physician or, in areas where no Veterans Administration physician is available, by a physician carrying out such function under contract or fee arrangement based on an examination by such physician.

(2) Need for a higher level of care shall be considered to be need for personal health care services provided on a daily basis in the veteran's home by a person who is licensed to provide such services or who provides such services under the regular supervision of a licensed health care professional. Personal health care services include (but are not limited to) such services as physical therapy, administration of injections, placement of indwelling catheters, and the changing of sterile dressings, or like functions which are required on a regular basis and which require professional health care training or the regular supervision of a trained health care professional to perform. A licensed health care professional includes (but is not limted to) a doctor of medicine or osteopathy, a registered nurse, a licensed practical nurse, or a physical therapist, and so forth, licensed to practice by a State or political subdivision thereof. (38 U.S.C. 314(r)(2))

(c) *Attendance by relative.* The performance of the necessary aid and attendance service by a relative of the beneficiary or other member of his or her household will not prevent the granting of the additional allowance.

§ 3.382 [Amended]

12. Section 3.382 is amended as follows:

(a) By adding the words "or she" after the word "he" in the third sentence of paragraph (a).

(b) By deleting the words "his service support his allegation," and inserting "his or her service support his or her allegation," in the first sentence of paragraph (b).

§ 3.383 [Amended]

13. Section 3.383 is amended by adding the words "or her" after the word "his" in paragraphs (a), (b) and (c).

14. Section 3.384 is added to read as follows:

§ 3.384 Additional compensation for non-service-connected loss or loss of use of paired extremity.

(a) *General.* Subject to the conditions in paragraph (b) and (c) of this section a veteran who has service-connected loss or loss of use of one ex-

tremity and non-service-connected loss or loss of use of the paired extremity is entitled to increased compensation in the amount specified in 38 U.S.C. 314(t).

(b) *Entitlement criteria.* (1) The loss or loss of use of the service-connected extremity is rated at 40 percent or more disabling; and

(2) The loss or loss of use of the non-service-connected paired extremity would be rated 40 percent or more disabling if service connected; and

(3) The loss or loss of use of the non-service-connected extremity is not the result of the veteran's own willful misconduct; and

(4) The veteran is entitled to receive compensation at any rate under 38 U.S.C. 314 (a) through (i) and special monthly compensation under 38 U.S.C. 314(k).

(c) *Effect of judgment or settlement.* If a veteran receives any money or property of value pursuant to an award in a judicial proceeding based upon, or a settlement or compromise of, any cause of action for damages for the loss or loss of use of the non-service-connected extremity, the increased compensation payable by reason of this section shall not be paid for any month following the month in which any such money or property is received until such time as the total amount of the increased compensation that would otherwise have been payable equals the total of the amout of any such money received and the fair market value of any such property received. (38 U.S.C. 314(t))

15. In § 3.552, the heading is changed and paragraphs (a)(1), (b)(2) and (g) are revised to read as follows:

§ 3.552 Adjustment of allowance for aid and attendance.

(a)(1) When a veteran is hospitalized, additional compensation or increased pension for aid and attendance will be discontinued as provided in paragraph (b) of this section except as to disabilities specified in paragraph (a)(2) of this section.

* * * * *

(b) * * *

(2) When a veteran is hospitalized at the expense of the United States Government, the additional aid and attendance allowance authorized by 38 U.S.C. 314(r) (1) or (2) will be discontinued effective the last day of the month following the month in which the veteran is admitted for hospitalization.

* * * * *

(g) Where a veteran entitled to one of the rates under 38 U.S.C. 314 (l), (m), or (n) by reason of anatomical losses or losses of use of extremities, blindness (visual acuity 5/200 or less or light perception only), or anatomical loss of both eyes is being paid compensation of $1,408 because of entitlement to another rate under section 314(l) on account of need for aid and attendance the compensation will be reduced while hospitalized to the following:

(1) If entitlement is under section 314(l) and in addition there is need for regular aid and attendance for another disability, the award during hospitalization will be $1,107 since the disability requiring aid and attendance is 100 percent disabling. (38 U.S.C. 314(p))

(2) If entitlement is under section 314(m), $1,258.

(3) If entitlement is under section 314(n), $1,408 would be continued, since the disability previously causing the need for regular aid and attendance would then be totally disabling entitling the veteran to the maximum rate under 38 U.S.C. 314(p).

* * * * *

§ 3.556 [Amended]

16. Section 3.556(a)(1) is amended by deleting the words "wife (husband)" and inserting the word "spouse" in the second sentence.

17. In § 3.802, paragraph (b) is revised to read as follows:

§ 3.802 Medal of Honor.

* * * * *

(b) An award of special pension of $200 monthly (prior to Jan. 1, 1979, $100 monthly) will be made as of the date of filing of the application with the Secretary concerned. The special pension will be paid in addition to all other payments under laws of the United States. However, a person awarded more than one Medal of Honor may not receive more than one special pension. (38 U.S.C. 562)

§ 3.803 [Amended]

18. Section 3.803 is amended by deleting "6159" in the citation following paragraph (a).

§ 3.805 [Amended]

19. Section 3.805 is amended by deleting the words "widows (widowers)" and inserting the words "surviving spouses" in the heading and in the introductory portion preceding paragraph (a).

20. In § 3.808, the introductory portion preceding paragraph (a) is revised to read as follows:

§ 3.808 Automobiles or other conveyances; certification.

A certification of eligibility for financial assistance in the purchase of one automobile or other conveyance in an amount not exceeding $3,800 (including all State, local, and other taxes where such are applicable and included in the purchase price) and of basic entitlement to necessary adaptive equipment will be made where the claimant meets the requirements of paragraphs (a), (b) and (c) of this section.

* * * * *

21. In § 3.1600, paragraphs (a), (c) and (g) are revised to read as follows:

§ 3.1600 Payment of burial expenses of deceased veterans.

* * * * *

(a) *Wartime veterans.* When a veteran of any war dies, an amount not to exceed $300 ($1,100 if death is service-connected) (where entitlement is based on § 3.8 (c) or (d), at a rate in Philippine pesos equivalent to $150 or $550 if death is service-connected) is payable on the burial and funeral expenses and transportation of the body to the place of burial, if otherwise entitled within the further provisions of §§ 3.1600 through 3.1611. For this purpose the period of any war is as defined in § 3.2, except that World War I extends only from April 6, 1917, through November 11, 1918, or if the veteran served with the United States military forces in Russia, through April 1, 1920. (38 U.S.C. 902; 907; 107(a))

* * * * *

(c) *Death while properly hospitalized.* If a person dies while properly hospitalized by the Veterans Administration, there is payable an allowance not to exceed $300 ($1,100 if he or she died of a service-connected disability) for the actual cost of funeral and burial, and an additional amount for transportation of the body to the place of burial. See § 3.1605. (38 U.S.C. 903; 907)

* * * * *

Transportation expenses for burial in national cemetery. Where a veteran dies as the result of a service-connected disability, or at the time of death was in receipt of disability compensation (or but for the receipt of military retired pay or non-service-connected disability pension would have been entitled to disability compensation at time of death) there is payable, in addition to the burial allowance (either $300 or $1,100 if cause of death was service connected), an additional amount for payment of the cost of transporting the body to a national cemetery for burial. This amount may not exceed the cost of transporting

the body from the veteran's place of death to the national cemetery nearest the veteran's last place of residence in which burial space is available. The amounts payable under this paragraph are subject to the limitations set forth in §§ 3.1604 and 3.1606.

22. In § 3.1601, paragraph (a)(1)(i) is revised to read as follows:

§ 3.1601 Claims and evidence.

(a) *Claims.* * * *

(1) Claims for burial allowance may be executed by;

(i) The funeral director, if entire bill or any balance is unpaid (if unpaid bill is under $300 only amount of unpaid balance will be payable to the funeral director); or

* * * * *

23. In § 3.1604, the introductory portion of paragraph (a) preceding subparagraph (1) and paragraph (b)(2) are revised to read as follows:

§ 3.1604 Payments from non-Veterans Administration sources.

(a) *Contributions or payments by public or private organizations.* When contributions or payments on the burial expenses have been made by a State, any agency or political subdivision of the United States or of a State, or the employer of the deceased veteran only the difference between the entire burial expenses and the amount paid thereon by any of these agencies or organizations, not to exceed $300 ($1,100 if death was service connected), will be authorized. Contributions or payments by any other public or private organization such as a lodge, union, fraternal of beneficial organization, society, burial association or insurance company, will bar payment of the burial allowance if such allowance would revert to the funds of such organization or would discharge such organization's obligation without payment.

* * * * *

(b) *Payment by Federal agency.* * * *

(2) A provision in any Federal law or regulation permitting the application of funds due or accrued to the credit of the deceased toward the expenses of funeral, transportation and internment (such as Social Security benefits), as distinguished from a provision specifically prescribing a definite allowance for such purpose, will not bar payment of the burial allowance. In such cases only the difference between the total burial expense and the amount paid thereon under such provision, not to exceed $300 will be authorized.

* * * * *

§ 3.1605 [Amended]

24. Section 3.1605 is amended by adding the words "or she" after the word "he" in the first sentence of the introductory portion preceding paragraph (a).

[FR Doc. 78-33275 Filed 11-27-78; 8:45 am]

[6560-01-M]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 65]

[FRL 1014-2]

STATE AND FEDERAL ADMINISTRATIVE ORDERS PERMITTING A DELAY IN COMPLIANCE WITH STATE IMPLEMENTATION PLAN REQUIREMENTS

Withdrawal of a Proposed Disapproval of an Administrative Order Issued by Illinois Environmental Protection Agency to Central Illinois Public Service Company

AGENCY: U.S. Environmental Protection Agency.

ACTION: Withdrawal of Proposed Disapproval.

SUMMARY: U.S. EPA is withdrawing its proposed disapproval of an Administrative Order issued by the Illinois Environmental Protection Agency to Central Illinois Public Service Company. The proposed disapproval was published in the FEDERAL REGISTER on May 10, 1978.

This action is being taken in response to the comment published below.

FOR FURTHER INFORMATION CONTACT:

Bertram Frey, Attorney, Enforcement Division, U.S. Environmental Protection Agency, 230 South Dearborn Street, Chicago, Illinois, 60604 312-353-2082.

SUPPLEMENTARY INFORMATION: The notice invited public comment on the proposed disapproval. Two comments were received. Central Illinois Public Service Company sent a comment to U.S. EPA on June 7, 1978. The U.S. EPA responded to this comment in a letter on August 8, 1978. The second comment received from the Illinois Environmental Protection Agency (IEPA), is shown below.

Re EPA Proposed Disapproval of Delayed Compliance Order for Central Public Service, 43 FR 20022, May 10, 1978.

Dear Mr. McDonald: In response to request for written comments appearing in Notice in FEDERAL REGISTER Vol. 43, No. 91, dated Wednesday, may 10, 1978, the Illinois Environmental Protection Agency (hereinafter referred to as the "Agency") has the following comments to make:

1. The Agency was aware of the deficiencies of Illinois Pollution Control Board Order PCB 77-145 (hereinafter referred to as the "Order") in respect to variance granted to Central Illinois Public Service *Company Newton Unit I* (hereinafter referred to as the "Petitioner") in that the Order granted a variance for final compliance later than July 1, 1979, as allowed by Section 113(d)(1)(D) of the Clean Air Act as amended (42 U.S.C. Section 7413(d)(1)(D) hereinafter referred to as the "Act"). The Agency was also aware that the Order failed to notify the Petitioner that it would be required to pay penalties under the provisons of Section 120 of the Act if the Petitioner failed to achieve final compliance by July 1, 1979, also that the Order failed to require compliance with applicable interim requirements as provided by paragraph (6) and (7) of Section 113(d) of the Act, and contained no requirement for emission monitoring and reports contrary to the provisions of Section 113(d) of the Act.

2. Because of the deficiencies referred to in comment 1 above, the Agency was mindful that a Delayed Compliance Order would probably not be approved by the Administrator as an addition to the Illinois State Implementation Plan under the provisions of Section 110 of the Act. Therefore, the Agency as the official State authority, under the provisions of Section 4m of the Illinois Environmental Protection Agency Act, designated to submit State implementation Plans or their revisions to the Administrator for approval, did not do so for the reasons stated above.

3. The Board's Order in this instance is a shield against State Prosecution of the Petitioner for violations of Section 9(b) of the Illinois Environmental Act or regulation 204(a)(1) of the Illinois Air Pollution Control Regulations, although such Order was deficient under the provisions of the Clean Air Act.

The U.S. EPA finds the IEPA's point well taken. Since the IEPA has not made an official submittal of the Order in question for U.S. EPA approval, the U.S. EPA is withdrawing its proposed disapproval.

Dated: November 14, 1978.

JOHN MCGUIRE,
Regional Administrator.

[FR Doc. 78-33095 Filed 11-27-78; 8:45 am]

[6560-01-M]

[40 CFR Part 65]

[FRL 1014-4; Docket No. DCO-78-28]

STATE AND FEDERAL ADMINISTRATIVE ORDERS PERMITTING A DELAY IN COMPLIANCE WITH STATE IMPLEMENTATION PLAN REQUIREMENTS

Proposed Approval of a Delayed Compliance Order Issued by the Knox County Department of Air Pollution Control to Tamko Asphalt Products Co., Knoxville, Tenn.

AGENCY: Environmental Protection Agency.

ACTION: Proposed Rule.

SUMMARY: EPA proposed to approve a delayed compliance order issued by the Knox County Department of Air Pollution Control to Tamko Asphalt Products Company located in Knoxville, Tennessee. The delayed compliance order requires the Tamko Asphalt Company to bring air emissions from their coal fired boilers in Knoxville, Tennessee into compliance with applicable regulations contained in the Tennessee State Implementation Plan (SIP) by June 1, 1979. Because the order has been issued to a major source and permits a delay in compliance with the provisions of the SIP, it must be approved by EPA before it becomes effective as a delayed compliance order under the Clean Air Act (the Act). If aproved by EPA, the order will constitute an addition to the SIP. In addition, a source in compliance with an approved order may not be sued under the federal enforcement or citizen suit provisions of the Act for violations of the SIP regulations covered by the order. The purpose of this notice is to invite public comment on EPA's proposed approval of the order as a delayed compliance order.

DATE: Written comments must be received on or before December 28, 1978.

ADDRESSES: Comments should be submitted to Director, Enforcement Division, EPA, Region IV, 345 Courtland Street, N.E., Atlanta, Georgia 30308. The State order, supporting material, and public comments received in response to this notice may be inspected and copied (for appropriate charges) at this address during normal business hours.

FOR FURTHER INFORMATION CONTACT:

Mr. Bert Cole, U.S. Environmental Protection Agency, 354 Courtland Street, N.E., Atlanta, Georgia 30308, telephone 404-881-4298.

SUPPLEMENTARY INFORMATION: Tamko Asphalt Products Company operates a roof felt manufacturing facility in Knoxville, Tennessee. The order under consideration addresses emissions from the coal fired boilers which are subject to sections 17.0 and 41.0 of the Knox County Air Pollution Control Regulations. These regulations limit visible emissions and particulate emissions from the coal fired boiler stack and are part of the federally-approved Tennessee State Implementation Plan. The order requires final compliance with the regulations by June 1, 1979, through the implementation of the following schedule for the construction or installation of control equipment:

1. July 15, 1978: Evaluate all options for achieving and maintaining compliance, and determine specific method to be employed. Options include, but are not limited to the following:

a. Purchase and installation of pollution control equipment for coal-fired boilers.

b. Substitution of wood industry by-products (e.g., "Woodex") for coal.

c. Conversion of present coal-fired boiler to oil firing.

d. Abandon present coal-fired boilers and purchase new package boiler units capable of meeting referenced regulations.

2. September 1, 1978: Issue purchase order for any equipment attendant to the control option selected.

3. March 1, 1979: Initiate on-site construction as appropriate to control option selected.

4. June 1, 1979: Complete performance testing and achieve compliance with all applicable particulate and visible emission limiting regulations, and certify such compliance to Knox County Department of Air Pollution Control and EPA.

Interim limits for Tamko Asphalt Products Company require that the visible emission be limited to 20% equivalent opacity or less and that the mass particulate emission rate be reduced to 14 pounds per hour or less prior to the attainment of the last milestone.

Because this order has been issued to a major source of visible and particulate emissions and permits a delay in compliance with the applicable regulation, it must be approved by EPA before becoming effective as a delayed compliance order under Section 113(d) of the Clean Air Act (the Act). EPA may approve the order only if it satisfies the appropriate requirements of this subsection. EPA has tentatively determined that the order satisfies these requirements.

If the order is approved by EPA, source compliance with its terms would preclude federal enforcement action under Section 113 of the Act against the source for violations of the regulations covered by the order during the period the order is in effect. Enforcement against the source under the citizen suit provision of the Act (Section 304) would be similarly precluded. If approved, the order would also constitute an addition to the Tennessee SIP. Compliance with the proposed order will not exempt the company from complying with applicable requirements contained in any subsequent revisions to the SIP which are approved by EPA.

All interested persons are invited to submit written comments on the proposed order. Written comments received by the date specified above will be considered in determining whether EPA may approve the order. After the public comment period, the Administrator of EPA will publish in the FEDERAL REGISTER the Agency's final action on the order in 40 CFR Part 65.

(42 U.S.C. 7413, 7601.)

Dated: November 17, 1978.

JOHN A. LITTLE,
Acting Regional Administrator,
Region IV.

[FR Doc. 78-33246 Filed 11-27-78; 8:45 am]

[6712-01-M]

FEDERAL COMMUNICATIONS COMMISSION

[47 CFR Part 73]

[Docket No. 20954; RM-2684; RM-2772; RM-2982]

FM BROADCAST STATION IN STAUNTON, VA.

Order Extending Time for Filing Comments and Reply Comments

AGENCY: Federal Communications Commission.

ACTION: Order.

SUMMARY: Action taken herein extends the time for filing comments and reply comments in a proceeding involving the proposed assignment of an FM channel to Staunton, Virginia. Petitioner, WANV, Inc., states that the additional time is needed so that it can complete preparation of its comments.

DATES: Comments must be filed on or before December 1, 1978, and reply comments on or before December 22, 1978.

ADDRESSES: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT:

Stanley P. Wiggins, Broadcast Bureau, 202-632-7792.

SUPPLEMENTARY INFORMATION:

Adopted: November 17, 1978.

Released: November 20, 1978.

In the Matter of Amendment of § 73.202(b), Table of Assignments, FM Broadcast Stations (Staunton, Virginia). Order extending time for filing comments and reply comments (see also 43 FR 49552, October 24, 1978).

By the Chief, Broadcast Bureau:

1. On August 17, 1978, the Commission adopted a *Second Further Notice of Proposed Rule Making,* 43 FR 38060, proposing the assignment of Class B FM Channel 259 to Staunton, Virginia. The present dates for filing comments and reply comments are November 17, and December 8, 1978, respectively.

2. On November 9, 1978, counsel for WANV, Inc., filed a request for exten-

sion of time for filing comments and reply comments to and including December 1, and December 22, 1978, respectively. Counsel asserts that WANV's consulting engineers are awaiting comments from the National Radio Astronomy Observatory and the Naval Research Laboratory on WANV's proposed facilities. He adds that until they receive the views of these agencies they are unable to complete preparation of the engineering exhibits which WANV intends to submit in support of its comments. Counsel states that WANV's engineering consultants have been advised that the information they need will be supplied shortly.

3. We are of the view that the additional time is warranted in order to assure development of a sound and comprehensive record on which to base a decision in this proceeding. Accordingly, *It is ordered*, That the dates for filing comments and reply comments are extended to and including December 1, and December 22, 1978, respectively.

4. This action is taken pursuant to authority found in sections 4(i), 5(d)(1), and 303(r) of the Communications Act of 1934, as amended, and section 0.281 of the Commission's Rules.

FEDERAL COMMUNICATIONS COMMISSION,
WALLACE E. JOHNSON,
Chief, Broadcast Bureau.

[FR Doc. 78-33224 Filed 11-27-78; 8:45 am]

notices

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.

[3410-11-M]

DEPARTMENT OF AGRICULTURE

Forest Service

LOUISIANA-PACIFIC LONG-TERM TIMBER SALE—1979-84 OPERATING PERIOD

Ketchikan area, Tongass National Forest, Alaska; Intent To Prepare an Environmental Statement

Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969, the Forest Service, Department of Agriculture will prepare an Environmental Statement for the proposed timber harvest and related activities under this timber sale contract for the five-year operating period from 1979 to 1984.

Under this contract, the Forest Service is obligated to make available 960 MM bf every five years. It is to come from the primary sale area on Prince of Wales and Revillagigedo Islands as long as timber is available thereon.

The primary concern, and the reason for preparing an Environmental Statement, is that some of the sale area is roadless. Plans for logging are being coordinated with the second Roadless area Review and Evaluation (RARE II) and the Tongass Land Management Plan (TLMP) in order to avoid any areas of wilderness quality or other roadless management under these allocation plans.

The Forest Service is working with the Alaska Department of Fish and Game, the National Marine Fisheries Service, and the U.S. Fish and Wildlife Service in preparation of this plan. The purpose of this is to assure full coordination with and protection of fish and wildlife values on the sale area.

John McGuire, Chief of the Forest Service, is the responsible offical. The ES is being prepared under the direction of James S. Watson, Forest Supervisor. Ed Johnson, Timber Staff Assistant, is the team leader for the Environmental Assessment and Statement.

It is anticipated that the Draft Environmental Statement will be completed by late November 1978. A two-month review period will follow, with the Final Statement to be released about March 1979. Activities under the plan will begin July 1, 1979.

Comments on the Notice of Intent or on the project should be sent to James S. Watson, Forest Supervisor, Tongass National Forest, Federal Building, Ketchikan, Alaska 99901.

EINAR L. ROGET,
Acting Deputy Chief.

NOVEMBER 20, 1978.

[FR Doc. 78-33243 Filed 11-27-78; 8:45 am]

[6320-01-M]

CIVIL AERONAUTICS BOARD

ORDER ESTABLISHING FINAL SERVICE MAIL RATES

The Board adopted Order 78-11-80 on September 16, 1978, establishing the Final Service Mail Rates in the *Priority and Nonpriority Domestic Service Mail Rates Investigation*, Docket 23080-2.

After a full public hearing and consideration of the record the Board ordered that:

1. The fair and reasonable rates of compensation to be paid by the Postmaster General.

(a) From March 28 through October 12, 1973, for the transportation by air of nonpriority mail (*i.e.* all mail other than airmail and air parcel post, which may be tendered from time to time by the Postal Service in sacks and carried on a space-available basis) other than that for which rates are elsewhere established, the facilities used and useful therefor, and the services connected therewith, to:

Airlift International, Inc., Alaska Airlines, Inc., Allegheny Airlines, Inc., American Airlines, Inc., Braniff Airways, Inc., Caribbean-Atlantic Airlines, Inc., Continental Air Lines, Inc., Delta Air Lines, Inc., Eastern Air Lines, Inc., The Flying Tiger Line Inc., Frontier Airlines, Inc., Hughes Air Corp., National Airlines, Inc., North Central Airlines, Inc., Northwest Airlines, Inc., Ozark Air Lines, Inc., Pan American World Airways, Inc., Piedmont Aviation, Inc., Seaboard World Airlines, Inc., Southern Airways, Inc., Texas International Airlines, Inc., Trans World Airlines, Inc., United Air Lines, Inc., Western Air Lines, Inc.

for operations over their routes authorized under certificates in effect on or subsequent to March 28, 1973, within the 48 contiguous States and the District of Columbia; between points in the 48 contigious States and the District of Columbia, on the one hand, and, on the other hand, points in the State of Alaska; Hilo and Honolulu, Hawaii; San Juan, Puerto Rico, St. Croix and St. Thomas, Virgin Islands; Wake Island; Agana, Guam; Pago Pago, American Samoa; Acapulco, Guaymas, La Paz, Mazatlan, Merida, Mexico City, Monterrey, Puerto Vallarta, Tempico, and Veracruz, Mexico; and terminal points in Canada; between Honolulu, Hawaii, on the one hand, and, on the other hand, Agana, Guam; Wake Island; and Pago Pago, American Samoa; between points in Puerto Rico, on the one hand, and St. Croix and St. Thomas, Virgin Islands, on the other; between points in Puerto Rico; and between St. Croix and St. Thomas, Virgin Islands; and to the air carriers specified in Order 74-7-91, dated July 19, 1974, over the routes and subject to the conditions specified by the orders set forth therein or subsequent orders of the Board; shall be the sum of a line-haul charge of 7.56 cents per nonstop great-circle ton-mile and a terminal charge of 6.990 cents per pound originated subject to the terms and conditions specified in Order 70-4-9, dated April 2, 1970.

(b) From March 28 through October 12, 1973, for the transportation by air of priority mail in sacks other than that for which rates are elsewhere established, the facilities used and useful therefor, and the services connected therewith, to:

Airlift International, Inc., Allegheny Airlines, Inc., Eastern Air Lines, Inc., Frontier Airlines, Inc., Hughes Air Corp., North Central Airlines, Inc., Ozark Air Lines, Inc., Piedmont Aviation, Inc., Southern Airways, Inc., Texas International Airlines, Inc., United Air Lines, Inc.

for operations over their entire systems as constituted on or subsequent to March 28, 1973, and:

Alaska Airlines, Inc., American Airlines, Inc., Braniff Airways, Inc., Caribbean-Atlantic Airlines, Inc., Continental Air Lines, Inc., Delta Air Lines, Inc., The Flying Tiger Line, Inc., National Airlines, Inc., Northwest Airlines, Inc., Pan American World Airways, Inc., Seaboard World Airlines, Inc., Trans World Airlines, Inc., Western Air Lines, Inc.

for operations over their routes within the 48 contiguous States and the District of Columbia insofar as authorized under certificates for interstate air transportation; over their routes between points within the 48 contiguous States and the District of Colunbia, on the one hand, and, on the other, points in the State of Alaska, Hilo and Honolulu, Hawaii, Acapulco, Merida,

Mexico City, and Monterrey, Mexico, San Juan, Puerto Rico, points in the Virgin Islands, and terminal points in Canada; and between points in Puerto Rico, on the one hand, and points in the Virgin Islands, on the other; between points in Puerto Rico; between points in the Virgin Islands; and between points in the State of Alaska and Hilo and Honolulu, Hawaii; which are in effect on or subsequent to March 28, 1973; and to the air carriers specified in Order 74-7-91, dated July 19, 1974, over the routes and subject to the conditions specified by the orders set forth therein or subsequent orders of the Board; shall be the sum of a line- haul charge of 10.69 cents per nonstop great-circle ton-mile and a terminal charge of 7.751 cents per pound originated, subject to the terms and conditions specified in Order E-25610, dated August 28, 1967.

(c) For the transportation by air of mail in sacks (Sack mail, Con-Con mail, Express mail), or in Con-Con containers, ½ F containers, or 3150 trays, other than that established elsewhere for Parcel Airlift mail, the facilities used and useful therefor, and the services connected therewith to:

Airlift International, Inc., Air New England, Inc., Allegheny Airlines, Inc., Eastern Air Lines, Inc., Frontier Airlines, Inc., Hughes Air Corp., North Central Airlines, Inc., Ozark Air Lines, Inc., Piedmont Aviation, Inc., Southern Airways, Inc., Texas International Airlines, Inc., United Air Lines, Inc.

for operations over their entire systems as constituted on or subsequent to October 13, 1973, and:

Alaska Airlines, Inc., American Airlines, Inc., Braniff Airways, Inc., Continental Air Lines, Inc., Delta Air Lines, Inc., The Flying Tiger Line, Inc., National Airlines, Inc., Northwest Airlines, Inc., Pan American World Airways, Inc., Seaboard World Airlines, Inc., Trans World Airlines, Inc., Western Air Lines, Inc.

for operations over their routes within the 48 contiguous States and the District of Columbia insofar as authorized under certificates for interstate air transportation; over their routes between points within the 48 contiguous States and the District of Columbia, on the one hand, and, on the other, points in the State of Alaska, Hilo and Honolulu, Hawaii, Acapulco, Merida, Mexico City, and Monterrey, Mexico, San Juan, Puerto Rico, points in the Virgin Islands, and terminal points in Canada; and between points in Puerto Rico, on the one hand, and points in the Virgin Islands, on the other; between points in Puerto Rico; between points in the Virgin Islands, and between points in Alaska, on the one hand, and Hilo and Honolulu, Hawaii, on the other hand; which are in effect on or subsequent to October 13, 1973; and to the air carriers specified in Order 74-7-91, dated July 19, 1974, over the routes and subject to the conditions specified by the orders set forth therein or subsequent orders of the Board; shall be (1) the sum of a linehaul charge charge of 9.28 cents per nonstop great-circle ton-mile and a terminal charge of 7.185 cents per pound originated for the period October 13, 1973 through December 31, 1973, (2) the sum of a linehaul charge of 11.49 cents per nonstop great-circle ton-mile and a terminal charge of 8.241 cents per pound originated for the period January 1, 1974 through December 31, 1974, (3) the sum of a linehaul charge of 12.50 cents per nonstop great-circle ton-mile and a terminal charge of 8.920 cents per pound originated for the period January 1, 1975 through December 31, 1975, (4) the sum of a linehaul charge of 13.25 cents per nonstop great-circle ton-mile and a terminal charge of 9.586 cents per pound originated for the period January 1, 1976 through December 31, 1976, (5) the sum of a linehaul charge of 14.32 cents per nonstop great-circle ton-mile and a terminal charge of 10.028 cents per pound originated for the period January 1, 1977 through December 31, 1977, (6) the sum of a linehaul charge of 15.15 cents per nonstop great-circle ton-mile and a terminal charge of 10.463 cents per pound originated for the period January 1, 1978 through December 31, 1978, and (7) the sum of a linehaul charge of 14.86 cents per nonstop great-circle ton-mile and a terminal charge of 10.677 cents per pound originated for the period January 1, 1979 through June 30, 1979, subject to the terms and conditions specified in Order E-25610, dated August 28, 1967.

(d) For the transportation by air in sacks of that mail matter described in 39 U.S.C. 3401 (Parcel Airlift mail—PAL), the facilities used and useful therefor, and the services connected therewith for the carriers and the points stated in subparagraph (c) above, shall be (1) the sum of a linehaul charge of 7.56 cents per nonstop great-circle ton-mile and a terminal charge of 6.990 cents per pound originated for the period October 13, 1973 through December 31, 1973, (2) the sum of a linehaul charge of 6.50 cents per nonstop great-circle ton-mile and a terminal charge of 7.653 cents per pound originated for the period January 1, 1974 through December 31, 1974, (3) the sum of a linehaul charge of 7.07 cents per nonstop great-circle ton-mile and a terminal charge of 8.300 cents per pound originated for the period January 1, 1975 through December 31, 1975, (4) the sum of a linehaul charge of 7.49 cents per nonstop great-circle ton-mile and a terminal charge of 8.929 cents per pound originated for the period January 1, 1976 through December 31, 1976, (5) the sum of a linehaul charge of 8.09 cents per nonstop great-circle ton-mile and a terminal charge of 9.340 cents per pound originated for the period January 1, 1977 through December 31, 1977, (6) the sum of a linehaul charge of 8.56 cents per nonstop great-circle ton-mile and a terminal charge of 9.740 cents per pound originated for the period January 1, 1978 through December 31, 1978, and (7) the sum of a linehaul charge of 8.40 cents per nonstop great-circle ton-mile and a terminal charge of 9.945 cents per pound originated for the period January 1, 1979 through June 30, 1979, subject to ther terms and conditions specified in Order 70-4-9, dated April 2, 1970.

(e) For the transportation by air of mail containers, the facilities used and useful therefor, and the services connected therewith for the carriers and between the points listed in subparagraph (c) above, (1) for standard container service between 9:00 p.m. and 6:00 a.m. local time, shall be (1) for standard container service between 9:00 p.m. and 6:00 a.m. local time, shall be (i) the sum of a linehaul charge of 7.12 cents per nonstop great-circle ton-mile and a terminal charge of 3.801 cents per pound originated for the period March 28, 1973 through December 31, 1973, (ii) the sum of a linehaul charge of 8.79 cents per nonstop great-circle ton-mile and a terminal charge of 3.901 cents per pound originated for the period January 1, 1974 through December 31, 1974, (iii) the sum of a linehaul charge of 9.56 cents per nonstop great-circle ton-mile and a terminal charge of 4.178 cents per pound originated for the period January 1, 1975 through December 31, 1975, (iv) the sum of a linehaul charge of 10.13 cents per nonstop great-circle ton-mile and a terminal charge of 4.466 cents per pound originated for the period January 1, 1976 through December 31, 1976, (v) the sum of a linehaul charge of 10.95 cents per nonstop great-circle ton-mile and a terminal charge of 4.675 cents per pound originated for the period January 1, 1977 through December 31, 1977, (vi) the sum of a linehaul charge of 11.58 cents per nonstop great-circle ton-mile and a terminal charge of 4.891 cents per pound originated for the period January 1, 1978 through December 31, 1978, and (vii) the sum of a linehaul charge of 11.36 cents per nonstop great-circle ton-mile and a terminal charge of 4.980 cents per pound originated for the period January 1, 1979 through June 30, 1979; and (2) for daylight container service between 6:01 a.m. and 8:59 p.m. local time, shall be (i) the sum of a linehaul charge of 5.45 cents per nonstop great-circle ton-mile and a terminal charge of 3.997 cents per

pound originated for the period March 28, 1973 through December 31, 1973, (ii) the sum of a linehaul charge of 7.05 cents per nonstop great-circle ton-mile and a terminal charge of 3.884 cents per pound originated for the period January 1, 1974 through December 31, 1974, (iii) the sum of a linehaul charge of 7.67 cents per nonstop great-circle ton-mile and a terminal charge of 4.161 cents per pound originated for the period January 1, 1975 through December 31, 1975, (iv) the sum of a linehaul charge of 8.13 cents per nonstop great-circle ton-mile and a terminal charge of 4.448 cents per pound originated for the period January 1, 1976 through December 31, 1976, (v) the sum of a linehaul charge of 8.79 cents per nonstop great-circle ton-mile and a terminal charge of 4.656 cents per pound originated for the period January 1, 1977 through December 31, 1977, (vi) the sum of a linehaul charge of 9.30 cents per nonstop great-circle ton-mile and a terminal charge of 4.871 cents per pound originated for the period January 1, 1978 through December 31, 1978, and (vii) the sum of a linehaul charge of 9.12 cents per nonstop great-circle ton-mile and a terminal charge of 4.960 cents per pound originated for the period January 1, 1979 through June 30, 1979; subject to the terms and conditions specified in Order 74-1-89, dated January 16, 1974, and subject to a minimum charge for each container equal to the product of the rate specified in (1)(i), (1)(ii), (1)(iii), (1)(iv), (1)(v), (1)(vi), (1)(vii), (2)(i), (2)(ii), (2)(iii), (2)(iv), (2)(v), (2)(vi), or (2)(vii), of this subparagraph as applicable, in which the mail is transported:

Container type	Through Dec. 31, 1973		Beginning Jan. 1, 1974	
	Standard container	Daylight container	Standard container	Daylight container
M-2			13,250	14,750
M-1			6,700	7,450
A-3	4,900	6,400	5,400	6,000
A-2	4,750	6,200	5,200	5,800
A-1	3,950	5,150	4,350	4,800
LD-9			4,300	4,800
LD-7	3,750	4,950	4,150	4,600
LD-5	2,750	3,600	3,000	3,350
LD-11	2,550	3,350	2,850	3,150
LD-10			2,750	3,050
FT-B	2,200	2,850	2,400	2,650
B			2,250	2,500
LD-1	1,800	2,350	2,000	2,200
LD-3	1,600	2,100	1,750	1,950
FT-C	1,600	2,100	1,750	1,950
LD-W	800	1,050	900	1,000

(f) Any prior order of the Board notwithstanding, all container types not specified in subparagraph (e), above, shall be subject to minimum chargeable weights established as follows: (1) For standard container service the internal cubic footage of the container will be multiplied by 11.70 pounds per cubic foot, and (2) for daylight container service the internal cubic footage of the container will be multiplied by 13.00 pounds per cubic foot.

(g) All weight in excess of the minimum chargeable weight per container established herein shall be charged at the sum of the full linehaul charge for the applicable service established in subparagraph (e) above, and the capacity-related portion of the teminal charge per pound originated as follows:

	Standard container, cents	Daylight container, cents
Mar. 28-Dec. 31, 1973	1.847	2.032
Jan. 1-Dec. 31, 1974	2.155	2.137
Jan. 1-Dec. 31, 1975	2.270	2.252
Jan. 1-Dec. 31, 1976	2.405	2.386
Jan. 1-Dec. 31, 1977	2.520	2.500
Jan. 1-Dec. 31, 1978	2.648	2.627
Jan. 1-June 30, 1979	2.686	2.665

(h) On and after March 28, 1973, for the pickup and delivery of mail in containers, by the carriers and at the points indicated in subparagraph (c) above, (1) at on-airport Postal Service facilities, *i.e.* those where the pickup or delivery vehicle does not leave airport property, there shall be no additional charge for these services, and (2) at off-airport Postal Service facilities the charges for these services shall be those applicable to the pickup and delivery of freight in containers as stated in ATP Tariff C.A.B. No. 19, superseded by ATP Tariff C.A.B. No. 231.

2. The mail ton-miles for each shipment shall be computed by using the nonstop great-circle ton-miles between the station of origin and the station of destination for each shipment as the standard mileage between such points.

3. *Definitions*—As used herein "station (or point) of origin" means the station at which the carrier first enplanes the mail shipment after receipt thereof from the Postal Service or its representatives, from another ratemaking division of the same carrier, the operations of which division are not encompassed herein, or from another carrier; and "station (or point) of destination" means the station at which the carrier deplanes the mail shipment for delivery to the Postal Service or its representatives, to a separate ratemaking division of the same carrier, the operations of which division are not encompassed herein, or to another carrier. When a mail shipment is transported by a carrier, between domestic points (as defined in paragraphs 1(a), 1(b), and 1(c) to the extent applicable for the type of mail and period involved) and international or overseas points (not within the geographical scope of paragraphs 1(a), 1(b), and 1(c)), the last scheduled station in the domestic operations subject to this order which is departed on the way to the international or overseas destination and the first scheduled station in the domestic operations subject to this order which is entered on the way from the international or overseas origination shall be considered both a "station (or point) of destination" and a "station (or point) of origin" even though the mail does not pass through the airport mail facility at such station. Each interchange point on a through flight of two or more carriers flown pursuant to an interchange agreement shall not be considered as a seaprate point of origin and destination. Except as otherwise stated above a point at which a mail shipment is transferred from one flight to another flight of the same carrier shall not be considered as a point of origin or point of destination for such shipment.

4. *Equalization of Rates.* (a) Any carrier or, pursuant to agreement, any two or more carriers providing services on an interline or interchange basis, may, by notice, elect to transport mail between stated points served by such carrier or carriers at a reduced rate equal to the rate then in effect for such service between such points by any other carrier or carriers.

(b) In the case of equalization of rates by agreement pursuant to (a) above, the agreement shall provide for the proration of the mail compensation by the participating carriers on the basis of the relative compensation which would otherwise be payable to each carrier in the absence of the provisions of paragraph (a).

(c) In the absence of an agreement among carriers, pursuant to (a) above, for equalization of rates for interline shipments between a stated pair of points, any carrier (or two or more carriers jointly) may, by notice, elect to receive as its portion of the total compensation for each such shipment the amount remaining after subtracting

from such total compensation the compensation due the other carrier or carriers involved (non-electing carriers). Such total compensation shall be computed on the basis of the lowest rate then in effect for service between the stated pair of points for any carrier or carriers. The compensation due the non-electing carrier or carriers shall be determined on the basis of all the provisions of this formula.

In those instances where two or more carriers elect to receive payment under this provision, the total payment due such carriers shall be prorated by them on the basis of the relative compensation which would otherwise be payable to each carrier in the absence of the provisions of this paragraph.

(d) In the event that any carrier is unable to enter into an agreement with any other carrier to transport mail between any stated points at a reduced rate pursuant to paragraphs (a) and (b) and elects initially to accept compensation as provided in paragraph (c), it may file an application with the Board requesting it to determine and fix a different method of apportioning the total compensation for each such shipment of mail between the participating carriers. In reviewing such applications, the Board will consider, among other pertinent factors, the need for the proposed service, the historical participation of the electing carrier or carriers in transportation of mail between such stated points, the amount of absortion required, and the grounds for refusal by the carrier or carriers to enter into an equalization agreement. After hearing the carriers concerned, either orally or in writing, in those cases where it deems such action appropriate the Board will by order prescribe the method for apportioning the total compensation between such carriers, but in no event shall the carrier or carriers refusing to enter into an agreement to equalize compensation be required to accept less than the compensation which would have been payable if the service were performed under voluntary agreement pursuant to paragraphs (a) and (b).

(3) An original and 3 copies of each notice of election and agreement, and an original and 19 copies of each application under the preceding paragraph 4(d) shall be filed with the Board and a copy thereof shall be served upon the Postmaster General and each carrier providing service between the stated points. Such notices shall contain a complete description of the reduced charge being established, the routing over which it applies, and how it is constructed and shall similarly describe the charge being equalized with. Applications filed pursuant to paragraph 4(d) shall not be deemed to reopen the mail rates or rate structure prescribed herein. All notices and agreements outstanding as of March 28, 1973, shall continue in effect under this Order until canceled as provided herein.

Any rate established pursuant to paragraph (a), (b), or (c) shall be effective for the electing carrier or carriers as of the date of filing of the notice required by such paragraphs, or such later date as may be specified in the notice, until said election is terminated: *Provided, however,* That in no event shall any such rates be effective prior to March 28, 1973. Elections may be terminated by any electing carrier upon 10 days notice filed with the Board, as aforesaid, and served upon the Postmaster General and each carrier providing service between the stated points.

Applications filed pursuant to paragraph 4(d) shall conform generally to the provisions of the rules of practice governing the filing of petitions in mail rate cases. Within seven days after the application is served, any party may file an answer in support of or in opposition to the application together with any documentary material upon which it relies. Any order upon such application pursuant to paragraph 4(d) shall be effective no earlier than the date of filing of the application within the Board: *Provided,* That in no event shall any such rates be effective prior to March 28, 1973.

5. *Eastern Flight Ordered by the Postmaster General.* (a) The fair and reasonable rates of compensation to be paid to Eastern Air Lines, Inc. for the operation of the Boston-New York-Atlanta flight ordered by the Postmaster General are as follows: $4,941 for the period June 3, 1974 through December 31, 1974, $5,714 for the period January 1, 1975 through December 31, 1975, and $5,669 for the period January 1, 1976 through December 6, 1976; all rates being established after offsetting the revenues received by the carriers for non-mail traffic.

(b) On any of the Eastern Air Lines, Inc., flights ordered by the Postmaster General, where mail was refused and the mail on board the aircraft weighed less than 12,000 pounds on either the Boston-New York or the New York-Atlanta segment, the rate applicable to that flight shall be reduced by the following amounts for each pound less than 12,000 pounds which was tendered and refused: Boston-New York segment—14.733 cents a pound for the period June 3, 1974 through December 31, 1974, 17.192 cents a pound for the period January 1, 1975 through December 31, 1975, 16.933 cents a pound for the period January 1, 1976 through December 6, 1976; and for the New York-Atlanta segment—26.442 cents a pound for the period June 3, 1974 through December 31, 1974, 30.425 cents a pound for the period January 1, 1975 through December 31, 1975, and 30.308 cents a pound for the period January 1, 1976 through December 6, 1976.

6. The terms and conditions under which the rates for containerized mail have been established herein are set forth in the attachment to this order and are an integral part thereof.

7. All service mail rates fixed and determined herein shall be paid in their entirety by the Postmaster General.

8. The petitions for reconsideration of Order 77-12-157 filed in this docket by American Airlines, Inc., The Flying Tiger Line, Inc., Pan American World Airways, Inc., and United Air Lines, Inc. are dismissed.

9. The July 14, 1978 petition of United Air Lines, Inc., requesting a revision of the temporary mail rates established by Order 77-12-157 is dismissed.

10. This order shall be served upon all parties to the proceeding in Docket 23080-2.

11. The investigation herein is terminated.

PHYLLIS T. KAYLOR,
Secretary.

ATTACHMENTS

TERMS AND CONDITIONS FOR CONTAINERIZED MAIL

1. "Container" and the various types of containers used herein refer to the types of containers defined in Tariff ATP No. CT-7, CAB No. 227, Rule 10, and Tariff ATC C-P-2, CAB 52, Rule 20(E), and Petition of the Flying Tiger Line Inc, for the establishment of container mail rates in Docket 23080-2, Appendix A, paragraph 35. The containers referred to herein are owned by the carrier.

2. A "pallet supporter" is a portable conveyor base placed under a container for the purpose of positioning such container for loading and unloading while in the possession of the Postal Service.

3. "Airbill" refers to a non-negotiable shipping document issued by the Postal Service or by the carrier. It also refers to a Postal Service dispatch document issued by USPS and approved by the airline.

4. "Advance arrangement" shall mean that the Postal Service is required to contact the carrier at least six hours prior to tender of a shipment in order to enable the Postal Service and/or the carrier to make special arrangements for the shipment.

5. "Legal holiday" shall mean any national, state or local legal holiday.

6. "Shipment" shall mean a single consignment of one or more containers from one Postal Service facility at one time at one address, receipted for in one load and moving on the airbill or Postal Service dispatch document, to one destination Postal Service facility.

7. Fractions shall be treated as follows:

(A) Fractions of pounds will be assessed at the charge for the next higher pound.

(B) In computing charges, fractions of less than one-half cent will be dropped and frac-

[1] All members concurred except Member Schaffer who did not participate.

tions of one-half cent or more will be considered as one cent.

8. Unless otherwise provided, in computing time in days, full calendar days shall be used and Sundays and legal holidays shall be included, except when the last day falls on a Sunday or legal holiday in which event the next following calendar day (other than a Sunday or legal holiday) shall be included.

9. Packing and Marking Requirements.

(A) Containers must be so prepared or packed as to insure safe transportation with ordinary care in handling. Carrier acceptance of a container shipment shall be *prima facie* evidence of the Postal Service's compliance with this paragraph.

(B) Each container must be legibly and durably marked with the name and address of the origination and destination Postal Service facility.

(C) The Postal Service shall load a container to distribute the container load so as not to exceed 200 lbs. per square foot of floor contact surface: *Provided, however,* That, for mail shipments in Type FT-O) containers, the Postal Service shall load such containers to distribute the container load so as not to exceed 150 lbs. per square foot of floor contact surface.

(D) The containers must be loaded and unloaded by the Postal Service at places other than the carrier's business.

(E) The Postal Service shall indicate in the airbill, or USPS dispatch document that the container shipment is subject to the terms and conditions of this mail rate order and shall also indicate therein and to a carrier representative if such shipment contains any articles listed in the Board's Regulations, 14 CFR 221.38(a)(5) and the other federal regulations referenced therein.

10. Unless otherwise indicated, the rates and conditions referred to herein apply airport-to-airport and are applicable only to the transportation of mail wholly loaded in containers owned by the carrier. Any mail carried outside containers will be carried at applicable non-container mail rates established by the civil Aeronautics Board.

11. (A) The Standard Container rates described herein are applicable to container mail shipments on flights departing between the hours of 9:00 p.m. and 6:00 a.m. local time.

(B) The Daylight Container rates described herein are applicable to container mail shipments on flights departing between the hours of 6:01 a.m. and 8:59 p.m. local time.

12. The following will be acceptable for carriage only upon advance arrangement:

(A) Shipments liable to impregnate or otherwise damage equipment or other shipments.

(B) Shipments requiring special attention, protection or care.

13. The carrier will reject a container prior to the performance of any transportation by air from the airport of origin when it reasonably appears to the carrier that such container is:

(A) Improperly packed or packaged, damaged, or structurally impaired;

(B) Not accompanied by proper documentation and necessary information as required by the terms and conditions herein;

(C) Subject to advance arrangements unless such arrangements have been satisfactorily completed;

(D) Packed so as to exceed the following pounds in gross weights:

Container type:	*Pounds*
A-1/A-3	10,000
A-2	12,500
LD-7	10,200
LD-11	7,000
LD-5/FT-B/FT-C	5,000
LD-3/LD-1	3,500
LD-W	1,200
M-2	25,000
M-1	15,000
LD-9	10,000
LD-10	6,500
B	5,000

14. (A) Subject to advance arrangements and the availability of a container, the carrier will furnish such container(s) (including pallet supporter) for the carriage of a shipment. The charge for the use of such container(s) (including pallet supporter) is included in the rates and charges established herein.

(B) (1) An empty container delivered to the Postal Service for loading must be tendered loaded to the carrier within 36 hours after receipt by the Postal Service.

(2) After transportation has been provided to destination a loaded container delivered to the Postal Service for unloading must be returned empty to the carrier within 36 hours after receipt by the Postal Service.

(3) In the event such container(s) (including pallet supporter) is not so tendered to the carrier as provided in (B)(1) above, or returned to the carrier as provided in (B)(2) above, a rental charge of $10.00 for each container (including pallet supporter) shall be assessed for each 24-hour period or fraction thereof in excess of 36 hours, computed (1) from the time of delivery of the empty container to the Postal Service to the time of the return of the loaded container to the carrier, or (2) from the time of delivery of the loaded container to the Postal Service to the time of the time of the return of the empty container to the carrier.

(4) A Postal Service official shall sign a container receipt, documenting the date and time of receipt for each container provided to the USPS for loading at a on-airport or off-airport location. A similar document will be excuted at destination when loaded containers are tendered to the USPS for unloading at an on-airport and off-airport location. This container receipt shall serve to document any applicable container charges which the carrier may assess the USPS.

(C) In Computing time in hours as provided in (B)(1), (2), (3) and (4) above, Saturdays, Sundays and legal holidays shall be excluded, except that when an empty container is delivered to the Postal Service for loading or a loaded container is delivered to the Postal Service for the balance of that day and then commence again on the next following calendar day other than Saturday, Sunday or legal holiday.

15. When the carrier furnishes a container (including pallet supporter) the Postal Service shall be liable to the carrier for loss of or damage to such container (including pallet supporter), occurring at any time or place other than when in the possession of the carrier.

16. The mail rates established apply also when the carrier performs motor truck transportation in lieu of transportation by aircraft for that part of the transportation between points specified in its tariff, such as Rule 13 of Tariff C.T.C. (A) No. 116, CAB No. 227.

17. (A) The Postal Service shall prepare an airbill or other non-negotiable Postal Service dispatch document indicating the number of containers in each shipment tendered, and the serial number, weight, routing and condition of each container. If the Postal Service fails to present such an airbill, the carrier will prepare a non-negotiable airbill subject to these terms and conditions.

(B) The airbill shall apply at all times when the shipment is being handled by or for the carrier, including pick-up and delivery and other ground services rendered by or for the carrier in connection with the shipment.

18. All container mail shipments shall contain mail conforming to the postal regulations applicable thereto. The carrier shall not be liable to the Postal Service for loss or expense due to the Postal Service's failure to conform to its own regulations. No liability shall attach to the carrier if the carrier in good faith determines that what it understands to be the applicable law, postal regulation, demand, order or requirement provides that it refuse and it does refuse a shipment.

19. (A) The Postal Service shall be responsible for the correctness of the particulars and statements relating to the shipment which it inserts in the airbill and shall be liable for all damages suffered by the carrier or any other person by reason of the irregularity, incorrectness or incompletness of the said particulars and statements.

(B) The statements in the airbill relating to the weight of the mail shipments shall be *prima facie* evidence of the facts stated: those relating to the number of containers in the shipment and the condition thereof shall not constitute evidence against the carrier except as far as they have been, and are stated in the airbill to have been, checked by the carrier in the presence of the Postal Service or related to the apparent conditions of the shipment.

20. By tendering the container(s) to the carrier for tansportation, the Postal Service agrees to the limitations set forth in these rules and regulations and affirms the description of the shipment as recited on the airbill, and the fact that the container and its contents are not of a nature unsuitable for the carriage of air or hazardous thereto.

21. The Postal Service shall be liable to pay or indemnify the carrier for all claims, fines, penalties, damages, costs or other sums which may be incurred, suffered or disbursed by the carrier by reason of any violation of any of the terms contained herein or any other default of the Postal Service with respect to a mail shipment.

22. The Postal Service shall be liable for all unpaid charges payable on account of a shipment including, but not confined to, sums advanced or disbursed by the carrier on account of such shipment.

23. Except as otherwise provided herein the carrier will promptly notify the Postal Service of the arrival of a mail container shipment except when delivery is to be provided by the carrier. Where the Postal Service fails to pick up a mail container shipment within 24 hours of notification or where delivery by the carrier is impossible due to a work stoppage at the destination post office, or due to any other reason outside the carrier's control, the mail container shall be stored by the carrier at the expense of the Postal Service. Such shipment wil be held subject to a charge of 50 cents per day per 100 pounds of any fraction thereof.

24. The carrier, in the exercise of due diligence and in order to protect all containerized mail accepted for transportation, will determine the routing of any shipment.

With respect to the carrier's routing of any shipment pursuant to this paragraph and unless the Postal Service specifies to the contrary at the time the carrier accepts the shipment, the carrier shall choose the most expeditious routing available via the carrier's flights.

25. Except as otherwise provided herein, the carrier has no obligation to commence or complete transportation within a certain time or according to any specific schedule, or for error in any statement of times of arrival or departure.

(a) The carrier undertakes to transport, consistent with its capacity to carry, all containerized mail accepted for transportation on flights to which such containers are tendered within the time periods established herein. All shipments are subject to the availability of equipment of the kind and type capable of handling the shipment. Nothing in this paragraph shall be construed as relieving the carrier with respect to Standard Container service of liability for fines or penalties authorized by 49 U.S.C. 1471 and 39 U.S.C. 5401(b).

(B) With respect to the Daylight containerized mail service proposed herein, such traffic will be subject to the availability of space and will be boarded after the accommodation of passengers and their baggage; and after shipments of loose sack rated mail and express. The carrier will determine on a reasonable and not unjustly discriminatory basis the boarding priority of Daylight containerized mail shipments and air freight shipments. The carrier will determine which such shipments shall not be carried on a particular flight and which shall be removed at any time or place whatsoever and when a flight shall proceed without all or any part of such a shipment. Nothing in this paragraph shall be construed as relieving the carrier of liability for negligent delay.

(C) Any shipment will be subject to refusal, delay or embargo by the carrier if such mail container shipment cannot be transported with reasonable dispatch by reason of any governmental rules, regulations, or orders or because of unavailability of equipment of the kind or type capable of handling the shipment, or for other conditions beyond the control of the carrier.

(D) All shipments are subject to three hours advance notification and to the availability of equipment of the type and kind capable of handling the shipment.

26. Charges will be paid pursuant to procedures established for the payment of charges for the transportation of mail outside of containers.

27. No employee, agent, or representative of the carrier has the authority to alter, modify, amend or waive any provisions of the rates, terms or conditions contained herein.

[FR Doc. 78-33261 Filed 11-27-78; 8:45 am]

[6335-01-M]

COMMISSION ON CIVIL RIGHTS

REGIONAL ADVISORY COMMITTEES

Agenda and Notice of Open Meeting

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a Conference of the Illinois, Indiana, Michigan, Minnesota, Ohio and Wisconsin Advisory Committees (SACs) of the Commission will convene at 9:00 am and will end at 5:00 pm on December 15, 1978, 230 South Dearborn, Room 3280—Conference Room, Chicago, Illinois 60604.

Persons wishing to attend this conference should contact the Committee Chairperson, or the Midwestern Regional Office of the Commission, 230 South Dearborn Street, 32nd Floor, Chicago, Illinois 60604.

The purpose of this meeting is to discuss advisory committee and staff operation for Fiscal Year 1979. Review of Commission program planning process of Fiscal Year 1981 program planning.

This meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., November 22, 1978.

JOHN I. BINKLEY,
Advisory Committee Management Officer.

[FR Doc. 78-33281 Filed 11-27-78; 8:45 am]

[3510-15-M]

DEPARTMENT OF COMMERCE

[S-628]

Maritime Administration

GREAT LAKES-ATLANTIC STEAMSHIP CO.

Trade Area No. 1—Great Lakes/Western Europe; Proposed Determination of Essentiality of the Proposed Intermodal Service by the Great Lakes-Atlantic Steamship Co. between U.S. Great Lakes Ports and Ports in the United Kingdom and Continent, Via the Port of Albany, N.Y.

Notice is hereby given that the Assistant Secretary of Commerce for Maritime Affairs, acting pursuant to section 211 of the Merchant Marine Act, 1936, as amended (the Act), proposes to determine that between the annual dates of December 15, and April 15, approximately, intermodal service between U.S. Great Lakes ports and ports in the United Kingdom and Continent, via the port of Albany, New York, under through intermodal bills of lading issued to and from Great Lakes ports in conjunction with connecting rail carriers, as proposed by Great Lakes-Atlantic Steamship Company, when offered in connection with all-water service during the balance of the year, is essential for the promotion, development, expansion, and maintenance of the foreign commerce of the United States. The purpose of the service via Albany, New York, is to provide a continuing year-round service from the Great Lakes during those months when the St. Lawrence Seaway is closed to navigation. In making this determination, the Assistant Secretary has taken special cognizance of the physical limitations and climatic conditions which preclude regular U.S.-flag service on a normal year-round basis and which merit special consideration if the provisions set forth in section 809(a) of the Act are to be met.

Any person, firm, or corporation having an interest in the foregoing who desires to offer views and comments thereon for consideration by the Assistant Secretary of Commerce for Maritime Affairs should submit such views and comments in writing, in triplicate, to the Secretary, Maritime Administration, Room 3099-B, Department of Commerce Building, 14th and E Streets, NW., Washington, DC 20230, by the close of business on Dec. 8, 1978, The Assistant Secretary of Commerce for Maritime Affairs will consider such views and comments and take such action with respect thereto as may be deemed appropriate.

(Catalog of Federal Domestic Assistance Program No. 11.504, Operating-Differential Subsidy (ODS).)

Dated: November 21, 1978.

By Order of the Assistant Secretary of Commerce for Maritime Affairs.

JAMES S. DAWSON, Jr.,
Secretary.

[FR Doc. 78-33211 Filed 11-27-78; 8:45 am]

[3510-13-M]

National Bureau of Standards

APPROVED INTERPRETATIONS FOR FEDERAL STANDARD COBOL (FIPS PUB 21-1)

Correction

In FR Doc. 78-32318 appearing at page 53787 in the issue for Friday, November 17, 1978, on page 53787, in the third column, under the heading, EFFECTIVE DATE OF INTERPRETATION, the date should be "May 17, 1979," and not May 17, 1978, as given.

[3510-13-M]

APPROVED INTERPRETATION FOR FEDERAL STANDARD COBOL (FIPS PUB 21-1)

Correction

In FR Doc. 78-32319 appearing at page 53789 in the issue for Friday, November 17, 1978, on page 53790, in the third column, the last paragraph should read, "Effective Date of Interpretation: This interpretation is effective on May 17, 1979."

[3510-22-M]

National Oceanic and Atmospheric Administration

MID-ATLANTIC FISHERY MANAGEMENT COUNCIL

Public Meeting

AGENCY: National Marine Fisheries Service, NOAA.

ACTION: Notice of Public Meeting.

SUMMARY: Representatives of the Gulf of Mexico, New England, South Atlantic and Caribbean Councils and representatives of the National Marine Fisheries Service Northeast Fisheries Center, Southeast Fisheries Center, and Northeast Regional Office, will meet with representatives of the Mid-Atlantic Council to discuss the draft shark fishery management plan. The Regional Fishery Management Councils were established by the Fishery Conservation and Management Act of 1976 (Pub. L. 94-265).

DATES: The meeting will convene on Monday, December 11, 1978, at 10:00 a.m. and adjourn at approximately 3:00 p.m. The meeting is open to the public.

ADDRESS: The meeting will take place at the Best Western Motel, Philadelphia Airport, Route 291, Philadelphia, PA 19153, 215-365-7000.

FOR FURTHER INFORMATION CONTACT:

Mr. John C. Bryson, Executive Director, Mid-Atlantic Fishery Management Council, Federal Building, Room 2115, North and New Streets, Dover, Delaware 19901, Telephone: 302-674-2331.

Dated: November 22, 1978.

WINFRED H. MEIBOHM,
Associate Director, National Marine Fisheries Service.

[FR Doc. 78-33217 Filed 11-27-78; 8:45 am]

[3510-11-M]

Travel Service

TRAVEL ADVISORY BOARD

Meeting

On October 24, 1978, notice was given in the FEDERAL REGISTER (43 FR, Page 49556), that the Travel Advisory Board would meet on December 5, 1978. Notice is hereby given that the Travel Advisory Board meeting will begin at 9:00 a.m., in the Capitol Room of the Hotel Washington, 15th Street and Pennsylvania Avenue, N.W., Washington, D.C. 20004.

Established in July, 1968, the Travel Advisory Board consists of senior representatives of 15 U.S. travel industry segments who are appointed by the Secretary of Commerce.

Members advise the Secretary of Commerce and Assistant Secretary of Commerce for Tourism on policies and programs designed to accomplish the purposes of the International Travel Act of 1961, as amended, and the Act of July 19, 1940, as amended.

Agenda items are as follows:

1. Report of Regional Directors Meeting
2. Report of Airline Round Table Meeting
3. Report of Personnel Relocations-ICO-Paris; Regional Directors Paris/London-Mexico City
4. Report Regarding USTS London Operation
5. Presentation by Albert N. Alexander, Director of newly established International Services Division of the Industry & Trade Administration of the Department of Commerce
6. Report of USTS Task Force on New Directions for USTS
7. Miscellaneous.

A limited number of seats will be available to observers from the public and the press. The public will be permitted to file written statements with the Committee before or after the meeting. To the extent time is available, the presentation of oral statements will be allowed.

Sue Barbour, Travel Advisory Board Liaison Officer, of the United States Travel Service, Room 1856, U.S. Department of Commerce, Washington, D.C. 20230, (telephone (202) 377-4752) will respond to public requests for information about the meeting.

FABIAN CHAVEZ, Jr.,
Assistant Secretary for Tourism.

[FR Doc. 78-33216 Filed 11-27-78; 8:45 am]

[3710-08-M]

DEPARTMENT OF DEFENSE

Department of the Army

Office of the Assistant Secretary

ARMY SCIENCE BOARD

Closed Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following Committee meeting:

Name of the committee: Army Science Board.
Dates of meeting: December 18-19, 1978.
Place: Pentagon, Washington, D.C. (exact location can be determined by contacting LTC Sweeney at 202 697-9703).
Time: 0800 to 1700 hours, December 18-19, 1978. (Closed.)

Proposed agenda. The ASB Chemical Decontamination/Contamination Avoidance AHSG will hold classified discussions of briefings they have received on the threat and other issues and programs which relate to the defensive posture of the U.S. This meeting will be closed to the public in accordance with Section 552b(c) of Title 5, U.S.C., Specifically subparagraph (1) thereof. The classified and nonclassified matters to be discussed are so inextricably intertwined so as to preclude opening any portion of the meeting.

ROBERT F. SWEENEY,
Lieutenant Colonel, GS, Executive Secretary, Army Science Board.

[FR Doc. 78-33247 Filed 11-27-78; 8:45 am]

[6450-01-M]

DEPARTMENT OF ENERGY

NATIONAL PETROLEUM COUNCIL, COORDINATING SUBCOMMITTEE AND TASK GROUPS OF THE SUBCOMMITTEE ON PETROLEUM INVENTORIES AND STORAGE AND TRANSPORTATION CAPACITIES

Meetings

Notice is hereby given that the Coordinating Subcommittee on Petroleum Inventories and Storage and Transportation Capacities of the National Petroleum Council will meet on December 4, 1978. In addition, the Tank Cars and Trucks Task Group will meet on November 28, 1978, the Waterborne Transportation Task Group and the Gas Pipeline Task Group will meet on November 29, 1978. The Petroleum Pipeline Task Group will meet on December 4, 1978, and the Inventory and Storage Task Group will meet on December 12, 1978.

The National Petroleum Council was established to provide advice, information, and recommendations to the Secretary of Energy on matters relating to oil and gas or the oil and gas industries. The Subcommittee on Petroleum Inventories and Storage and Transportation Capacities will make an analysis of the Petroleum inventories, and storage and transportation capacities of the United States, and will report its findings to the National Petroleum Council. Its analysis and findings will be based on information and data to be gathered by task groups whose efforts will be coordinated by the Coordinating Subcommittee.

The third meeting of the Coordingating Subcommittee of the Subcommittee on Petroleum Inventories and Storage and Transportation Capacities will meet on Monday, December 4, 1978, starting at 2 p.m., in the Conference Room National Petroleum Council, 1625 K Street NW., Suite 601,

Washington, D.C. Its tentative agenda is as follows:

1. Introductory Remarks by R. Scott VanDyke, Chairman.
2. Remarks by Mario Cardullo, Government Cochairman.
3. Discuss and Review Study Scope.
4. Discuss Progress of Task Groups.
5. Discuss Any Other Matters Pertinent to the Overall Assignment of the Coordinating Subcommittee.

The individual task groups will meet at the following times and locations.

Tank Cars and Trucks Task Group: Second meeting—Tuesday, November 28, 1978, starting at 10 a.m., in the Conference Room, National Petroleum Council, 1625 K Street, N.W., Suite 601, Washington, D.C.

Waterborne Transportation Task Group: Second meeting—Wednesday, November 29, 1978, starting at 11:30 a.m. in the Presidential Suite, Marriott Hotel I-70 & Lambert Airport, St. Louis, Missouri.

Gas Pipeline Task Group: Third meeting—Wednesday, November 29, 1978, starting at 12 p.m. in Room 393, Marriott-O'Hare Hotel, 8535 West Higgins Road, Chicago, Illinois.

Petroleum Pipeline Task Group: Third meeting—Monday, December 4, 1978, starting at 10 a.m. in the Conference Room, National Petroleum Council, 1625 K Street, NW., Suite 601, Washington, D.C.

Inventory and Storage Task Group: Third meeting—Tuesday, December 12, 1978, starting at 10 a.m. in Room 1031, The Midland Building, 101 Prospect Avenue, Cleveland, Ohio.

The agenda for each of these task groups will be as follows:

Remarks by Chairman Government Cochairman.
Discuss and Review Study Scope.
Discuss Questions and data sources for planned survey.
Discuss Format, Distribution and Tabulation of the Survey.
Discuss Any Other Matters Pertinent to the Overall Assignment of the Task Group.

The meetings are open to the public. The chairmen of the Coordinating Subcommittee and task groups are empowered to conduct the meetings in a fashion that will, in their judgment facilitate the orderly conduct of business. Any member of the public who wished to file a written statement with the Coordinating Subcommittee or task groups will be permitted to do so, either before or after the meeting but not later than December 29, 1978. Members of the public who wish to make oral statements should inform Dr. Erik A. Svenson, Office of Policy and Evaluation, 202-376-1846, prior to the meeting and reasonable provision will be made for their appearance on the agenda.

Transcripts of the meeting will be available for public review at the Freedom of Information Public Reading Room, Room GA-152, Department of Energy Forrestal Building, 1000 Independence Avenue, SW., Washington, D.C., between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. Any person may purchase a copy of the transcripts from the reporter.

Issued at Washington, D.C., on November 22, 1978.

WILLIAM P. DAVIS,
Deputy Director of Administration.

[FR Doc. 78-33283 Filed 11-27-78; 8:45 am]

[6450-01-M]

Energy Information Administration

INVENTORY OF CURRENT DOE ENERGY INFORMATION REPORTING REQUIREMENTS

AGENCY: Energy Information Administration.

ACTION: Notice of inventory of current Department of Energy, energy information reporting forms and expiration dates for these documents.

SUMMARY: The Energy Information Administration (EIA) of the Department of Energy (DOE) hereby gives notice to respondents and other interesterd parties of an inventory of current energy information reporting forms and their respective expiration dates. The listing which follows this notice indicates for each form the current form number, the former form number (if any), the title of the reporting form and the expiration date for the reporting form which has been set by the Office of Management and Budget (OMB).

In the future, whenever an energy information form is developed, revised, or discontinued, EIA will publish a notice in the FEDERAL REGISTER summarizing the action which is being taken.

FOR FURTHER INFORMATION CONTACT:

Carolyn Sinclair, Energy Information Administration, Room BG-035, Forrestal Building, 1000 Independence Avenue SW., Washington, D.C. 20585, 202-252-5147.

SUPPLEMENTARY INFORMATION: This notice, as well as future notices issued by EIA relating to changes in reporting requirements, includes only those forms for which EIA is responsible. Neither this notice nor future notices issued by EIA will reference the existence of reporting documents or changes in the statue of reporting requirements which are controlled by the Office of Administration within DOE.

Issued in Washington, D.C., November 16, 1978.

LINCOLN E. MOSES,
Adminstrator, Energy Information Administration.

[6450-01-C]

U.S. DEPARTMENT OF ENERGY

Energy Information Administration

Inventory of Current Energy Related* Reporting Forms

As of October 27, 1978

FORM NUMBER	OLD FORM NUMBER	FORM TITLE	FORM EXPIRATION DATE
BOM-6-1302-MS		BULK TERMINAL STOCKS OF NO. 6 AND RESIDUAL FUEL OILS BY SULFUR CONTENT	04/30/81
BOM-6-1305-M		NATURAL GAS PROCESSING PLANT RPT.	01/31/79
BOM-6-1308-M		TANKER AND BARGE SHIPMENTS OF CRUDE OIL AND PETROLEUM PRODUCTS BETWEEN STATES	04/30/81
BOM-6-1320-M		DISTRICT 5 MONTHLY PETROLEUM RPT. SUPPLEMENT	03/31/81
BOM-6-1325-T		CRUDE OIL AND PETROLEUM PRODUCTS PIPELINE SURVEY	08/31/80
BOM-6-1329-A		SALES OF ASPHALTS AND ROAD OILS	11/30/80
BOM-6-1334-A		CAPACITY OF PETROLEUM REFINERIES	01/31/79
BOM-6-1335-A		FUEL CONSUMED FOR ALL PURPOSES AT REFINERIES	01/31/79
BOM-6-1337-A,AS		FUEL OIL AND KEROSINE SALES AND INVENTORIES	11/30/79
BOM-6-1340,1341		SUPPLY AND DISTRIBUTION OF NATURAL GAS - PRODUCERS AND DISTRIBUTORS	11/30/80

*Does not include reporting requirements controlled by DOE Office of Administration

U.S. DEPARTMENT OF ENERGY

Energy Information Administration

Inventory of Current Energy Related* Reporting Forms

As of October 27, 1978

FORM NUMBER	OLD FORM NUMBER	FORM TITLE	FORM EXPIRATION DATE
BOM-6-1343-A		NATURAL GAS PROCESSING REPORT	11/30/80
BOM-6-1345-A,AS		SALES OF LIQUIFIED PETROLEUM GASES	11/30/80
BOM-6-1370-A		COKE AND COAL-CHEMICAL MATERIALS	06/30/79
BOM-6-1385-A		PENNSYLVANIA ANTHRACITE PRODUCTION	11/30/78
BOM-6-1386-A		PENNSYLVANIA ANTHRACITE PRODUCTION (MINE WITHOUT PREPARATION PLANTS)	11/30/78
BOM-6-1387-A		PENNSYLVANIA ANTHRACITE PRODUCTION (CONTRACTOR'S REPORT)	11/30/78
BOM-6-1392-A		DISTRIBUTION OF PENNSYLVANIA ANTHRACITE	11/30/78
CS-43	FEA-U531-S-0	BUILDING WORKSHOP FOLLOW-UP SURVEY	06/30/79
CS-44	FEA-532-S-0	INDUSTRY WORKSHOP FOLLOW-UP SURVEY	06/30/79
CS-45	FEA-U533-S-0	VANPOOL WORKSHOP FOLLOW-UP SURVEY	06/30/79
EIA-14	FEA-P110-M-2	REFINERS MONTHLY COST ALLOCATION REPORT	08/31/79
EIA-19	FEA-P136-M-0	SYNTHETIC NATURAL GAS PLANT REPT	08/31/79
EIA-2,3,5		MONTHLY COAL REPORT, FUEL CONSUMPTION REPORT, COKE AND COAL CHEMICAL REPORT	01/31/80
EIA-25	FEO-1000	PRIME SUPPLIERS REPORT	06/30/79
EIA-28		FINANCIAL REPORTING SYSTEM	12/31/79
EIA-35		EPA-DOE FUEL ECONOMY GUIDE EVALUATION SURVEY	06/30/79

*Does not include reporting requirements controlled by DOE Office of Administration

U.S. DEPARTMENT OF ENERGY

Energy Information Administration

Inventory of Current Energy Related* Reporting Forms

As of October 27, 1978

FORM NUMBER	OLD FORM NUMBER	FORM TITLE	FORM EXPIRATION DATE
EIA-50	FEA-G101-A-2 FPC-69 FEA-G101-0-0	ALTERNATIVE FUEL DEMAND DUE TO NATURAL GAS CURTAILMENTS	12/31/78
EIA-52		SURVEY OF FUEL SWITCHING BY END USE CUSTOMERS	12/31/78
EIA-6	BOM-6-1019-0	DISTRIBUTION OF BITUMINOUS COAL AND LIGNITE SHIPMENTS	01/31/80
EIA-63		SOLAR COLLECTOR MANUFACTURING SURVEY	04/30/79
EIA-65		FIELD EVALUATION OF ROOM AIR CONDITIONERS	12/31/78
EIA-7	BOM-6-1001-A	BITUMINOUS COAL AND LIGNITE PRODUCTION AND MINE OPERATION	01/31/80
EIA-72		MONTHLY ENERGY REVIEW SURVEY	12/31/78
EIA-79	EIA-8	RETAIL MOTOR GASOLINE SERVICE STATION SURVEY	07/31/79
EIA-84		NATIONAL ENERGY CONSUMPTION INTERIM SURVEY	06/30/79
EIA-9	FEA-P112-M-0 CLC-92	NO.2 HEATING OIL SUPPLY PRICE MONITORING REPORT (SCHEDULE A)	08/31/80
EIA-97			12/31/79
ERA-100	FEA-25	CERTIFICATION OF REQUIREMENTS FOR USE UNDER ALLOCATION LEVELS NOT SUBJECT TO AN ALLOCATION FRACTION	03/31/79
ERA-89	FEA-P102-M-0	DOMESTIC CRUDE OIL ENTITLEMENTS PROGRAM REFINERS MONTHLY RPT.	03/31/79
ERA-60	FEA-1005-IM FEA-P126-M-0 88-02 FEA-P113-M-0	REPORT OF OIL IMPORTS INTO THE UNITED STATES AND PUERTO RICO	08/30/79

*Does not include reporting requirements controlled by DOE Office of Administration

U.S. DEPARTMENT OF ENERGY

Energy Information Administration

Inventory of Current Energy Related* Reporting Forms

As of October 27, 1978

FORM NUMBER	OLD FORM NUMBER	FORM TITLE	FORM EXPIRATION DATE
ERA-99	FEA-17	REQUEST FOR ASSIGNMENT OF BASE PERIOD SUPPLY VOLUME	01/31/79
ERDA-HQ-254		QUARTERLY PROGRESS REPORT ON STATUS OF REACTOR CONSTRUCTION	07/31/81
ERDA-0170		SURVEY OF U.S. URANIUM MARKETING ACTIVITY	01/31/81
ERDA-0171		ANNUAL SURVEY URANIUM EXPLORATION AND SURFACE DRILLING COSTS AND ANTICIPATED EXPENDITURES	04/30/81
FEA-AHS-?		HOUSING ENERGY CONSERVATION	09/30/81
FEA-C602-S-1		MFRI COAL CONVERSION REPORT	12/31/78
FEA-C603-S-0		POWERPLANT IN EARLY PLANNING PROCESS IDENTIFICATION REPORT	12/31/78
FEA-C607-S-01		MAJOR FUEL BURNING INSTALLATION-EARLY PLANNING PROCESS IDENTIFICATION REPORT	12/31/78
FEA-C607-S-03		MAJOR FUEL BURNING INSTALLATION-EARLY PLANNING PROCESS IDENTIFICATION REPORT	12/31/78
FEA-F701-M-0		TRANSFER PRICING REPORT	01/31/79
FEA-G318-M-0		UNDERGROUND GAS STORAGE REPORT	06/30/79
FEA-P101-Q-1		REFINER QUARTERLY REPORT	12/31/78
FEA-P103-M-0		OLD OIL ENTITLEMENTS PROGRAM ENTITLEMENT TRANSACTION REPORT	01/31/79
FEA-P105-S-0		COMPLAINTANT'S REPORT	01/31/79
FEA-P106-S-0		APPLICATION TO STATE FOR PETROLEUM HARDSHIP OR EMERGENCY RELIEF	01/31/79

*Does not include reporting requirements controlled by DOE Office of Administration

U.S. DEPARTMENT OF ENERGY

Energy Information Administration

Inventory of Current Energy Related* Reporting Forms

As of October 27, 1978

FORM NUMBER	OLD FORM NUMBER	FORM TITLE	FORM EXPIRATION DATE
FEA-P107-S-0		STATE OFFICE OF PETROLEUM ALLOCATION STATE ACTION ON APPLICATION FOR HARDSHIP OR EMERGENCY RELIEF	01/31/79
FEA-P108-S-0		WHOLESALE PURCHASER-RESELLER'S CERTIFICATION OF DISTRIBUTION TO PURCHASERS	01/31/79
FEA-P114-M-0		MONTHLY REMITTANCE ADVICE	01/31/79
FEA-P115-S-0		OTHER REMITTANCE ADVICE	01/31/79
FEA-P116-S-0		REQUEST FOR REFUND OF OIL IMPORT FEES	01/31/79
FEA-P118-Q-1		REFINER REPORT OF BUY/SELL CRUDE OIL TRANSACTIONS (FOR ALLOCATION PROGRAM)	12/31/78
FEA-P124		DOMESTIC CRUDE OIL PURCHASER'S REPORT	07/31/80
FEA-P127-P-0		SELECTED PETROLEUM PRODUCTS PRICE REPORT	12/31/78
FEA-P302-M-1		PETROLEUM INDUSTRY MONTHLY REPORT FOR PRODUCT PRICES	06/30/79
FEA-P306-M-0		REFINER/IMPORTER MONTHLY REPORT OF PETROLEUM PRODUCT DISTRIBUTION	12/31/79
FEA-P314-M-0		MONTHLY SURVEY OF DISTILLATE & RESIDUAL FUEL SALES VOLUME TO ULTIMATE CONSUMERS	12/31/79
FEA-P315-M-0		MONTHLY SURVEY OF PROPANE SALES VOLUME TO ULTIMATE CONSUMERS	12/31/79
FEA-P320-M-0	FEO-1001 BOM-6-1300-M	REFINERY REPORT	01/31/79

*Does not include reporting requirements controlled by DOE Office of Administration

U.S. DEPARTMENT OF ENERGY

Energy Information Administration

Inventory of Current Energy Related* Reporting Forms

As of October 27, 1978

FORM NUMBER	OLD FORM NUMBER	FORM TITLE	FORM EXPIRATION DATE
FEA-P321-M-0	FEO-1006 BOM-6-1302-M	BULK TERMINAL STOCKS OF FINISHED PETROLEUM PRODUCTS	01/31/79
FEA-P322-M-0	FEO-1004 BOM-6-1303-M	PIPELINE PRODUCTS REPORT	01/31/79
FEA-P323-M-0	FEO-1002 BOM-6-1311-M	CRUDE OIL STOCKS	01/31/79
FEA-P328-Q-0		FOREIGN CRUDE OIL COST REPORT	06/30/80
FEA-SG-1,2,4		SURVEY OF GALLONAGE SALES OF GASOLINE	12/31/78
FEA-U501-S-0		LIGHTING AND THERMAL OPERATIONS AWARD APPLICATION	12/31/78
FEA-U502-Q-1		ENERGY CONSERVATION PERFORMANCE REPORT	07/31/80
FEA-U524-P-0		INDUSTRIAL ENERGY CONSERVATION AND CONSUMPTION REPORT	05/30/81
FEA-U535-A-0		ENERGY SAVINGS REPORT	09/30/80
FEA-U537-S-0		MEDIA SURVEY (RADIO AND TELEVISION)	06/30/79
FEA-U544-S-0		OFFICE OF CONSUMER SERVICES GRANT APPLICATION	07/31/80
FERC-15	FPC-15	TOTAL GAS SUPPLY OF NATURAL GAS COMPANIES ANNUAL REPORT	12/31/79
FERC-42	ICC-ACV-162	APPLICATION FOR ANNUAL OR BASIC VALUATION	07/31/80
FERC-66	FPC-1003	DATA FOR HEADWATER BENEFITS	07/31/81
FPC-R0016		REPORT ON SERVICE INTERRUPTIONS ON PIPELINE SYSTEMS	03/31/79
FPC-R0211		REPORT OF EVENTS AFFECTING BULK POWER SUPPLY (ORDER NO. 331, 361)	03/31/79

*Does not include reporting requirements controlled by DOE Office of Administration

U.S. DEPARTMENT OF ENERGY

Energy Information Administration

Inventory of Current Energy Related* Reporting Forms

As of October 27, 1978

FORM NUMBER	OLD FORM NUMBER	FORM TITLE	FORM EXPIRATION DATE
FPC-R0281		DATA ON MEASURES TO IMPLEMENT CONSERVATION OF NATURAL RESOURCES (R-454, APPENDIX B)	06/30/79
FPC-R0288		ANNUAL REPORTS OF SYSTEM FLOW DIAGRAMS	07/31/79
FPC-R0309		RESPONSE TO ORDER NO. 383-3, APPENDIX A-1, RELIABILITY AND ADEQUACY OF ELECTRIC SERVICE	06/30/79
FPC-R0326		TEMP EMERGENCY SALES/DELIVERIES OF NAT GAS FOR RESALE IC BY PERSONS WITH EXEMPTIONS UNDER NAT GAS ACT	06/30/79
FPC-R0327		RELIABILITY OF ELECTRIC AND GAS SERVICE:POLICY STATEMENT AND PROPOSED RULEMAKING (R-405)	06/30/79
FPC-1		ANNUAL REPORT FOR ELECTRIC UTILITIES, LICENSEES AND OTHERS (CLASS A AND CLASS B)	12/31/79
FPC-1-F		ANNUAL REPORT FOR PUBLIC UTILITIES AND LICENSEES (CLASS C AND CLASS D)	12/31/79
FPC-1-M		ANNUAL REPORT FOR MUNICIPAL ELECTRIC UTILITIES (HAVING ANNUAL REVENUES OF $250,000 OR MORE)	12/31/79
FPC-10A		QUESTIONNAIRE SCHED FOR CONTINUING REVIEW OF RATE SCHEDULES ANLYSIS FILED RATES, VOLUMES, QUALITY COND	09/30/79
FPC-11		NATURAL GAS PIPELINE COMPANY MONTHLY STATEMENT	06/30/79
FPC-12		POWER SYSTEM STATEMENT (CLASS I & II SYSTEMS & REQUESTED CLASS IV & V SYSTEMS)	12/31/79

*Does not include reporting requirements controlled by DOE Office of Administration

U.S. DEPARTMENT OF ENERGY

Energy Information Administration

Inventory of Current Energy Related* Reporting Forms

As of October 27, 1978

FORM NUMBER	OLD FORM NUMBER	FORM TITLE	FORM EXPIRATION DATE
FPC-12-A		POWER SYSTEM STATEMENT (CLASSES III, IV, AND V SYSTEMS)	12/31/79
FPC-12-C		INDUSTRIAL ELECTRIC GENERATING CAPACITY-SMALLER INDUSTRIAL PLANTS	06/30/79
FPC-12-D		POWER SYSTEM STATEMENT (CLASS I & II SYSTEMS & REQUESTED CLASS IV & V SYSTEMS)	12/31/79
FPC-12-F		POWERLINE AND CONSTRUCTION DATA	12/31/79
FPC-12E-2		SUPPLEMENTAL POWER STATEMENT	06/30/79
FPC-13		SUMMARY FOR NATIONAL ELECTRIC RATE BOOK	06/30/79
FPC-14		ANNUAL REPORT FOR IMPORTERS AND EXPORTERS OF NATURAL GAS	03/31/79
FPC-16		REPORT OF GAS SUPPLY, REQUIREMENTS AND CURTAILMENTS	09/30/79
FPC-17		MONTHLY REPORT OF NATURAL GAS PIPELINE CURTAILMENTS	06/30/79
FPC-2		ANNUAL REPORT OF NATURAL GAS COMPANIES (CLASS A AND CLASS B)	12/31/79
FPC-2-A		NATURAL GAS PROCESSING REPORT	12/31/79
FPC-237A		WEEKLY FUEL EMERGENCY REPORT-COAL	03/31/79
FPC-237B		WEEKLY FUEL EMERGENCY REPORT-OIL	03/31/79
FPC-3		TYPICAL NET MONTHLY BILLS FOR ELECTRICAL SERVICE	06/30/79

*Does not include reporting requirements controlled by DOE Office of Administration

U.S. DEPARTMENT OF ENERGY

Energy Information Administration

Inventory of Current Energy Related* Reporting Forms

As of October 27, 1978

FORM NUMBER	OLD FORM NUMBER	FORM TITLE	FORM EXPIRATION DATE
FPC-3-A		ALL ELECTRIC HOMES DATA SHEET	06/30/79
FPC-3-P(1)		MONTHLY RESIDENTIAL, COMMERCIAL, AND INDUSTRIAL ELECTRIC BILL DATA FOR BLS	12/31/78
FPC-3-P(2)		MONTHLY RESIDENTIAL, COMMERCIAL, AND INDUSTRIAL ELECTRIC BILL DATA FOR BLS	09/30/79
FPC-314A		APPLICATION FOR SMALL PRODUCER EXEMPTION	12/31/79
FPC-314B		ANNUAL STATEMENT TO SUPPORT SMALL PRODUCER EXEMPTION	06/30/79
FPC-334		RESERVE DEDICATION REPORT	12/31/79
FPC-38		ELECTRIC GENERATING STATION AND SUBSTATION DATA AND LOCATION	06/30/79
FPC-4		MONTHLY POWER PLANT REPORT	03/31/79
FPC-423		MONTHLY REPORT OF COST AND QUALITY OF FUELS FOR ELECTRIC PLANTS	03/31/79
FPC-45		REPORTING OF NEW NON-JURISDICTIONAL SALES OF NAT GAS BY NAT GAS CO SUBJECT TO JURISDICTION OF FPC	06/30/79
FPC-5		MONTHLY STATEMENT OF ELECTRIC OPERATING REVENUE AND INCOME	06/30/79
FPC-6		INITIAL COST STATEMENT FOR LICEASED PROJECTS	06/30/79
FPC-67		STEAM - ELECTRIC PLANT AIR AND WATER QUALITY CONTROL	12/31/79
FPC-7		STATEMENT OF ACTUAL LEGITIMATE ORIGINAL COST OF CONSTRUCTION	06/30/79

*Does not include reporting requirements controlled by DOE Office of Administration

U.S. DEPARTMENT OF ENERGY

Energy Information Administration

Inventory of Current Energy Related* Reporting Forms

As of October 27, 1978

FORM NUMBER	OLD FORM NUMBER	FORM TITLE	FORM EXPIRATION DATE
FPC-8	FPC-2 FPC-11 FPC-16	UNDERGROUND GAS STORAGE REPORT	01/31/80
FPC-80		LICENSED PROJECTS RECREATION REPORT	12/31/79
FPC-9		ANNUAL REPORT FOR LICENSEES OF PRIVATELY OWNED MAJOR PROJECTS (UTILITY AND INDUSTRIAL)	12/31/79
ICC-ACR-41		REPORT OF EXPENDITURES FOR ADDITIONS AND BETTERMENT-OIL PIPELINE COMPANIES	03/31/79
ICC-ACV-1		STATEMENT OF PROPERTY CHANGES OTHER THAN LAND AND RIGHTS-OF-WAY PIPELINE CARRIERS	03/31/79
ICC-ACV-11		INFORMATION FOR USE IN DEVELOPMENT OF WORKING CAPITAL	03/31/79
ICC-ACV-159		SERVICE LIFE DATA	12/31/78
ICC-ACV-2		SUMMARY OF LAND AND RIGHTS-OF-WAY PROPERTY CHANGES-PIPELINE CARRIERS	03/31/79
ICC-ACV-3		SUMMARY OF CHANGES IN ORIGINAL COST AND TOTAL ORIGINAL COST AT END OF PERIOD-PIPELINE CARRIERS	03/31/79
ICC-ACV-4		SUMMARY OF COST REPRODUCTION NEW AND REPRODUCTION NEW LESS DEPRECIATION-PIPELINE CARRIERS	03/31/79
ICC-ACV-5		INVENTORY OF PROPERTY OTHER THAN LAND AND RIGHTS-OF-WAY	03/31/79
ICC-ACV-6		INVENTORY OF LAND AND RIGHTS-OF-WAY	03/31/79

*Does not include reporting requirements controlled by DOE Office of Administration

U.S. DEPARTMENT OF ENERGY

Energy Information Administration

Inventory of Current Energy Related* Reporting Forms

As of October 27, 1978

FORM NUMBER	OLD FORM NUMBER	FORM TITLE	FORM EXPIRATION DATE
ICC-ACV-7		SUMMARY OF ORIGINAL COST OF INVENTORY	03/31/79
ICC-ACV-8		COST DATA FOR EQUIPMENT AND TANKS	03/31/79
ICC-ACV-9		COST DATA FOR PIPELINE CONSTRUCTION	03/31/79
ICC-P		ANNUAL REPORT - CARRIERS BY PIPELINE	03/31/79
ICC-QPS		QUARTERLY REPORT OF PIPELINE COMPANIES	12/31/79
MA-412		MANUFACTURERS OF COAL INVENTORIES AS OF 10/31/77	04/30/79
RA-16	FEA-C613-S-0	COAL LOAN GUARANTEE APPLICATION	09/30/83
S-380, 3808, 3805		SOLAR COLLECTOR MANUFACTURING SURVEY	12/31/78

*Does not include reporting requirements controlled by DOE Office of Administration

[FR Doc. 78-33145 Filed 11-27-78; 8:45 am]

[6450-01-M]

Economic Regulatory Administration

PROCEDURE FOR EARLY FILING AS PROVIDED FOR UNDER SECTION 902 OF THE POWERPLANT AND INDUSTRIAL FUEL USE ACT OF 1978

Notice is hereby given that the Economic Regulatory Administration is prepared to receive, consider and take action on:

1. Filings by certain powerplants as provided for in Section 902(a) of the Powerplant and Industrial Fuel Use Act of 1978 (FUA); and

2. Filings by major fuel burning installations for the use of petroleum under Section 211(d) of FUA as provided for in Section 902(b) of FUA.

If you wish to file early as provided for in Section 902 of FUA you must submit appropriate documents signed by your Chief Executive Officer. Such filings must be clearly labeled as filed pursuant to the Powerplant and Industrial Fuel Use Act of 1978 both on the filing itself and on the outside of the envelope in which it is sent. Your filing must be sent to the Assistant Administrator for Fuels Regulations, Room 6128, 2000 M Street NW., Washington, D.C. 20461. For further information contact: Mr. Barton R. House, Office of Fuels Regulation, Economic Regulatory Administration, Department of Energy, Room 6128, 2000 M Street NW., Washington, D.C. 20461, (202) 254-3905.

Issued in Washington, D.C., November 17, 1978.

BARTON R. HOUSE,
Assistant Administrator, Fuels Regulation, Economic Regulatory Administration, Department of Energy.

[FR Doc. 78-33282 Filed 11-27-78; 8:45 am]

[6740-02-M]

Federal Energy Regulatory Commission

[Project No. 2305]

SABINE RIVER AUTHORITY OF TEXAS AND SABINE RIVER AUTHORITY, STATE OF LOUISIANA

Application for Approval of Revised Recreation Plan

NOVEMBER 21, 1978.

Take notice that an application was filed May 24, 1978, by the Sabine River Authority, State of Lousiana (correspondence to: Mr. R. D. Morgan, Chief Engineer, Sabine River Authority of the State of Louisiana, P.O. Box 44155 Capitol Station, Baton Rouge, Louisiana 70804) under the Federal Power Act, 16 U.S.C. §§ 791a-825r, for approval of revised plans for recreational development at the constructed Toledo Bend Project, FERC No. 2305. The Authority is, with the Sabine River Authority of Texas, a joint licensee of the project, located on the Sabine River in Newton, Sabine, and Shelby Counties, Texas, and Sabine and Desoto Parishes, Louisiana. The project occupies lands of the Sabine National Forest.

The revised recreation plan proposed by the Authority is for the Louisiana portion of the project. A revised plan is also being proposed by the Sabine River Authority of Texas for the Texas portion of the project. A separate notice will be issued for that plan when the filing is completed.

The revised plan of the Sabine River Authority, State of Louisiana calls for transferring the responsibility for recreational development now vested with it to the Louisiana State Parks and Recreational Commission (La SPARC). The present recreation plan for the project approved some 16 recreational areas on the Louisiana shore. La SPARC would trade land in these areas to acquire land to develop two major state parks to be known as North and South Toledo Bend Parks, under two consecutive 5 year programs. It is anticipated that the North Toledo Bend State Park would be constructed during the first five year period, would consist of approximately 1000 to 1200 acres, and would be located on the northern half of the Louisiana side of the reservoir. The park would offer water-related recreational opportunities such as swimming, boating, skiing, and fishing, as well as facilities for activities usually available in large state parks including camping grounds, hiking trails, playgrounds and cabins. The South Toledo Bend State Park, which would be constructed during the second 5 year period, would be a 1200-acre facility near the project dam. Striped bass fishing is already established. Other recreational opportunities would be similar to those described for the North Toledo Bend Park. The estimated cost for both parks is 9.7 million dollars.

Anyone desiring to be heard or to make any protest about this application should file a petition to intervene or a protest with the Federal Energy Regulatory Commission, in accordance with the requirements of the Commission's Rules of Practice and Procedure, 18 CFR § 1.8 or § 1.10 (1977). In determining the appropriate action to take, the Commission will consider all protests filed, but a person who merely files a protest does not become a party to the proceeding. To become a party, or to participate in any hearing, a person must file a petition to intervene in accoredance with the Commission's Rules. Any protest or petition to intervene must be filed on or before January 2, 1979. The Commission's address is: 825 N. Capitol Street, NE., Washington, D.C. 20426.

The application is on file with the Commission and is available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-33270 Filed 11-27-78; 8:45 am]

[6450-01-M]

Intergovernmental and Institutional Relations

NATIONAL PETROLEUM COUNCIL; SUBCOMMITTEE ON PETROLEUM INVENTORIES AND STORAGE AND TRANSPORTATION CAPACITIES

Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92-463, 86 Stat. 770), notice is hereby given that the Subcommittee on Petroleum Inventories and Storage and Transportation Capacities of the National Petroleum Council will meet Wednesday, December 13, 1978, at 2:00 p.m. in the Mount Vernon Room, Madison Hotel, 15th and M Streets, NW., Washington, D.C.

The parent Committee was established to provide advice, information and recommendations to the Secretary of Energy on matters relating to oil and gas or the oil and gas industries.

The subcommittee will make an analysis of the petroleum inventories, and storage and transportation capacities of the United States, and will report its findings to the parent Committee.

The tentative agenda is as follows:

Discuss the Scope of the Study Being Conducted in Response to the Secretary of Energy's Request.

Discuss the Methodology and Data Collection of the Study.

Discuss the Timetable for Completion of the Study.

Discuss Any Other Matters Pertinent to the Overall Assignment From the Secretary.

The meeting is open to the public. The Chairperson of the subcommittee is empowered to conduct the meeting in a fashion that will, in his judgment, facilitate the orderly conduct of business. Any member of the public who wishes to file a written statement with the subcommittee will be permitted to do so, either before or after the meeting. Members of the public who wish to make oral statements pertaining to items on the agenda should inform Georgia Hildreth, Director, Advisory Committee Management, 202-252-5187, at least 5 days prior to the meet-

ing and reasonable provision will be made for their appearance on the agenda.

Transcripts of the meeting will be available for public review at the Freedom of Information Public Reading Room, Room GA-152, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C., between the hours of 8:00 a.m., and 4:30 p.m., Monday through Friday, except Federal holidays. Any person may purchase a copy of the transcript from the reporter.

Issued at Washington, D.C. on November 24, 1978.

GEORGIA HILDRETH,
Director, Advisory Committee Management.

[FR Doc. 78-33458 Filed 11-27-78; 9:30 am]

[6450-01-M]

Office of Hearings and Appeals

APPLICATION FOR EXCEPTION FILED BY SHELL OIL CO.

Public Hearing

AGENCY: Office of Hearings and Appeals, Department of Energy.

ACTION: Notice of public hearing.

SUMMARY: The Office of Hearings and Appeals of the Department of Energy (DOE) gives notice of a public hearing to be held to receive comments with respect to an Application for Exception filed by Shell Oil Company (Shell) on November 16, 1978. In its submission, Shell requests relief from the provisions of 10 CFR 211.10, which requires that allocations of motor gasoline be determined by reference to volumes supplied during 1972, as adjusted. The purpose of this hearing is to provide suppliers and any other interested persons an opportunity to make oral presentations regarding the basis for Shell's request that exception relief be granted to Shell which permits the firm to determine allocation levels on the basis of 1977 supply levels.

DATES: Hearing: December 8, 1978, 9:30 a.m.

Request to Speak: December 5, 1978.

ADDRESSES: Request to Speak: Debra Kidwell, Office of Public Hearing Management, Box WG, 2000 M Street, NW., Room 2313, Washington, D.C. 20461, (202) 254-5201.

Hearing Location: Room 2105, 2000 M Street, NW., Washington, D.C. 20461.

Comments and Further Information to: Thomas O. Mann, Acting Deputy Director, Office of Hearings and Appeals, 2000 M Street, NW., Room 8014, Washington, D.C. 20461, (202) 254-8606.

SUPPLEMENTARY INFORMATION: Currently pending before the Office of Hearings and Appeals are an Application for Stay, and an Application for Exception which were filed by the Shell Oil Company (Shell) on November 16, 1978.

In its Application for Exception, Shell states that the firm's current supply of gasoline is insufficient to meet the needs of its customers. Shell attributes this shortfall to two factors. According to the Shell submissions, the DOE price regulations have held Shell's gasoline prices at levels below other major oil companies. Shell states that this situation has resulted in an increased demand for the gasoline that Shell refines. Shell also indicates that the production of gasoline at the firm's Wood River, Illinois and Norco, Louisiana refineries has been partially curtailed. This curtailment, according to the firm, has been necessitated by repairs and maintenance.

Shell claims that it will be unable to fully meet its customers' current gasoline requirements until the end of December 1978. Shell contends that in order to equitably distribute its available supplies of gasoline until that time, an exception should be granted which permits it to use an allocation method which more closely reflects current demand than the 1972 base period specified in Section 211.102 of the DOE allocation regulations.

On November 22, 1978, the Office of Hearings and Appeals granted the relief which Shell had requested for a period of 20 days. That action was taken in response to an Application for Temporary Stay that had been filed on November 16, 1978. However, because of the potential impact on the various customers of Shell and the precedential effect that granting exception relief would have on other purchasers and suppliers, the DOE has determined that it would prove beneficial to convene a public hearing at which all interested parties will have an opportunity to make oral presentations regarding the merits of the underlying Shell exception application. Comments will also be accepted as to whether the Temporary Stay should be extended for an additional period of time.

Any party that wishes to make an oral presentation at the hearing should contact the individual whose name appears at the beginning of this notice. The Office of Hearings and Appeals reserves the right to limit the number of persons to be heard and to establish the procedures governing the conduct of the hearing. The Director of the Office of Hearings and Appeals or his designee will preside at these hearings.

At the hearings, representatives from Shell will be afforded an opportunity to make an initial statement. Following those statements, interested parties, including customers affected by the exception application, will be permitted to make statements, subject to reasonable time constraints. If any person wishes to ask a question of any person who has made an oral presentation at the hearing, he or she may submit the question, in writing, to the presiding officer. The presiding officer will determine whether the question is relevant and whether the time limitations permit it to be presented for an answer.

At the conclusion of all initial oral statements, each person who has made an oral statement will be given the opportunity to make a rebuttal statement. The rebuttal statements will be given in the order in which the initial statements were made and will be subject to time limitations. Any further procedural rules needed for the proper conduct of the hearing will be announced by the presiding officer.

A transcript of the hearings will be made and may be purchased from the reporter. The entire record of the hearings will be retained by DOE and will be made available for inspection at the Office of Hearings and Appeals Public Docket Room, Room B-120, 2000 M Street, NW., Washington, D.C. 20461, between the hours of 1:00 p.m. and 5:00 p.m., e.s.t., Monday through Friday.

Issued in Washington, D.C., November 22, 1978.

MELVIN GOLDSTEIN,
Director,
Office of Hearings and Appeals.

[FR Doc. 78-33396 Filed 11-24-78; 8:45 am]

[6450-01-M]

Office of Hearings and Appeals

NO. 2 (HOME) HEATING OIL

Issuance of a Decision and Recommendations

AGENCY: Department of Energy, Office of Hearings and Appeals.

ACTION: Notice of Issuance of Decision and Recommendations Concerning the Possibility of Further Regulatory Action on Home Heating Oil.

EFFECTIVE DATE: November 21, 1978.

FOR FURTHER INFORMATION CONTACT:

George B. Breznay, Deputy Director, Office of Hearings and Appeals, Department of Energy, 2000 M Street, NW., Room 8014, Washington, D.C. 20461, telephone 202-254-9681.

On January 13, 1978, the Department of Energy announced the program which it had implemented to monitor the prices of No. 2 (home) heating oil over the course of the 1977-1978 heating season. 43 FR 2917 (January 20, 1978). At the same time, the Deputy Secretary of the Department of Energy indicated that the Office of Hearings and Appeals would conduct an evidentiary hearing to evaluate the performance of the No. 2 heating oil industry since the exemption of that product from Federal price and allocation controls on July 1, 1976. *Id.* at 2919. The purpose of the hearing was to consider the need for further regulatory action regarding No. 2 heating oil in light of information which had been collected as a result of the monitoring program and any other information submitted at the hearing. The evidentiary hearing was convened on August 21, 1978 and adjourned on August 29, 1978.

Notice is hereby given that on November 20, 1978 the Office of Hearings and Appeals issued a Decision and Recommendations regarding No. 2 (home) heating oil. The findings contained in the Decision are based on the record of the August 1978 evidentiary hearing. A copy of the Decision is available at the Public Docket Room of the Office of Hearings and Appeals in Washington, D.C., Room B-120, 2000 M Street, NW. between the hours of 1 p.m. and 5 p.m. Copies may also be obtained by submitting a written request to:

Marcia B. Proctor, Chief, Docket and Publications Branch, Office of Hearings and Appeals, Department of Energy, 2000 M Street, NW., Washington, D.C. 20461.

See also 43 FR 17393 (April 24, 1978); 43 FR 24588 (June 6, 1978).

Issued in Washington, D.C., November 21, 1978.

MELVIN GOLDSTEIN,
Director,
Office of Hearings and Appeals.

[FR Doc. 78-33234 Filed 11-27-78; 8:45 am]

[6450-01-M]

ISSUANCE OF PROPOSED DECISIONS AND ORDERS

October 16 Through October 20, 1978

Notice is hereby given that during the period October 16 through October 20, 1978, the Proposed Decisions and Orders which are summarized below were issued by the Office of Hearings and Appeals of the Department of Energy with regard to Applications for Exception which had been filed with that Office.

Amendments to the DOE's procedural regulations, 10 CFR, Part 205, were issued in proposed form on September 14, 1977 (42 FR 47210 (September 20, 1977)), and are currently being implemented on an interim basis. Under the new procedures any person who will be aggrieved by the issuance of the Proposed Decision and Order in final form may file a written Notice of Objection within ten days of service. For purposes of the new procedures, the date of service of notice shall be deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. The new procedures also specify that if a Notice of Objection is not received from any aggrieved party within the time period specified in the regulations, the party will be deemed to consent to the issuance of the Proposed Decision and Order in final form. Any aggrieved party that wishes to contest any finding or conclusion contained in a Proposed Decision and Order must also file a detailed Statement of Objections within 30 days of the date of service of the Proposed Decision and Order. In that Statement of Objections an aggrieved party must specify each issue of fact or law contained in the Proposed Decision and Order which it intends to contest in any further proceeding involving the exception matter.

Copies of the full text of these Proposed Decisions and Orders are available in the public Docket Room of the Office of Hearings and Appeals, Room B-120, 2000 M Street NW., Washington, D.C. 20461, Monday through Friday, between the hours of 1 p.m. and 5 p.m., e.s.t., except federal holidays.

MELVIN GOLDSTEIN,
Director,
Office of Hearings and Appeals.

NOVEMBER 21, 1978.

Allison Propane Gas, Allison, Iowa, DEE-0082, propane

Allison Propane Gas filed an Application for Exception from the provisions of 10 CFR 212.93. The exception request, if granted, would result in the assignment by the DOE of a new base period supplier of propane to Allison. On October 20, 1978, the DOE issued a Proposed Decision and Order which determined that the exception request should be denied.

Belco Petroleum Corp., Houston, Tex., DEE-1426, crude oil

The Belco Petroleum Corporation filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D. The exception request, if granted, would permit Belco to sell the crude oil produced from the White River Unit Green River Participating Area "B," Secondary Water Flood Unit located in Uintah County, Utah at upper tier ceiling prices. On October 17, 1978, the DOE issued a Proposed Decision and Order which permits Belco to sell 70.20 percent of the crude oil produced from the White River Unit at upper tier ceiling prices.

City of Long Beach, Long Beach, Calif., DXE-1870, crude oil

The City of Long Beach filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D. The exception request, if granted, would permit the firm to continue to sell a portion of the crude oil produced from the Fault Block Unit 3, located on the Wilmington Oil Field, California, at upper tier ceiling prices. On October 16, 1978, the DOE issued a Proposed Decision and Order in which it determined that the exception relief should be granted.

Cooper & Brain, Inc., and Robert E. Brain, Wilmington, Calif., DEE-1405, crude oil

Cooper and Brain, Inc. and Robert E. Brain filed an Application for Exception from the provisions of 10 CFR 212.73. The request, if granted, would result in a retroactive exception permitting Cooper and Brain to retain overcharges resulting from their improper certification of the Brea Canyon Fee Lease as a stripper well property during 1974. On October 16, 1978, the DOE issued a Proposed Decision and Order in which it determined that the Application for Exception be denied.

Gulf Oil Corporation, Tulsa, Okla., DXE-1167, crude oil

Gulf Oil Corporation filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D. The exception request, if granted, would permit Gulf to continue to sell certain quantities of crude oil which it produces at the Northwest Graylin "D" Sand Unit at upper tier ceiling prices. On October 16, 1978 the DOE issued a Proposed Decision and Order in which it determined that Gulf should be permitted to sell at upper tier ceiling prices 45.73 percent of the crude oil produced from the Northwest Graylin "D" Sand Unit for the benefit of the working interest owners.

Charles F. Haas, Corpus Christi, Tex., DEE-1026; DEE-1027, curide oil

Charles F. Haas filed two Applictions for exception from the provisions of 10 CFR, Part 212, Subpart D. The exception requests, if granted, would relieve Haas of any obligation to make refunds for revenues which he realized during the period September 1, 1973 through November 30, 1975 as a result of charging prices for crude oil which exceeded the applicable ceiling prices. In considering the Haas exception requests, the DOE concluded that: (i) Haas failed to provide financial data relating to the firm's overall petroleum related operations the therefore failed to substantiate its claim of serious financial hardship; and (ii) Haas failed to present any compelling reasons which would justify retroactive relief. On October 17, 1978, the DOE therefore issued a Proposed Decision and Order in which it determined that the exception request should be denied.

Parente's Oil Service, Inc., Coventry, R.I., DEE-1780, No. 2 heating oil

Parente's Oil Service, Inc. filed an Application for Exception which, if granted, would relieve the firm of any obligation to prepare and submit Form EIA-9 (No. 2 Heating Oil Supply/Price Monitoring Report). On October 17, 1978, the DOE issued a Proposed Decision and Order in which it determine that the exception request should be denied.

Phillips Petroleum Co., Bartlesville, Okla., DEE-1357, crude oil

The Phillips Petroleum Company filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D. The exception request, if granted, would permit the working interest owners of the Theimer D lease located in Oklahoma County, Oklahoma to sell crude oil produced from the lease at upper tier ceiling prices. On October 17, 1978, the DOE issued a Proposed Decision and Order in which it determined that the Phillips exception request should be granted.

Puerto Rico Olefins Co., Penuelas, P.R., DEE-1303, naphtha

Puerto Rico Olefins Company filed an Application for Exception which, if granted, would result in the issuance of additional entitlements to the firm for each barrel of naptha which it imported into Puerto Rico during the period from January 2, 1977 through October 31, 1977. On October 20, 1978, the DOE issued a Proposed Decision and Order which determined that the exception request be denied.

Pyramid Corp., Inc., Wichita, Kans., DEE-0843, crude oil

Pyramid Corporation, Inc. filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D. The exception request, if granted, would permit Pyramid to retain the revenues which the firm may have realized during the period September 1, 1973 through December 31, 1974 by charging unlawful prices for the crude oil it produced and sold from the "Pascoe A" property and the "Pasco B" property, located in Barton County, Kansas. On October 16, 1978 the DOE issued a Proposed Decision and Order which determined that the exception request should be denied.

Samedan Oil Corp., Ardmore, Okla., DEE-1171, crude oil

Samedan Oil Corporation filed an Applicatoin for Exception from the provisions of 10 CFR, Part 212, Subpart D. The exception request, if granted, would permit the firm to sell the crude oil produced for its benefit from the Martin Muncrief No. 2 Lease, located in McClain County, Oklahoma at upper tier ceiling prices. On October 19, 1978, the DOE issued a Proposed Decision and Order in which it determined that the exception request be denied.

Texaco, Inc., Atlanta, Ga., DEE-4842, motor gasoline

Texaco, Inc. (Texaco) filed an Application for Exception from the provisions of 10 CFR 211.9 The exception request, if granted, would permit Texaco to terminate its base period supplier/purchaser relationship with J. C. Varn and relieve the firm of its obligation to supply Varn with motor gasoline. On October 20, 1978, the DOE issued a Proposed Decision and Order in which the DOE determined that the exception request should be granted in part.

Texaco, Inc., Denver, Colo., DEE-1306 crude oil

Texaco Inc. filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D. The exception request, if granted, would permit Texaco to sell the crude oil produced from the Northern Pacific "G" Lease at upper tier ceiling prices. On October 16, 1978, the DOE issued a Proposed Decision and Order in which it tentatively determined that the exception request should be granted.

Wallace & Wallace, Fuel Oil Co., Inc.; Wallace & Wallace Chemical & Oil Corp., St. Albans, N.Y., DEE-0388, No. 2 fuel oil

Wallace and Wallace Fuel Oil Co., Inc., and Wallace and Wallace Chemical and Oil Corporation jointly filed an Application for Exception from the provisions of 10 CFR 212.93. In the Application Wallace requested that it be permitted to retain the revenues which it realized during the period from November 1, 1973 through December 31, 1974 as a result of charging prices for No. 2 fuel oil which exceeded those permitted under CFR 212.93. On October 19, 1978, the Department of Energy issued a Proposed Decision and Order in which it determined that the Wallace exception request should be granted in part and that Wallace should be relieved of the requirement that it refund overcharges attributable to sales under contracts awarded under the 8(a) program adminstered by the Small Business Administration. The DOE also determined that wallace should not be required to refund certain overcharges made on sales of No. 2 fuel oil to other resellers.

[FR Doc. 33235 Filed 11-27-78; 8:45 am]

[6450-01-M]

ISSUANCE OF PROPOSED DECISIONS AND ORDERS

November 6 Through November 10, 1978

Notice is hereby given that during the period November 6 through November 10, 1978, the Proposed Decisions and Orders which are summarized below were issued by the Office of Hearings and Appeals of the Department of Energy with regard to Applications for Exception which had been filed with that Office.

Amendments to the DOE's procedural regulations, 10 CFR, Part 205, were issued in proposed form on September 14, 1977 (42 FR 47210 (September 20, 1977)), and are currently being implemented on an interim basis. Under the new procedures any person who will be aggrieved by the issuance of a Proposed Decision and Order in final form may file a written Notice of Objection within ten days of service. For purposes of the new procedures, the date of service of notice shall be deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. The new procedures also specify that if a Notice of Objection is not received from any aggrieved party within the time period specified in the regulations, the party will be deemed to consent to the issuance of the Proposed Decision and Order in final form. Any aggrieved party that wishes to contest any finding or conclusion contained in a Proposed Decision and Order must also file a detailed Statement of Objections within 30 days of the date of service of the Proposed Decision and Order. In that Statement of Objections an aggrieved party must specify each issue of fact or law contained in the Proposed Decision and Order which it intends to contest in any further proceeding involving the exception matter.

Copies of the full text of these Proposed Decisions and Orders are available in the Public Docket Room of the Office of Hearings and Appeals, Room B-120, 2000 M Street, N.W., Washington, D.C. 20461, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., e.s.t., except federal holidays.

MELVIN GOLDSTEIN,
Director,
Office of Hearings and Appeals.

NOVEMBER 21, 1978.

PROPOSED DECISIONS AND ORDERS

Commonwealth Oil Refining Co., Inc., Penuelas, P.R., DEE-1022, crude oil; naphtha

The Commonwealth Oil Refining Co., Inc. (Corco) filed an Application for Exception which, if granted, would have resulted in an increase in the firm's entitlement sales obligation sufficient to enable it to realize $36 million in additional revenues over a three month period. On November 7, 1978, the DOE issued a Proposed Decision and Order in which it determined that Corco should be granted an exception from the provisions of Section 211.67(d)(5)(ii) of the naphtha entitlements program and that the Corco exception request should be denied in all other respects.

Crown Central Petroleum Corp., Bellaire, Tex., DEE-1872, crude oil

The Crown Central Petroleum Corporation filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D. The exception request, if granted, would permit the working interest owners to sell the crude oil which is produced from the Santa Ana and Fresno Land Leases located in the Raisin City Field in Fresno County, California, at upper tier ceiling prices. On November 9, 1978, the DOE issued a Proposed Decision and Order which would permit Crown Central to sell at upper tier ceiling prices 82.16 percent of the crude oil produced for the benefit of the working interest owners from the Santa Ana and Fresno Land Leases.

Earlsboro Oil & Gas Co., Inc., Oklahoma City, Okla., DEE-1375, crude oil

Earlsboro Oil & Gas Co., Inc., filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D, which, if granted, would permit the firm to sell the crude oil produced from the Schroeder-Post No. 1 Well, located in Kingfisher County, Oklahoma, at upper tier ceiling prices. On November 7, 1978, the DOE issued a Proposed Decision and Order in which it determined that the exception request be denied.

Gulf Oil Corp., Houston, Tex., DXE-1973, crude oil

Gulf Oil Corporation filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D. The exception

request, if granted, would permit Gulf to continue to sell a portion of the crude oil produced from the Sidney A. Smith Lease located in Liberty County, Texas, at upper tier ceiling price levels. On November 7, 1978, the DOE issued a Proposed Decision and Order in which it determined that exception relief should be granted to the working interest owners of the Smith Lease.

Hughes & Hughes Oil & Gas, Beeville, Tex., FEE-4450, crude oil

Hughes & Hughes Oil and Gas filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D. The exception request, if granted, would permit Hughes & Hughes to retain the revenues that it realized in the sale of crude oil produced from the East Pleasanton Field Unit during the period June 1974 through January 1976. In addition, Hughes & Hughes requested prospective exception relief which would enable the firm to undertake an enhanced recovery waterflood project on the East Pleasanton Field Unit. On November 7, 1978, the DOE issued a Proposed Decision and Order in which it determined that the retroactive portions of Hughes & Hughes' exception application should be denied. The DOE also determined that prospective exception relief should be granted which would permit Hughes & Hughes to implement the enhanced recovery project at the East Pleasanton Field Unit.

Maguire Oil Co., Howard County, Tex., DXE-1791, crude oil

The Maguire Oil Company filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D. The exception request, if granted, would permit Maguire to sell the crude oil produced for the benefit of the working interest owners at the Chandler Lease at market prices. On November 6, 1978, the DOE issued a Proposed Decision and Order which determined that the exception request be granted.

[FR Doc. 78-33236 Filed 11-27-78; 8:45 am]

[6450-01-M]

ISSUANCE OF DECISIONS AND ORDERS BY THE OFFICE OF HEARINGS AND APPEALS

Week of September 11 Through September 15, 1978

Notice is hereby given that during the week of September 11 through September 15, 1978, the Decisions and Orders summarized below were issued with respect to Appeals and Applications for Exception or other relief filed with the Office of Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions which were dismissed by the Office of Hearings and Appeals and the basis for the dismissal.

APPEALS

Davison Oil Co., Inc., Mobile, Ala., DRA-0021, diesel fuel

Davison Oil Company, Inc. filed an Appeal from a Remedial Order which FEA Region VI issued to it on August 29, 1977. In the Remedial Order, Region IV found that during the period November 1, 1973 through April 30, 1974, Davison had improperly sold No. 2-D diesel fuel at prices in excess of the maximum selling prices permitted by the Mandatory Petroleum Price Regulations. The Remedial Order directed Davison to make refunds to its purchasers through direct payments within thirty days. In its appeal, Davison argued that the FEA should have been precluded from auditing the firm because an earlier audit had found no pricing violations. In considering this contention, the DOE noted that the previous audit concerned the firm's pricing of motor gasoline rather than diesel fuel. The DOE also pointed out that it is not precluded from re-investigating a firm's pricing practices when circumstances warrant. Davison also argued that it had received conflicting advice concerning the computation of maximum lawful selling prices from FEO and FEA representatives whom it contacted during the audit period. However, the DOE found that Davison had failed to submit any documentary evidence of such oral advice. In addition, the DOE determined that in the absence of countervailing factors, oral advice cannot ratify conduct which is unlawful under federal regulations. Davison also contended that the FEA improperly excluded certain freight costs from the calculation of increased product costs in determining its maximum lawful selling prices. However, the DOE found that those costs were incurred in transporting diesel fuel directly from Davison's supplier to its customers without bringing the product into inventory. The DOE determined that under the applicable regulations, that type of cost cannot be passed through as a product cost. Davison also argued that the FEA and DOE improperly delayed releasing information to the firm which prevented it from adequately preparing its Appeal. However, the DOE found that Davison had obtained the information through a Freedom of Information Act request and had ample opportunity to review the information and supplement its Appeal. Finally, Davison contended that enforcement of the Remedial Order would cause the firm to experience a serious hardship. The DOE concluded on the basis of financial data which the firm submitted that the time period for refunding overcharges to customers should be extended from thirty days to 18 months. Accordingly, the Davison Appeal was granted in part and denied in part.

Phillips-Good Oil Co., Enid, Okla., DRA-0108, crude oil

Phillips-Good Oil Company appealed from a Remedial Order issued to it by DOE Regional VI on December 20, 1977. In the Remedial Order, Region VI found that during the period November 1973 through August 1976, Phillips-Good had sold crude oil produced from seven properties at unlawful prices. The Remedial Order directed Phillips-Good to refund the overcharges plus interest to its purchasers. In its Appeal, Phillips-Good contended that Ruling 1975-12 was improperly issued and should not have been used in determining the average daily production of the seven properties. In considering the Appeal, the DOE observed that since Ruling 1975-12 was interpretive of the stripper well rule set forth in 10 CFR 212.54, it was specifically exempt from the notice and hearing requirements of the Administrative Procedure Act. The DOE also rejected the firm's contention that Ruling 1975-12 is discriminatory because it distinguishes between wells that produce crude oil from independent formations through multiple tubing strings and wells that produce through a single string of tubing. The DOE also refused to grant a stay of the Remedial Order pending resolution of similar issues in two district court proceedings. The DOE noted that administrative stays of enforcement proceedings pending federal district court determinations would have a disruptive effect on the agency's enforcement program. The DOE therefore denied the Phillips-Good Appeal.

REQUESTS FOR EXCEPTION

L. W. Babcock, Montecito, Calif., DEE-1408, crude oil

L. W. Babcock filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D. The exception request, if granted, would permit the working interest owners of the Union Avenue Field, located in Kern County, California, to sell a certain percentage of the crude oil produced from the lease at upper tier prices. In considering the exception request, the DOE observed that the data submitted by the applicant indicated that operating costs at the Union Avenue Field has increased to the point where they exceeded the revenues received from the sale of crude oil produced at lower tier prices. The DOE also found that the abandonment of the lease by Babcock would result in the loss of a significant quantity of otherwise recoverable crude oil. On the basis of the precedent established in a number of prior Decisions, the DOE approved exception relief which permitted Babcock to sell 90.86 percent of the crude oil produced from the Union Avenue Field at upper tier prices for a period of six months.

Commonwealth Oil Refining Co., Inc., San Antonio, Tex., DEE-1369, crude oil

The Commonwealth Oil Refining Company, Inc. (Corco) filed an Application for Exception in which it requested additional benefits under the Old Oil Entitlements Program for using low quality crude oil from California in its Puerto Rican refinery. In addition, the firm requested an exception from the provisions of 10 CFR 211.67(d)(4) which would permit it to earn full entitlement benefits for residual fuel oil refined from California crude oil and sold in the East Coast market. On June 30, 1978, the DOE issued a Proposed Decision and Order in which it approved the exception relief sought by Corco.

Fourteen firms filed Statements of Objections to the Proposed Decision and Order. In their Statements, the firms maintained that: (i) the DOE lacks authority to approve exception relief on gross inequity grounds to a firm that is not itself experiencing an inequity and (ii) the approval of exception relief in this proceeding constitutes unlawful rulemaking. In considering the first argument, the DOE observed that it has approved exception relief to alleviate an inequity to a third party on numerous occasions. The DOE concluded that there was no basis to the claim that it lacked authority to grant exception relief to Corco in order to mitigate the gross inequity currently experienced by California crude oil producers due to the price and allocation regulations. In response to the second argument, the DOE held that it has the discretion to proceed by either rule-making or individual

adjudication in addressing situations in which gross inequity exists.

The parties filing Statements of Objections also contended that the approval of exception relief would not result in the production of additional California crude oil, that exception relief was unnecessary since posted prices for California crude oil were recently increased, and that there was no evidence that the crude oil which Corco intends to purchase represents shut-in production. In considering these contentions, the DOE found that the production of certain types of California crude oil was either shut-in or curtailed as a result of insufficient market demand. The DOE also found that the recent increases in posted prices for California crude oil were insufficient to encourage increased production. The DOE also held that since the record contained substantial evidence of shut-in production and insufficient market demand for certain types of low gravity California crude oil Corco should not be required to supply specific evidence that the crude oil it intends to purchase would not otherwise be produced.

In view of these circumstances, the DOE determined that Corco should receive $4.13 in additional entitlement benefits for each barrel of California crude oil which it processes in its refinery, subject to certain specified restrictions. That amount was based on Corco's projected increased costs and decreased revenues due to the use of California crude oil and an incentive factor varying with the gravity of the crude oil. Finally, the DOE determined that Corco should be permitted to earn full entitlement benefits for each barrel of residual fuel oil which it produces from California crude oil and sells in the East Coast market.

Gibson Oil & Refining Co., Bakersfield, Calif., FEE-4387, crude oil

Gibson Oil & Refining Company filed an Application for Exception from the provisions of 10 CFR 211.67 (the Old Oil Entitlements Program). The exception request, if granted, would permit Gibson to receive additional entitlements for the crude oil which is refined for its account pursuant to processing agreements. In its Application, Gibson stated that a fire had destroyed its refinery, and it requested that it be granted small refiner bias entitlements for its processing agreements pending the construction of a new refinery. In considering Gibson's request, the DOE determined that the firm had failed to demonstrate that its operational difficulties were attributable to DOE regulations. The DOE also rejected Gibson's contention that exception relief would promote the national interest by increasing domestic refining capacity for California crude oil. The DOE noted that neither the entitlements program nor the exceptions process is the appropriate mechanism for receiving aid in building new refining facilities. Accordingly, the Gibson exception request was denied.

W. N. McMurry, Casper, Wyo., DXE-1477, crude oil

W. N. McMurry filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D. The request, if granted, would result in an extension of exception relief previously granted to McMurry and would permit the firm to continue to sell a portion of the crude oil produced from the West Sage Creek Lease in Park County, Wyoming, at upper tier ceiling prices. *W. N. McMurry*, 1 DOE Par. 81,117 (April 26, 1978). In considering the exception application, the DOE found that McMurry continued to incur increased operating expenses on the West Sage Creek Lease. The DOE also found that in the absence of exception relief, the working interest owners would lack an economic incentive to continue to produce crude oil from the property. In view of these determinations and on the basis of the operating data which McMurry had submitted for the most recently completed fiscal period, the DOE concluded that exception relief should be continued to permit McMurry to sell 16.31 percent of the crude oil produced from the West Sage Creek Lease for the benefit of the working interest owners at upper tier ceiling prices.

Monsanto Co., Houston, Tex., DXE-1424; DXE-1425, crude oil

Monsanto Company filed two Applications for Exception from the provisions of 10 CFR, Part 212, Subpart D. The exceptions, if granted, would result in the extension of the exception relief previously granted to Monsanto and would permit the firm to sell a portion of the crude oil produced from the Milo No. 1 and State 16 No. 1 Wells at upper tier ceiling prices. In considering the Monsanto exception request, the DOE found that the firm continued to incur increased operating expenses at the properties and that, in the absence of exception relief, the working interest owners would lack an economic incentive to produce crude oil. In view of this determination and on the basis of the operating data which Monsanto submitted for the most recently completed fiscal period, the DOE concluded that Monsanto should be permitted to sell at upper tier ceiling prices 78.36 percent of the crude oil produced from the Milo Well and 62.29 percent of the crude oil produced from the State Well for the benefit of the working interest owners.

REMEDIAL ORDER

Jimmie Austin, d.b.a. Austin Drilling Co., Seminole, Okla., DRO-0001, crude oil

Jimmie Austin, d.b.a. Austin Drilling Company filed an Objection to a Proposed Remedial Order issued to it by DOE Region VI. In the Proposed Remedial Order, Region VI determined that Austin had charged excessive prices in sales of crude oil and had thereby violated the applicable ceiling price regulations. In its objection, Austin claimed that Region VI had improperly excluded an injection well in determining the average daily production of crude oil. In considering this claim, the DOE noted that the identical contention had been considered and rejected in a number of previous decisions. The DOE also concluded that the pendency of litigation involving that issue did not provide sufficient justification for suspending enforcement of the remedial action. Austin also claimed that the Regional Office erred in finding that a $.15 per barrel payment to the firm by a purchaser constituted a bonus in excess of the posted price. The DOE found that this contention had also been denied in previous decisions and concluded that Austin had presented no basis for reaching a contrary result. Therefore, the DOE denied Austin's Objection and issued a final Remedial Order to the firm.

REQUEST FOR STAY

O. B. Mobley, Jr., Lafayette County, Ark., DES-0100, crude oil

O. B. Mobley, Jr. filed an Application for Stay of an Interpretation which was issued to him by the DOE General Counsel on March 16, 1978 and affirmed on Appeal by the DOE on June 16, 1978. *O. B. Mobley, Jr.*, 2 DOE Par. —— (June 16, 1978). If his pres<ent request were granted, Mobley would not be required to comply with the provisions of 10 CFR Part 212, Subpart D, pending judicial review of the Interpretation. In considering the Application, the DOE concluded that Mobley should not be permitted to continue to charge prices determined to be unlawful in two previous agency proceedings. The DOE also noted that approval of stay relief would frustrate the public interest in timely compliance with DOE regulations. Finally, the DOE noted that Mobley is unlikely to succeed on the merits of his lawsuit. Accordingly, the Application for Stay was denied.

SUPPLEMENTAL ORDER

Varibus Corp., Beaumont, Tex., DEX-0106, No. 2 fuel oil

The Acting Director of Enforcement of DOE Region VI requested that the Office of Hearings and Appeals issue an Order directing the disbursement of funds which the Varibus Corporation has deposited in an escrow account pursuant to a Decision and Order which the FEA issued to the firm on October 28, 1976. *Varibus Corporation*, 4 FEA Par. 85,030 (October 28, 1976). In support of his request, the Acting Director of Enforcement stated that on June 23, 1978, the United States District Court for the Eastern District of Texas sustained previous agency actions in the matter and directed Varibus to comply with the provisions of a Remedial Order which the agency issued to it on September 20, 1976. *See Varibus Corporation*, 4 FEA Par. 80,593 (December 17, 1976). The Acting Director of Enforcement also stated that Varibus informed the DOE that it does not intend to further contest the Remedial Order. Accordingly, the Office of Hearings and Appeals issued an order directing the Acting Director of Enforcement to disburse the funds in the escrow account in a manner consistent with the provisions of the Remedial Order.

DISMISSALS

The following submissions were dismissed following a statement by the applicant indicating that the relief requested was no longer needed:

Courtney F. Foos Coal Company, Virginia Beach, Virginia, DEE-1052.
Marvel Heat Corporation, Boston, Massachusetts, DEE-1017.

The following submissions were dismissed on the grounds that alternative regulatory procedures existed under which relief might be obtained:

Hill, Christopher & Phillips, Washington, D.C., DFA-0208.
Wyoming Refining Company, Denver, Colorado, DED-0495.

Copies of the full text of these decisions and orders are available in the Public Docket Room of the Office of Hearings and Appeals, Room B-120, 2000 M Street, NW., Washington, D.C.

20461, Monday through Friday, between the hours of 1 p.m. and 5 p.m., e.d.t., except Federal holidays. They are also available in *Energy Management: Federal Energy Guidelines*, a commercially published loose leaf reporter system.

MELVIN GOLDSTEIN,
Director,
Office of Hearings and Appeals.

NOVEMBER 9, 1978.

[FR Doc. 78-33237 Filed 11-27-78; 8:45 am]

[6450-01-M]

ISSUANCE OF DECISIONS AND ORDERS BY THE OFFICE OF HEARINGS AND APPEALS

Week of September 18 Through September 22, 1978

Notice is hereby given that during the week of September 18 through September 22, 1978, the Decisions and Orders summarized below were issued with respect to Appeals and Applications for Exception or other relief filed with the Office of Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions which were dismissed by the Office of Hearings and Appeals and the basis for the dismissal.

APPEALS

Gas Del Oro, Inc.; Gas Del Oro International, Inc.; El Dorado Marketing Co. of Laredo, Houston, Tex., FXA-1478, natural gas liquid products

Gas del Oro, Inc. and two affiliated companies filed an Appeal from a Decision and Order which the FEA issued on May 27, 1977 to Suburban Propane Gas Corporation, and three of its affiliated companies (collectively referred to as Ozona). In the May 27 Decision, the FEA granted Ozona's Application for Exception from the provisions of 10 CFR, Part 212, Subpart K by permitting that firm to increase its prices for natural gas liquid products above the maximum permissible levels, in order to reflect certain increased non-product costs incurred in connection with the operation of the Ozona natural gas processing plant located in Crockett County, Texas. In its Appeal, Gas del Oro contended that Ozona's non-product cost increases should have been attributed to the entire production of the Ozona plant, rather than being limited to the propane and butane which was "owned and sold" by Ozona. The DOE rejected this claim because Ozona's actual out-of-pocket costs of operating the plant were allocated only to the sales of Ozona's "owned and sold" production, rather than total plant production. In addition, the DOE found that Ozona returned all plant condensate to its suppliers and concluded that non-product costs should not be attributed to the condensate portion of the plant production. The DOE also found that the expenses that Ozona incurred in operating its gathering system should be included as a non-product cost eligible for passthrough. The record indicated, however, that Ozona received substantial income by charging producers a fee for the use of its gathering system to transport natural gas to Ozona's plant. The DOE concluded that this fee should be offset against the costs incurred at the plant and modified the exception relief approved in the May 27, 1977 Decision in order to reflect this conclusion. Finally, the DOE rejected Gas del Oro's contention that it was denied due process because it did not have access to certain information concerning Ozona's operations. The DOE concluded that this information was commercial and financial information of a confidential nature which the agency is required to protect from unwarranted disclosure. Accordingly, the Gas del Oro Appeal was granted in part with respect to the offset of the gathering system fee at the Ozona plant, but was denied in all other respects.

General Motors Corp.; Petrochemical Energy Group, Detroit, Mich.; Washington, D.C., DEA-0183; DEA-0180, natural gas liquids

The General Motors Corporation (GM)—and the Petrochemical Energy Group (PEG) filed Appeals from a Decision and Order which the DOE Economic Regulatory Administration (ERA) issued to the Consumers Power Company on March 31, 1978. In the March 31 Order, the ERA assigned Consumers the same base period use of feedstock for its Marysville, Michigan synthetic natural gas (SNG) plant that it had received under prior DOE orders. In considering the GM and PEG Appeals, the DOE found that: (i) Consumers had sufficient supplies of natural gas to satisfy the estimated needs of its priority users and industrial boiler users as specified in Section 211.29(c), without regard to the base period use of SNG feedstock granted in the March 31 order; (ii) the record did not support the ERA's determination that the current allocation should be maintained for an additional period of time; (iii) a substantial reduction in Consumers' allocation would not adversely affect the environment; and (iv) Consumers' SNG feedstock allocation could be significantly reduced without impeding the efficient transportation of butane and propane through Canada's Interprovincial Pipeline or diminishing imports of Canadian petroleum products into the United States. On the basis of these findings, the DOE concluded that the March 31 Order should be modified by substantially reducing the firm's allocation. In addition, the DOE noted that the agency had extended Consumers' SNG feedstock assignment for more than two years through the issuance of a series of interim orders. In each of those orders, the agency stated that Consumers' allocation would be continued on an interim basis to allow the firm to complete the assessment of the environmental consequences relating to a request for permanent SNG feedstock assignment which Consumers filed on June 1, 1976. In accordance with the National Environmental Policy Act of 1969 (NEPA), an environmental assessment must be undertaken to determine whether an environmental impact statement was required in connection with the disposition of the firm's petition. Because this mandatory assessment had not yet been completed, the DOE concluded that the March 31 Order might have contravened the NEPA. Therefore, the DOE held that any future allocation order issued to Consumers should take the environmental considerations into account.

Laketon Asphalt Refining, Inc., Evansville, Ind., FXA-1432, crude oil

Laketon Asphalt Refining, Inc. filed an Appeal of a Decision and Order issued to the firm on July 20, 1977. *Laketon Asphalt Refining, Inc.*, 6 FEA Par. 87,019 (July 20, 1977). In the July 20 determination, the FEA concluded that no adjustment should be made in the exception relief granted to the firm with respect to its obligations under the Entitlements Program (10 CFR 211.67) during the period April 1, 1976 through December 31, 1976. In its Appeal, Laketon contended that the FEA erred in failing to relieve the firm of its April and May 1976 entitlement purchase obligations. Laketon also challenged the FEA's finding that it would not incur a severe and irreparable injury in the absence of retroactive exception relief from its April and May 1976 entitlement purchase obligations. In evaluating Laketon's contentions, the DOE found that Laketon had failed to present evidence that it would incur an irreparable injury in the absence of retroactive exception relief. Accordingly, its Appeal was denied.

Oahu Gas Service, Inc., Ewa Beach, Hawaii, FEA-1469, propane

Oahu Gas Service, Inc. (OGS) filed an Appeal from a Decision and Order issued to it by FEA Region IX on August 7, 1977. OGS initially filed an exception application with Region IX in which it requested an increase in its annual base period volume of propane to 425,000 gallons. In denying this request, Region IX concluded that OGS had failed to demonstrate that it was incurring a gross inequity or serious hardship. In its present Appeal, OGS claimed that an increased allocation would significantly enhance the competitive structure of the Hawaiian propane market. OGS also argued that the DOE allocation regulations have severely impeded its efforts to establish itself as a viable competitor to Gasco, Inc., the only other reseller of propane in the state. According to OGS, this situation constituted a gross inequity. OGS also maintained that it was experiencing a serious hardship which will require it to terminate operations the absence of exception relief.

In considering the OGS Appeal, the DOE examined the structure of the Hawaiian propane market and made the following findings. OGS is a reseller of propane in Hawaii which is suppled by the Standard Oil Company of California (Chevron), the only refiner in that state which is capable of producing commercial propane. Because OGS initially possessed a low base period volume of propane, the ERA Region IX Office issued an order on June 6, 1974 which established the firm's base period volume of propane as 208,333 gallons per month, or 2,500,000 gallons per year. OGS currently sells 18.12 percent of propane sold on the Island of Oahu and 8.65 percent of propane sold in Hawaii. The propane produced at the Chevron refinery is currently divided between OGS and Gasco on the basis of the two firms' adjusted base period volumes. In order to meet the demand for propane in Hawaii, Gasco also imports substantial volumes of propane from foreign sources. Imported propane is considerably more expensive than the domestic price-controlled propane produced by Chevron, and Gasco's weighted average cost and price of propane are considerably greater than those of OGS. The approval of the OGS request for an increased allocation would necessar-

ily divert a portion of the domestic propane produced by Chevron from Gasco to OGS, thereby increasing the differential between their product costs. This result would benefit the OGS customers at the expense of the Gasco customers. The DOE found no evidence, however, that the exception relief requested by OGS would benefit consumers by enhancing competition. The DOE did find that OGS might be compelled by adverse financial considerations to terminate its operations on December 1, 1979 in the absence of some form of exception relief. In order to avoid the undesirable competitive effect of that situation, the DOE granted exception relief to OGS by permitting the firm to increase its price of propane by $0.05 per gallon, but denied the firm's request in all other respects.

Pennsylvania Petroleum Corp., Norwalk, Conn,. FXA-1435, motor gasoline

Pennsylvania Petroleum Corporation (PPC) filed an Appeal from a Decision and Order which the FEA issued to it on July 11, 1977. *See Pennsylvania Petroleum Corporation,* 6 FEA Par. 83,039 (July 11, 1977). In that Decision, the FEA granted prospective exception relief which permitted PPC to adjust its May 15, 1973 selling prices for gasoline. The FEA also granted retroactive exception relief, which was made effective as of January 10, 1974, the date on which PPC first filed its request for exception. On Appeal, PPC contended that it should also be relieved of the obligation to refund overcharges which occurred during November and December 1973. In considering PPC's Appeal, the DOE affirmed the prior determination that retroactive relief was warranted for the period subsequent to January 10, 1974, when PPC affirmatively sought administrative relief. The DOE found, however, that the PPC Appeal presented no basis for granting additional retroactive relief prior to January 10, 1974. Accordingly, the PPC Appeal was denied.

Phillips Petroleum Co., Bartlesville, Okla., DFA-0203, freedom of information

Phillips Petroleum Company filed an Appeal from a partial denial by the DOE Information Access Officer of a Request for Information which the firm had submitted under the Freedom of Information Act (the Act). In its initial request, Phillips sought disclosure of documents relating to the DOE Transfer Pricing Program. The Information Access Officer released ten documents to the firm, but withheld all or part of 20 other documents as exempt from mandatory disclosure under 5 USC 552(b)(4) and (5). In considering Phillips' Appeal, the DOE determined that the Information Access Officer's decision to withhold portions of one document pursuant to Exemption 4 of the Act was consistent with prior DOE determinations since the information withheld was confidential financial information which, if released, would be traceable to identifiable petroleum firms. *See, e.g., Kerr-McGee Corporation; Standard Oil Company (Indiana),* 1 DOE Par. 80,155 (December 15, 1977). With respect to 17 of the 19 documents which the Information Access Officer withheld pursuant to Exemption 5, the DOE noted that it had previously affirmed the withholding of those documents in prior Decisions. The DOE found, however, that the Information Access Officer had failed to release to Phillips certain portions of one document which the agency had ordered released in a prior Decision. *See Marathon Oil Company; Murphy Oil Corporation,* 1 DOE Par. 80,241 (April 18, 1978). The DOE therefore directed the Information Access Officer to disclose those portions of the document to Phillips. The DOE also determined that the remaining document was pre-decisional and recommendatory in nature and therefore was properly withheld pursuant to Exemption 5. Finally, the DOE found that the agency might have in its possession additional documents that were responsive to Phillips' request, but which the Information Access Officer had failed to identify. The DOE therefore remanded the matter and directed the Information Access Officer to conduct a further search for responsive documents.

REQUESTS FOR EXCEPTION

Adobe Oil & Gas Corp., Franklin County, Tex., DEE/0907, crude oil

Adobe Oil & Gas Corporation filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D which, if granted, would permit Adobe to sell a portion of the crude oil produced from the Bagwell Lease in Franklin County, Texas, at upper tier ceiling prices. In considering the Adobe request, the DOE found that the operating costs at the Bagwell Lease exceeded the revenues which the firm received from the sale of crude oil at lower tier ceiling prices. Consequently, the DOE determined that Adobe had no economic incentive to continue its production operations at the Bagwell Lease in the absence of exception relief. The DOE also found that the cessation of extraction activities at the lease would result in the loss of significant quantities of otherwise recoverable crude oil. On the basis of criteria applied in previous Decisions, the DOE determined that Adobe should be permitted to sell at upper tier ceiling prices 59.42 percent of the crude oil produced from the Bagwell Lease for the benefit of the working interest owners.

C. F. Lawrence & Associates, Inc., Midland, Tex., DEE-1304, crude oil

C. F. Lawrence & Associates, Inc. filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D which, if granted, would permit the firm to sell the crude oil produced from the Childress M. I. Masterson Lease, Located in the Apco Warner Field, Pecos County, Texas, at upper tier ceiling prices. In considering the exception request, the DOE found that Lawrence's operating costs had increased to the point where the firm no longer had an economic incentive to continue the production of crude oil from the Masterson Lease if the crude oil were subject to the lower tier ceiling price rule. The DOE also determined that if Lawrence abandoned its operations at the Masterson Lease, a substantial quantity of otherwise recoverable domestic crude oil would not be produced. On the basis of the criteria applied in previous Decisions of the FEA, the DOE determined that Lawrence should be permitted to sell 29.86 percent of the crude oil produced from the Masterson Lease for the benefit of the working interest owners at upper tier ceiling prices.

Continental Oil Co., Houston, Tex., DEE-0983; DEE-0984, crude oil

Continental Oil Company (Conoco) filed two Applications for Exception from the provisions of 10 CFR, Part 212, Subpart D, which, if granted, would permit the firm to sell the crude oil produced from the McCroskey and McNee leases located in Santa Barbara County, California at upper tier ceiling prices. In considering the exception request, the DOE found that the operating expenses incurred by Conoco at the McCroskey and McNee leases had increased to the point that the firm no longer had an economic incentive to continue the production of crude oil from the two properties if the crude oil remained subject to the lower tier ceiling price rule. The DOE also determined that if Conoco abandoned its operations at the McCroskey and McNee leases, a substantial quantity of otherwise recoverable crude oil would not be produced. On the basis of the principles enunciated in prior determinations, the DOE concluded that exception relief was warranted to provide Conoco with an economic incentive to continue its crude oil extraction operations at the two leases. In determining the appropriate level of relief, however, the DOE noted that a modification of the methodology applied in previous cases was necessary. The DOE observed that Conoco is the purchaser and refiner as well as the producer of the crude oil involved and that the ultimate benefits of any exception relief granted to Conoco as the working interest owner of the two leases will accrue to the firm in the form of reduced purchase obligations under the Domestic Crude Oil Entitlements Program (10 CFR 211.67). Consequently, the DOE determined that the levels of exception relief should be calculated with reference to the per barrel monetary benefit which the firm will realize through its reduced entitlement purchase obligation as the refiner of the crude oil. Using this methodology, the DOE determined that Conoco should be permitted to classify 77.98 percent of the crude oil produced for its benefit from the McCroskey lease and 73.41 percent of the crude oil produced for its benefit from the McNee lease as upper tier crude oil.

C. W. Culpepper, Oklahoma City, Okla., DEE-0248, crude oil

C. W. Culpepper filed an Application for Exception from the provisions of 10 CFR 212.74 which, if granted, would permit him to retroactively increase the maximum allowable ceiling price for the crude oil which he produced from the Mickie No. 1 lease in Dewey County, Oklahoma. Culpepper claimed that a mechanical breakdown in January 1972 significantly curtailed the production of crude oil for that month and resulted in an unrepresentatively low base production control level (bpcl). As a result, in January 1974, Culpepper produced 5.5 barrels of crude oil in excess of the bpcl, which he classified as new crude oil. His production level, however, did not exceed the bpcl in any month subsequent to January 1974 until he drilled a new well on the lease in October 1975. Because he had sold new crude oil in January 1974, Culpepper proceeded to accrue a cumulative deficiency which amounted to 25,942.90 barrels as of October 1975. After October 1975, Culpepper sold all of the production in excess of the bpcl as new crude oil without first eliminating the cumulative deficiency, as required by the price regulations. Thus, Culpepper was confronted with a potential liability arising from his failure to eliminate the cumulative deficiency before selling crude oil at upper tier ceiling prices. In con-

sidering Culpepper's request, the DOE concluded that the production level at the Mickie No. 1 lease during January 1972 was unrepresentative of Culpepper's normal operations. In addition, the DOE determined that he could incur a potential refund obligation of $296,334. The DOE concluded that a refund of that magnitude would have a significant adverse effect on Culpepper and would distort the intent of the price regulations. Therefore, Culpepper was granted an exception which permitted him to adopt a more representative bpcl for January 1972 and thereby eliminate his possible liability for overcharges.

Gala Gas Co., Eufala, Ala., DEO-0042, propane

Gala Gas Company filed an Application for Exception which, if granted, would permit the firm both retroactively and prospectively to sell propane at prices in excess of the maximum lawful price levels specified in 10 CFR 212.93. In considering the request, the DOE found that Gala's markup on May 15, 1973 was substantially below historic levels because the firm had not been able to increase its prices prior to the reference date by passing through cost increases which it had incurred. Based on this finding, the DOE determined that prospective exception relief was warranted because the unrepresentative markup would seriously affect the firm's ability to continue operations. The DOE also determined, however, that Gala had failed to demonstrate that it would experience irreparable financial injury without retroactive relief. Accordingly, the DOE granted the firm's request for prospective relief, but denied its request for retroactive relief.

Placid Oil Co., Washington, D.C., DEE-0156, crude oil

Placid Oil Company filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D which, if granted, would permit the firm to sell at market prices a portion of the crude oil which it intends to produce from the Black Lake Pettit Zone Unit, located in the Black Lake Field, Natchitoches Parish, Louisiana. In considering the request, the DOE found that Placid would be able to recover a substantial additional quantity of crude oil if it undertakes a proposed capital investment at the Black Lake Unit. The DOE further determined that the investment would be uneconomic if the incremental crude oil production were sold at the applicable ceiling prices specified in 10 CFR, Part 212. On the basis of these findings, the DOE concluded that an exception should be granted which would provide the firm with a sufficient economic incentive to undertake the capital investment. Placid contended that in establishing the appropriate level of relief, the DOE should depart from its standard which permits a firm to earn a 15 percent pre-tax internal rate of return on its investment. Placid argued that the DOE should instead permit the firm to realize a 15 percent after-tax return. In rejecting this contention, the DOE determined that Placid had failed to establish that the risks associated with its capital investment program were sufficiently great to warrant a departure from the standard employed in crude oil investment cases. Accordingly, the DOE permitted Placid to sell at market prices a portion of crude oil produced for the benefit of the working interest owners of the Black Lake Unit that would enable the firm to realize a 15 percent pre-tax return on its investment.

REMEDIAL ORDERS

Amax Petroleum Corp., Houston, Tex., DRO-0011, crude oil

Amax Petroleum Corporation filed a Statement of Objections to a Proposed Remedial Order which the Director of Enforcement of DOE Region IV issued to the firm. In the Proposed Remedial Order, the Regional Office determined that Amax had improperly treated each of the thirteen wells on the Martinville and Laurel fields as a separate property, thereby selling the crude oil produced from the wells at unlawful price levels. In considering the Statement of Objections, the DOE held that the existence of individual "drilling units" for each well did not create new rights to produce and therefore did not constitute separate properties. The DOE also determined that with respect to two fault blocks, Amax had failed to present sufficient geological evidence to satisfy the criteria in Ruling 1977-1 that would allow separate property treatment for separate producing formations. The DOE also affirmed the Regional Office's finding that the existence of four separate reservoirs at the Martinville field prior to September 1, 1976 did not permit Amax to consider each reservoir as a separate property. In addition, the DOE found that the Regional Office did not abuse its discretion by serving Amax with the Proposed Remedial Order as the operator of the properties. Finally, the DOE held that a Mississippi statute of limitations did not preclude federal enforcement action against Amax. Accordingly, the Amax Objection was denied and the Proposed Remedial Order was issued in final form.

W. W. Lindsey and W. E. Elliott, Pikeville, Ky., DRO-0014, crude oil

The partnership of W. W. Lindsey and W. E. Elliott filed a Statement of Objections to a Proposed Remedial Order issued to it by DOE Region IV. In that Order, the Regional Office found that during 1973 and 1974, Lindsey and Elliott improperly classified its J. W. Bailey Lease as stripper well property and sold the crude oil produced from that property at prices in excess of the ceiling prices established pursuant to 10 CFR 212.73. The Regional Office therefore directed the firm to refund the revenues that it improperly obtained. In its Statement of Objections, Lindsey and Elliott claimed that the DOE regulations exceeded the agency's statutory authority by requiring producers to exclude substantial periods of curtailed production in calculating the average daily production to determine whether a property qualified for the stripper well exemption. The DOE rejected this claim, finding that it was reasonable to exclude lengthy periods of disruption in making stripper well lease calculations. Accordingly, the Lindsey and Elliott Objection was denied, and the Proposed Remedial Order was issued in final form.

REQUEST FOR MODIFICATION OR RESCISSION

Pennzoil Producing Co., Houston, Tex., DMR-0022, crude oil

Pennzoil Producing Co. filed an Application for Modification of a Decision and Order which the DOE had issued to the firm. *Pennzoil Producing Co.*, 1 DOE Par. 81,134 (May 15, 1978). In that Decision, the DOE granted Pennzoil an extension of an exception from the crude oil ceiling price regulations. In its request for modification, the firm contended that the DOE should consider as operating expenses those capital expenditures greater than $15,000 that were made solely for the purpose of maintaining its existing crude oil operations, notwithstanding the standards set forth in *M. J. Mitchell*, 1 DOE Par. 80,130 (November 25, 1977). The firm also requested that the DOE include the firm's initial authorizations for expenditures as expense items deemed to have occurred on the actual date of the expenditure. In considering the firm's request, the DOE concluded that Pennzoil had failed to satisfy the criteria for modification of a prior determination since there was no showing of significantly changed circumstances or frustration of the initial DOE Order. Accordingly, Pennzoil's Application for Modification was denied.

REQUEST FOR STAY

Texas City Refining, Inc., Texas City, Tex., DES-0095, crude oil

Texas City Refining, Inc. (TCR) filed an Application for Stay of 10 CFR 211.67 (the Entitlements Program). The stay relief, if granted, would relieve the firm of its obligation to purchase entitlements during September and October 1978. TCR requested the stay pending a final determination on an Application for Exception which it filed on July 12, 1978. In considering the request, the DOE found that TCR's request for stay relief was based largely on the claim that it would not have a sufficient cash balance as of October 31, 1978, to maintain its operations if the firm were required to satisfy its entitlement purchase obligation. The DOE determined, however, that TCR's financial projections included expenditures which were not essential to its continued operations. The DOE restated TCR's financial projections after excluding these non-essential expenditures and concluded that the firm would have ample funds both to discharge its entitlement obligations and to maintain its business operations. Consequently, the Application for Stay was denied.

MOTION FOR DISCOVERY

Point Landing Fuel Corp. and Point Landing, Inc., New Orleans, La., DRD-0059, motion for discovery

Point Landing Fuel Corp. and Point Landing, Inc. (PLFC) filed a Motion for Discovery in connection with a Statement of Objections to a Proposed Remedial Order which the firm had previously filed. In its Motion, PLFC requested that the Economic Regulatory Administration (ERA) make available to the firm certain documents concerning the DOE's calculations of the firm's weighted average cost of product in inventory and the particular transactions in which overcharges occurred. In considering the Motion, the DOE found that the evidence which PLFC sought appeared to be relevant and material to the contentions raised in its pending objection. The DOE also found no evidence in the record to indicate that the collection of these documents, which were already in ERA's possession, would be unduly burdensome or would delay the consideration of the firm's Statement of Objections. The PLFC Motion was therefore granted.

SUPPLEMENTAL ORDERS

Jimmie Austin, d.b.a. Austin Drilling Co., Seminole, Okla., DRX-0108, crude oil

On September 11, 1978, the DOE issued a Remedial Order to Jimmie Austin, d.b.a. Austin Drilling Company. In Paragraph (3) of that Order, the DOE indicated that any person aggrieved by the determination could file an appeal with the Federal Energy Regulatory Commission. However, in a Supplemental Order, the DOE reviewed the applicable statutory authority regarding the review of Remedial Orders and concluded that the correct procedure in this case was the filing of a complaint in federal district court. Since Paragraph (3) of the September 11 Remedial Order was inconsistent with that conclusion, the DOE rescinded that paragraph and substituted a new ordering paragraph which stated that any aggrieved party may seek judicial review.

Charter Oil Co., Jacksonville, Fla., DEX-0109, crude oil

On September 22, 1978, the DOE issued a Proposed Decision and Order to Charter Oil Company which, if issued in final form, would grant exception relief with respect to the firm's obligation to purchase entitlements under the Old Oil Entitlements Program. The DOE stated that, in accordance with the applicable procedural regulations, the Proposed Decision and Order would not be issued in final form for at least ten days. The DOE also stated, however, that it would issue its monthly Entitlement Notice without taking into account the exception relief proposed for Charter in the September 22 Proposed Decision and Order. To ensure that Charter would not be required to purchase entitlement prior to the issuance of a final Decision and Order on its exception request, the DOE issued a second determination to the firm on September 22 which stayed Charter's entitlement purchase obligation to the extent specified in the Proposed Decision and Order. The stay was made effective pending the issuance of a final order with respect to the firm's exception proceeding.

Little America Refining Co., Washington, D.C., DEX-0110, crude oil

On September 22, 1978, the DOE issued a Proposed Decision and Order to Little America Refining Company which, if issued in final form, would grant exception relief with respect to the firm's obligation to purchase entitlements under the Old Oil Entitlements Program. The DOE stated that, in accordance with the applicable procedural regulations, the Proposed Decision and Order would not be issued in final form for at least ten days. The DOE also stated, however, that it would issue its monthly Entitlement Notice without taking into account the exception relief proposed for Little America in the September 22 Proposed Decision and Order. To ensure that Little America would not be required to purchase entitlements prior to the issuance of a final Decision and Order on its exception request, the DOE issued a second determination to the firm on September 22 which stayed Little America's entitlement purchase obligation to the extent specified in the Proposed Decision and Order. The stay was made effective pending the issuance of a final order with respect to the firm's exception proceeding.

DISMISSALS

The following submissions were dismissed following a statement by the applicant indicating that the relief requested was no longer needed:

Kerr-McGee Corp., Washington, D.C., DEE-1074.
Green's Propane Gas Co., Alexandria, Va., DRO-0028.
Morton & Dolley, Los Angeles, Calif., DEE-1033.
Roger Cox Petroleum, Inc., Albuquerque, N. Mex., DEE-1476.

Copies of the full text of these Decisions and Orders are available in the Public Docket Room of the Office of Hearings and Appeals, Room B-120, 2000 M Street NW., Washington, D.C. 20461, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., e.d.t., except Federal holidays. They are also available in *Energy Management: Federal Energy Guidelines*, a commercially published loose leaf reporter system.

MELVIN GOLDSTEIN,
Director,
Office of Hearings and Appeals.

NOVEMBER 9, 1978.

[FR Doc. 78-33238 Filed 11-27-78, 8:45 am]

[6450-01-M]

APPEALS AND APPLICATIONS FOR EXCEPTION

Week of October 27 Through November 3, 1978

Notice is hereby given that during the week of October 27, 1978 through November 3, 1978, the appeals and applications for exception or other relief listed in the Appendix to this Notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Under the DOE's procedural regulations, 10 CFR, Part 205, any person who will be aggreived by the DOE action sought in such cases may file with the DOE written comments on the application within ten days of service of notice, as prescribed in the procedural regulations. For purposes of those regulations, the date of service of notice shall be deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. All such comments shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, D.C. 20461.

MELVIN GOLDSTEIN,
Director, Office of Hearings and Appeals.

NOVEMBER 21, 1978.

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS

[Week of Oct. 27 through Nov. 3, 1978]

Date	Name and location of applicant	Case No.	Type of submission
Oct. 25, 1978	Pyrofax Gas Corp., Washington, D.C	DSG-0037 DES-0113	Petition for special redress and request for stay. If granted: The Office of Hearings and Appeals would review the Oct. 10, 1978, denial of the application for review of Pyrofax Gas Corp.'s application to quash a subpoena. Compliance with the subpoena would be stayed pending a determination on the firm's petition for special redress.
Oct. 27, 1978	Brown & Fox, Kansas City, Mo	DFA-0237	Appeal of an information request denial. If granted: The DOE's Oct. 4, 1978, information request denial would be rescinded and Brown & Fox would receive access to all documents relating to a fall 1976 audit of Lowe Oil Co. performed by DOE region VII.
Oct. 30, 1978	Northern Illinois Gas Co., Washington, D.C.	DEA-0239	Appeal of an ERA decision and order. If granted: The Sept. 30, 1978, decision and order issued to the Northern Illinois Gas Co. by the Economic Regulatory Administration regarding assignment of synthetic natural gas feedstocks would be rescinded.
Do	Vinson & Elkins, Washington, D.C	DRA-0238	Appeal of an information request denial. If granted: The DOE's Sept. 22, 1978, information request denial would be rescinded and Vinson & Elkins would receive access to certain DOE data concerning the transfer pricing regulations (sec. 212.84).
Do	General Motors Corp., Washington, D.C	DEA-0242	Appeal of an ERA decision and order. If granted: The Sept. 30, 1978, decision and order issued to the Northern Illinois Gas Co. by the Economic Regulatory Administration regarding assignment of synthetic natural gas feedstocks would be rescinded.
Do	Karchmer Pipe & Supply Co., Inc., Washington, D.C.	DRA-0106	Motion for discovery. If granted: Discovery would be granted with respect to the statement of objections submitted by Karchmer Pipe & Supply Co., Inc. (case No. DRO-0106).

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS—Continued

[Week of Oct. 27 through Nov. 3, 1978]

Date	Name and location of applicant	Case No.	Type of submission
Do	Petrochemical Energy Group, Washington, D.C.	DEA-0240	Appeal of an ERA decision and order. If granted: The Sept. 30, 1978, decision and order issued to the Northern Illinois Gas Co. by the Economic Regulatory Administration regarding assignment of synthetic natural gas feedstocks would be rescinded.
Do	....do	DEA-0241	Appeal of an ERA decision and order. If granted: The Sept. 30, 1978, decision and order issued by the Economic Regulatory Administration regarding the base period assignment of natural gasoline to Columbia LNG Corp. would be rescinded.
Do	Taunton Municipal Lighting Plant, Taunton, Mass.	DEH-0011	Motion for evidentiary hearing. If granted: An evidentiary hearing would be convened in connection with the objections raised by the Taunton Municipal Lighting Plant with respect to a proposed decision and order issued to Quincy Oil, Inc.
Oct. 31, 1978	Continental Oil Co., Houston, Tex	DES-1947	Stay request. If granted: Continental Oil Co. would receive a stay of the provisions of 10 CFR 211.10(b) regarding the single allocation fraction requirements pending a final determination on its application for exception.
Nov. 1, 1978	Arizona Fuels Corp., Washington, D.C	DXE-1988	Exception to the entitlements program. If granted: Arizona Fuels Corp. would be granted an exception from its obligation to purchase entitlements under the provisions of 10 CFR 211.67.
Do	Ashland Oil, Inc., Washington, D.C	DFA-0243	Appeal of an information request denial. If granted: The DOE's Sept. 29, 1978, information request denial would be rescinded and Ashland Oil, Inc. would be granted access to certain DOE memoranda regarding the application of the regulatory definition of class of purchaser.
Do	Attorney General for Ohio, Columbus, Ohio.	DEA-0245	Appeal of an ERA decision and order. If granted: The decision and order issued by the Economic Regulatory Administration on Sept. 30, 1978, regarding the base period assignment of natural gasoline to Columbia LNG Corp. would be rescinded.
Do	Ben R. Briggs, Dallas, Tex	DXE-1987	Extension of the relief granted in *Ben R. Briggs*, case No. DEE-1068 (decided July 7, 1978) (unreported decision). If granted: Ben R. Briggs would be permitted to increase its prices to reflect nonproduct cost increases incurred in producing natural gas liquids and natural gas liquid products at the east Texas natural gas processing plant.
Nov. 1, 1978	Hugh M. Briggs, Dallas, Tex	DXE-1990	Extension of relief granted in *Hugh M. Briggs*, case No. DEE-1067 (decided July 7, 1978) (unreported decision). If granted: Hugh Briggs would be permitted to increase its prices to reflect nonproduct cost increases incurred in producing natural gas liquids and natural gas liquid products at its east Texas natural gas processing plant.
Do	Marvel Heat Corp., Boston, Mass	DEE-1989	Exception to reporting requirements. If granted: Marvel Heat Corp. would no longer be required to submit form EIA-9 (No. 2 Heating Oil Supply/Price Monitoring Report).
Do	New England Petroleum Corp., Washington, D.C.	DPI-0025	Exception from base fee requirements. If granted: New England Petroleum Corp. would be permitted to import residual fuel oil into PAD district I for the period May 1, 1978, through Apr. 30, 1979, on a fee-exempt basis.
Do	Trends Publishing, Inc., Washington, D.C	DFA-0246	Appeal of an information request denial. If granted: Trends Publishing, Inc. would receive access to certain DOE data.
Nov. 2, 1978	Northland OIL & Refining Co., Tulsa, Okla.	DES-0115	Stay request. If granted: Northland Oil & Refining Co. would be granted a stay of its obligation to purchase entitlements under the provisions of 10 CFR 211.67.
Do	T-C Oil Co., Washington, D.C	DRR-0035	Request for modification. If granted: The DOE's Oct. 12, 1978, decision and order (case No. DRA-0140) would be modified and T-C Oil Co. would be permitted to offset undercharges against ovecharges which it realized on sales of crude oil.
Do	Trends Publishing Co., Washington, D.C	DFA-0244	Appeal of an information request denial. If granted: The DOE's June 16, 1978, information request denial would be rescinded and Trends Publishing Co. would receive access to certain DOE documents relating to the Nuclear Materials and Equipment Corp.
Nov. 3, 1978	Atlantic Richfield Co., Los Angeles, Calif	DES-1981	Request for stay. If granted: Atlantic Richfield Co. would receive a stay of the provisions of 10 CFR 211.9 pertaining to its base period supplier relationships.

NOTICES OF OBJECTION RECEIVED

Date	Name and location of applicant	Case No.
Oct. 30, 1978	First Chemical Corp., Washington, D.C	DEE-0097
Oct. 27, 1978	Cooper & Brain, Inc., Washington, D.C	DEE-1405
Nov. 1, 1978	Herbell Oil Production Co., Long Beach, Calif	DEE-0497
Nov. 2, 1978	Texaco, Inc., Houston, Tex	DEE-1729 through DEE-1746
Nov. 1, 1978	Pyramid Corp., Inc., Wichita, Kans	DEE-0843

REMEDIAL ORDERS

Nov. 1, 1978	Ross Production Co., Shreveport, La	DRO-0142
Do	Domind Petroleum, Inc., Washington, D.C	DRO-0140

[FR Doc. 78-33239 Filed 11-27-78; 8:45 am]

[6450-01-M]

CASES FILED WITH THE OFFICE OF HEARINGS AND APPEALS

Week of November 3 Through November 9, 1978

Notice is hereby given that during the week of November 3 through November 9, 1978, the appeals and applications for exception or other relief listed in the Appendix to this Notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Under the DOE's procedural regulations, 10 CFR, Part 205, any person who will be aggrieved by the DOE action sought in this case may file with the DOE written comments on the application within ten days of service of notice, as prescribed in the procedural regulations. For purposes of those regulations, the date of service of notice shall be deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. All such comments shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, D.C. 20461.

MELVIN GOLDSTEIN,
Director, Office of Hearings and Appeals.

NOVEMBER 21, 1978.

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS

[Week of Nov. 3 through Nov. 9, 1978]

Date	Name and location of applicant	Case No.	Type of submission
Nov. 3, 1978	Champlin Petroleum Co., Fort Worth Tex.	DES-1309	Request for stay. If granted: Champlin Petroleum Co. would be granted a stay of the provisions of 10 CFR Part 212, Subpart D, pending a final determination of its application for exception.
Do	Chevron, U.S.A., San Francisco, Calif	DEE-1993	Price exception (sec. 212.73). If granted: Chevron U.S.A. would be permitted to sell the crude oil produced from the Huntington B-PE unit, located in Orange County, Calif., at upper tier ceiling prices.
Do	Mid-Michigan Truck Service, Inc., Kalamazoo, Mich.	DES-0118	Request for stay. If granted: Mid-Michigan Truck Service, Inc. would be granted a stay of the provisions of 10 CFR 211.25, pending a determination on an application for extension of exception relief which the firm has filed with DOE region V.
Do	Moran Pipe & Supply Co., Seminole, Okla.	DXE-1992	Extension of relief granted in *Moran Pipe and Supply Company, Inc.*, 1 DOE par. 81,135 (May 19, 1978). If granted: Moran Pipe & Supply Co. would be permitted to sell the crude oil produced from the Cozar lease, located in Seminole County, Okla., at upper tier ceiling prices.
Do	Rickelson Oil & Gas Co., Tulsa, Okla	DXE-2002	Extension of relief granted in *Rickelson Oil and Gas Company*, 1 DOE par. 81,015 (Nov. 10, 1977). If granted: Rickelson Oil & Gas Co. would be permitted to sell crude oil produced from the Rosa Washington No. 3 lease at upper tier ceiling prices.
Nov. 5, 1978	Charles Fusco, Revere, Mass	DEE-1996	Exception to reporting requirements. If granted: Charles Fusco would not be required to file form EIA-9 (Supply Price Monitoring Survey).
Nov. 6, 1978	Energy Cooperatives, Inc., Long Grove, Ill.	DPI-0026	Exception to the base fee requirements. If granted: Energy Cooperatives, Inc. would be permitted to import crude oil on a fee-exempt basis.
Nov. 7, 1978	Champlin Petroleum Co., Fort Worth, Tex	DXE-2001	Extension of relief granted in *Champlin Petroleum Company*, 1 DOE par. 80,144 (Dec. 8, 1977). If granted: Champlin Petroleum Co. would be permitted to sell the crude oil produced at the fault block II, III, and IV units located at the Wilmington field, Calif., at upper tier ceiling prices.
Do	Cities Service Co., Tulsa, Okla	DEE-2000	Price exception (sec. 212.73). If granted: Cities Service Co. would be permitted to sell the crude oil produced from the State AE lease, located in Lea County, N. Mex., at upper tier ceiling prices.
Do	Howell Corp., Houston, Tex	DES-0119	Stay request. If granted: Howell Corp. would receive a stay of the DOE's Aug. 21, 1978, decision and order issued to Monsanto Co. (case No. FEE-4397).
Do	Ikard & Newsom, Inc., Las Cruces, N. Mex.	DEE-1998	Exception to reporting requirements. If granted: Ikard & Newsom, Inc. would no longer be required to file form REA-P315-M-0.
Do	Mid-Michigan Truck Service, Inc., Kalamazoo, Mich.	DXE-1997	Extension of relief granted in *Mid-Michigan Truck Service, Inc.*, 2 DOE par. —— (Nov. 2, 1978). If granted: Mid-Michigan Truck Service, Inc. would continue to receive refined petroleum products directly from the Gulf Oil Corp., its base period supplier, rather than from Gulf's designated substitute supplier, Bestrom Oil Co.
Do	Palo Pinto, Dallas, Tex	DXE-1999	Extension of relief granted in *Palo Pinto Oil & Gas Company*, case No. DXE-1324 (decided Aug. 8, 1978) unreported decision. If granted: The applicant would be permitted to increase its prices to reflect nonproduct cost increases incurred in producing natural gas liquids and natural gas liquid products at its Markley plant.
Do	Standard Oil Co., Cleveland, Ohio	DEE-1995	Price exception (sec. 212.73). If granted: Standard Oil Co. would be permitted to sell the crude oil produced from the Barndt No. 1 well, located in the Sage Creek field, Wyoming, at upper tier ceiling prices.
Nov. 8, 1978	Navajo Refining Co., Washington, D.C	DEX-0122	Supplemental order. If granted: The DOE would review the entitlements exception relief granted to Navajo Refining Co. during its fiscal year ended July 31, 1978, in order to determine whether the level of relief accorded to the firm was appropriate.
Do	Office of Enforcement, Washington, D.C.	DRD-0012	Motion for discovery. If granted: The Office of Enforcement would be granted discovery in connection with a proposed remedial order issued by DOE region IV to Corpus Christi Management Co. and J. W. McKellip.

REMEDIAL ORDERS—NOTICES OF OBJECTION RECEIVED

Date	Name and location of applicant	Case No.
Nov. 3, 1978	A. H. Wadsworth, Jr., Houston, Tex	DRO-0143
Nov. 7, 1978	Austral Oil Co., Inc., Houston, Tex	DRO-0141

NOTICES OF OBJECTION RECEIVED

Nov. 3, 1978	Wallace & Wallace Fuel Oil Co., Washington, D.C	DEE-0388
Nov. 7, 1978	Texaco, Inc., Houston, Tex	FEE-4842
Do	Charles F. Haas, Corpus Christi, Tex	DEE-1026, DEE-1027
Nov. 3, 1978	Don Baldwin Oil, Gloversville, N.Y	DEE-1062

[FR Doc. 78-33240 Filed 11-27-78; 8:45 am]

[6560-01-M]

ENVIRONMENTAL PROTECTION AGENCY

[FRL 1015-1; OPP-180249]

CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE

Issuance of Specific Exemption To Use Sodium Chlorate as a Harvest Aid To Desiccate Blackeye, Lima, and Pinto Beans

The Environmental Protection Agency (EPA) has granted a specific exemption to the California Department of Food and Agriculture (hereafter referred to as the "Applicant") to use sodium chlorate as a pre-harvest desiccant on 154,000 acres of dry beans in California. This exemption was granted in accordance with, and is subject to, the provisions of 40 CFR Part 166, which prescribes requirements for exemption of Federal and State agencies for use of pesticides under emergency conditions.

This notice contains a summary of certain information required by regulation to be included in the notice. For more detailed information, interested parties are referred to the application on file with the Registration Division (TS-767), Office of Pesticide Programs, EPA, 401 M Steet, SW., Room E-315, Washington, D.C.

According to the Applicant, this year there is unusually high moisture in the bean crop due to unseasonal, heavy rains in California. The wet beans have prevented the proper operation of harvest machinery; green foliage on the plants prevents the soil from drying enough to permit the machinery to pass through the field. The Applicant further stated that seasonal rains normally start during the latter half of October, and it was essential that harvest be completed before the rains began. Finally, the Applicant stated that there was no desiccant registered for this use or alternative method of control presently available. Without the use of a desiccant chemical to facilitate harvesting, heavy losses are likely to occur; the Applicant estimated that the entire crop, valued at $65,411,000 was in jeopardy. Some 154,000 acres of blackeye, lima, and pinto beans are involved. It was proposed that sodium chlorate be applied by aircraft at a rate of not more than 6 pounds per acre of crop.

There is neither an established tolerance, nor an exemption from the requirement of a tolerance for sodium chlorate on blackeye, lima, and pinto beans. However, sodium chlorate is exempted from the requirement of a tolerance for residues in or on cottonseed, chili peppers, rice, and sorghum grain. The maximum rate of application proposed by the Applicant was equivalent to six pounds of sodium chlorate per acre, which is the same rate as that granted by EPA for the use of this pesticide on sorghum and rice; furthermore, the use pattern is essentially the same. The Applicant requested the use of FMC Corporation's Light MC Defoliant, which is registered by EPA and which has fire retardant capabilities.

After reviewing the application and other available information, EPA has determined that (a) an emergency situation has occurred; (b) there is no pesticide presently registered and available for use to desiccate the blackeye, lima, and pinto beans in California; (c) there are no alternative means of control, taking into account the efficacy and hazard; (d) significant economic problems may result if the situation is not controlled; and (e) the time available for action to mitigate the problems posed is insufficient for a pesticide to be registered for this use. Accordingly, the Applicant has been granted a specific exemption to use the pesticide noted above until December 15, 1978, to the extent and in the manner set forth in the application. The specific exemption is also subject to the following conditions:

1. The dosage rate shall not exceed six pounds of active ingredient sodium chlorate per acre;

2. FMC Corporation's Liquid MC Defoliant (EPA Reg. No. 279-1993) will be the product used;

3. The treated areas shall not exceed 154,000 acres;

4. A fourteen-day pre-harvest interval for all treated beans will be observed;

5. A restriction prohibiting grazing of treated fields or feeding treated bean foliage to livestock will be imposed;

6. Applications are limited to blackeye, lima, and pinto beans;

7. The Applicant will be responsible for instructing personnel applying the sodium chlorate in the proper application procedures;

8. The Applicant must supervise aerial applications to avoid to minimize drift to non-target areas;

9. EPA has determined that dried beans treated according to the conditions of use listed above should not pose a threat to human health. The Food and Drug Administration of the U.S. Department of Health, Education, and Welfare has been advised of this action;

10. The EPA will be immediately informed of any adverse effects resulting from the use of sodium chlorate in connection with this exemption;

11. California and concerned growers must pursue the appropriate tolerance clearance of sodium chlorate for use on dry beans either through the IR-4 project or the Registration Division, EPA; and

12. The Applicant is responsible for assuring that all of the provisions of this specific exemption are met and must submit a report summarizing the results of this program by July 15, 1979.

Dated: November 20, 1978.

(Sec. 18, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 89 Stat. 751; (7 U.S.C. 136(a) *et seq.*)

EDWIN L. JOHNSON,
Deputy Assistant Administrator for Pesticide Programs.

[FR Doc. 33200 Filed 11-27-78; 8:45 am]

[6560-01-M]

[FRL 1015-2; PP 5G1579/T173]

5-CHLORO-3-METHYL-4-NITRO-1*H*-PYRAZOLE

Renewal of Temporary Tolerance

On August 12, 1977, the Environmental Protection Agency (EPA) announced (42 FR 40969) the extension of temporary tolerance for residues of the plant regulator 5-chloro-3-methyl-4-nitro-1*H*-pyrazole in or on oranges at 0.1 part per million (ppm).

This tolerance was established (40 FR 17314) in response to a pesticide petition (PP 5G1579) submitted by Abbott Laboratories, Agricultural and Veterinary Products Div., North Chicago, IL 60064. This renewal expired June 20, 1978.

Abbott Laboratories requested a 15-month renewal of this temporary tol-

erance to permit the marketing of the above raw agricultural commodities when treated in accordance with the provisions of the experimental use permit that has been renewed under the Federal Register Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 89 Stat. 751; 7 U.S.C. 136(a) *et seq.*).

The scientific data reported and all other relevant material were evaluated, and it was determined that a renewal of the temporary tolerance would protect the public health. Therefore, the temporary tolerance has been renewed on condition that the pesticide is used in accordance with the experimental use permit with the following provisions:

1. The total amount of the pesticide to be used must not exceed the quantity authorized by the experimental use permit.

2. Abbott Laboratories must immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The firm must also keep records of production, distribution, and performance and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration.

This temporary tolerance expires October 5, 1979. Residues not in excess of 0.1 ppm remaining in or on the above Agricultural commodity after this expiration date will not be considered actionable if the pesticide is legally applied during the term of, and in accordance with, the provisions of the experimental use permit and temporary tolerance. This temporary tolerance may be revoked if the experimental use permit is revoked or if any scientific data or experience with this pesticide indicate such revocation is necessary to protect the public health. Inquiries concerning this notice may be directed to Product Manager (PM) 25, Registration Division (TS-767), Rm. E-359, Office of Pesticide Programs, EPA, 401 M Street SW., Washington, D.C. 20460, 202-755-7012.

Dated: November 17, 1978.

(Sec. 408(j), Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(j)).)

DOUGLAS D. CAMPT,
Acting Director,
Registration Division.

[FR Doc. 78-33199 Filed 11-27-78; 8:45 am]

[6560-01-M]

[FRL 1015-3; PP 8G2130/T172]

PROPYLENE

Establishment of a Temporary Exemption from the Requirement of a Tolerance

Great Western Sugar Co., Agricultural Research Center, Sugar Mill Road, Longmont, Co 80501, submitted a pesticide petition (pp 8G2130) to the Environmental Protection Agency (EPA). This petition requested that a temporary exemption from the requirement of a tolerance be established for residues of the growth regulator propylene in or on the raw agricultural commodity sugar beets.

This temporary exemption from the requirement of a tolerance will permit the marketing of the above raw agricultural commodity when treated in accordance with an experimental use permit that has been issued under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (86 Stat. 973, 89 Stat. 751; 7 U.S.C. 136(a) *et seq.*).

Based on an evaluation of the scientific data reported and other relevant material, it was concluded that the requested exemption from the requirement of a tolerance would protect the public health. The temporary exemption has been established for the pesticide, therefore, with the following provisions:

1. The total amount of the pesticide to be used must not exceed the quantity authorized by the experimental use permit.

2. Great Western Sugar Co. must immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The firm must also keep records of production, distribution, and performance and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration.

This temporary exemption from the requirement of a tolerance expires October 20, 1979. Residues of the pesticide remaining in or on sugar beets after this expiration date will not be considered actionable if the pesticide is legally applied during the term of, and in accordance with, the provisions of the experimental use permit and the temporary exemption. This temporary exemption may be revoked if the experimental use permit is revoked or if any scientific data or experience with this pesticide indicate such revocation is necessary to protect the public health. Inquiries concerning this notice may be directed to Mr. Robert Taylor, Product Manager (PM) 25, Registration Division (TS-767), Office of Pesticide Programs, East Tower, 401 M St., SW, Washington, DC 20460 (202-755-7012).

Dated: November 17, 1978.

DOUGLAS D. CAMPT,
Acting Director,
Registration Division.

(Sec. 408(j), Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(j)).

[FR Doc. 78-33198 Filed 11-27-78; 8:45 am]

[6560-01-M]

ENVIRONMENTAL PROTECTION AGENCY

[FRL 1014-1; OPP-42052B]

STATE OF WISCONSIN

State Plan for Certification of Commercial and Private Applicators of Restricted Use Pesticides—Approval Status

Section 4(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 7 U.S.C. 136 *et seq.*), and the implementing regulations of 40 CFR Part 171 require each State desiring to certifiy applicators to submit a plan for such purpose, subject to approval by the U.S. Environmental Protection Agency (EPA). On December 19, 1977, the Wisconsin State Plan was approved contingent upon promulgation by the Wisconsin Department of Agriculture (WIDA) of regulations necessary for the implementation of the Wisconsin State Plan. Notice of contingent approval was published in the FEDERAL REGISTER on December 30, 1977 (42 FR 65266). Subsequently, on September 1, 1978, implementing regulations promulgated by the WIDA became effective. Having reviewed these regulations and finding that all requisite legal authorities required by FIFRA and 40 CFR Part 171 are now enacted and promulgated, the Regional Administrator, EPA Region V, hereby gives notice that the Wisconsin State Plan is now a fully approved State Plan.

Dated: November 15, 1978.

JOHN MCGUIRE,
Regional Administrator,
Region V.

[FR Doc. 78-33094 Filed 11-27-78; 8:45 am]

[6712-01-M]

FEDERAL COMMUNICATIONS COMMISSION

RADIO TECHNICAL COMMISSION FOR MARINE SERVICES

Meetings

In accordance with Public Law 92-463, "Federal Advisory Committee Act," the schedule of future Radio Technical Commission for Marine Services (RTCM) meetings is as follows:

EXECUTIVE COMMITTEE MEETING

The next Executive Committee Meeting will be on Thursday, December 14, 1978, at 9:30 a.m. in Conference Room 7200, Nassif Building, 400 Seventh Street, SW. (at D Street), Washington, D.C.

AGENDA

1. Call to Order.
2. Administrative Matters.
3. Discussion on Petition to Amend By-laws, Article IV, Section 1.
4. Discussion on Resolution to Amend Constitution, Article VI, Section 8.
5. Acceptance of FY-78 Audit Report.
6. New business.

The RTCM has acted as a coordinator for maritime telecommunications since its establishment in 1947. All RTCM meetings are open to the public. Written statements are preferred, but by previous arrangement, oral presentations will be permitted within time and space limitations.

Those desiring additional information concerning the above meeting(s) may contact either the designated chairman or the RTCM Secretariat (phone: 202-632-6490).

FEDERAL COMMUNICATIONS COMMISSION,
WILLIAM J. TRICARICO,
Secretary.

[FR Doc. 78-33210 Filed 11-27-78; 8:45 am]

[6730-01-M]

FEDERAL MARITIME COMMISSION

AGREEMENTS FILED

The Federal Maritime Commission hereby gives notice that the following agreements have been filed with the Commission for approval pursuant to section 15 of the Shipping Act, 1916, as amended (39 Stat. 733, 75 Stat. 763, 46 U.S.C. 814).

Interested parties may inspect and obtain a copy of each of the agreements and the justifications offered therefor at the Washington Office of the Federal Maritime Commission, 1100 L Street NW., Room 10218; or may inspect the agreements at the Field Offices located at New York, N.Y.; New Orleans, La.; San Francisco, Calif.; Chicago, Ill.; and San Juan, Puerto Rico. Interested parties may submit comments on each agreement, including requests for hearing, to the Secretary, Federal Maritime Commission, Washington, D.C., 20573, on or before December 18, 1978. Comments should include facts and arguments concerning the approval, modification, or disapproval of the proposed agreement. Comments shall discuss with particularity allegations that the agreement is unjustly discriminatory or unfair as between carriers, shippers, exporters, importers, or ports, or between exporters from the United States and their foreign competitors, or operates to the detriment of the commerce of the United States, or is contrary to the public interest, or is in violation of the Act.

A copy of any comments should also be forwarded to the party filing the agreements and the statement should indicate that this has been done.

Agreement No. 161-34.

Filing party: Howard A. Levy, Esquire, Suite 727, 17 Battery Place, New York, N.Y. 10004.

SUMMARY: Agreement No. 161-34 modifies the basic agreement of the Gulf/United Kingdom Freight Conference to provide that the cost of maintaining a policing, cargo inspection and enforcement agency for the Conference shall be equitably apportioned among the members as they shall, from time to time, unanimously determine.

Agreement No. 5680-28.

Filing party: H. R. Rollins, Secretary, Pacific-Straits Conference, 320 California Street, Suite 600, San Francisco, Calif. 94104.

SUMMARY: Agreement No. 5680-28, among the member lines of Pacific-Straits Conference, modifies the basic agreement by changing the title of the Conference executive officer from "Secretary" to "Chairman."

Agreement No. 10028-9.

Filing party: John D. Straton, Jr., Director, Rates & Conferences, Moore-McCormack Lines, Inc., 2 Broadway, New York, N.Y. 10004.

SUMMARY: Agreement No. 10028-9 by and among Companhia de Navegacao Lloyd Brasileiro, Companhia de Navegacao Maritima, Moore-McCormack Lines, Inc., and Sea-Land Service, Inc., amends the parties' basic cargo revenue pooling and sailing agreement in the northbound trade from Brazilian ports within the Porto Alegre/Recife range to ports on the Atlantic Coast of the United States, and is a restatement of the basic agreement in its entirety. This restatement provides for the inclusion of transshipment cargo in the pooling of revenues on transshipment of cargoes to other than U.S. destinations when moving over U.S. Atlantic ports.

Agreement No. 10359.

Filing party: Lester Nelson, Esq., Miller, Montgomery, Sogi, Brady & Taft, 200 Park Avenue, New York, N.Y. 10017.

SUMMARY: Agreement No. 10359, among twenty-four owners, operators or agents engaged in water transportation who are members of the New York Credit & Financial Management Association, is a cooperative working arrangement known as the "Water Transportation Credit Group" of the New York Credit Group Service, Inc., (an affiliate of New York Credit & Financial Management Association), the purpose of which is the collection, compilation, and exchange of credit experience information and its distribution to members. The arrangement consists of, and is subject to, the terms and conditions of the Constitution and By-Laws set forth therein.

Agreement No. T-3743.

Filing party: Ms. Betty I. Crofoot, House Counsel, Port of Portland, P.O. Box 3529, Portland, Oreg. 97208.

SUMMARY: Agreement No. T-3743, between the Port of Portland (Port) and Port Services Company (PSC), provides for the Port's five-year lease to PSC (with renewal options) of certain premises at John Fulton Terminal 6, Rivergate Industrial District, Portland, Oreg., to be used for the receipt, storage, processing, assembly, staging, and shipment of vehicles or other vehicle related merchandise. As compensation for the first five-year period, PSC shall pay Port rental equal to the sum of six percent per annum on the value of land at $35,000 per acre, plus six percent per annum on the value of surface improvements, plus ten percent per annum on the processing building and its facilities.

Dated: November 22, 1978.

By order of the Federal Maritime Commission.

FRANCIS C. HURNEY,
Secretary.

[FR Doc. 78-33249 Filed 11-27-78; 8:45 am]

[6730-01-M]

[Docket No. 78-48]

ALLIED CHEMICAL INTERNATIONAL CORP. v. FARRELL LINES, INC.

Filing of Complaint

Notice is hereby given that a complaint filed by Allied Chemical International Corp. against Farrell Lines, Inc. was served November 20, 1978. The complaint alleges that respondent has assessed charges for ocean transportation in excess of those lawfully applicable in violation of section 18(b)(3) of the Shipping Act, 1916.

Hearing in this matter, if any is held, shall commence on or before May 20, 1979. The hearing shall include oral testimony and cross-examination in the discretion of the presiding officer only upon a proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record.

FRANCIS C. HURNEY,
Secretary.

[FR Doc. 78-33248 Filed 11-27-78; 8:45 am]

[6820-24-M]

GENERAL SERVICES ADMINISTRATION

FURNITURE TRADE ASSOCIATIONS

Discussion

Notice hereby is given that the Federal Supply Service, General Services Administration, will hold a one-day discussion with representatives of furniture trade associations on December 5, 1978, 8:00 a.m., 1941 Jefferson Davis Highway, Arlington, Virginia, Room 1129, for the purpose of exchanging information regarding how GSA may obtain greater competition in its procurement efforts and other matters relating to competition, including specification and acquisition.

The discussion will be open to the public.

WILLIAM P. KELLY, Jr.,
Commissioner,
Federal Supply Service.

[FR Doc. 78-33188 Filed 11-27-78; 8:45 am]

[6820-22-M]

REGIONAL PUBLIC ADVISORY PANEL ON ARCHITECTURAL AND ENGINEERING SERVICES

Meeting

NOVEMBER 24, 1978.

"Pursuant to Public Law 92-463, notice is hereby given of a meeting of the Regional Public Advisory Panel on Architectural and Engineering Services, Central Office, December 11 and December 12, 1978, from 9:00 A.M. to 4:00 P.M., Room 5206, General Services Administration, 18th & F Streets NW., Washington, D.C. The meeting will be devoted to the initial step of the procedures for screening and evaluating the qualifications of architect-engineers under consideration for selection to furnish professional services for the proposed Smithsonian Institution Museum Support Center, Suitland, Maryland. The meeting will be open to the public." In order to meet the schedule requirements of the full committee, it will be necessary to hold the meeting on the specified dates.

DAVID R. DIBNER,
Acting Commissioner.

[FR Doc. 78-33406 Filed 11-27-78; 8:45 am]

[6820-38-M]

[Federal Property Management Regs., Temporary Regulation E-54]

SECRETARY OF DEFENSE

Delegation of Authority

1. *Purpose.* This regulation delegates authority to the Secretary of Defense to represent the interests of the executive agencies of the Federal Government in a gas rate increase proceeding.

2. *Effective date.* This regulation is effective immediately.

3. *Delegation.*

a. Pursuant to the authority vested in me by the Federal Property and Administrative Services Act of 1949, 63 Stat. 377, as amended, particularly sections 201(a)(4) and 205(d) (40 U.S.C. 481(a)(4) and 486(d)), authority is delegated to the Secretary of Defense to represent the consumer interests of the executive agencies of the Federal Government before the Oklahoma Corporation Commission involving the application of the Arkansas Louisiana Gas Company for an increase in rates.

b. The Secretary of Defense may redelegate this authority to any officer, official, or employee of the Department of Defense.

c. This authority shall be exercised in accordance with the policies, procedures, and controls prescribed by the General Services Administration, and shall be exercised in cooperation with the responsible officers, officials, and employees thereof.

JAY SOLOMON,
Administrator of
General Services.

NOVEMBER 10, 1978.

[FR Doc. 78-33208 Filed 11-27-78; 8:45 am]

[4110-88-M]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Alcohol, Drug Abuse, and Mental Health Administration

BIOLOGICAL SCIENCES TRAINING REVIEW COMMITTEE

Meeting Change

In FR Doc. 78-31506 appearing on page 52061 in the issue of Wednesday, November 8, 1978, the Notice is changed as follows:

BIOLOGICAL SCIENCES TRAINING REVIEW COMMITTEE

December 20-22, 9 a.m., Conference Room I, Parklawn Building, 5600 Fishers Lane, Rockville, Md. 20857. Open: December 20, 9-10 a.m. Closed: Otherwise.

All other information remains as announced November 8.

Dated: November 21, 1978.

ELIZABETH A. CONNOLLY,
Committee Management Officer,
Alcohol, Drug Abuse, and
Mental Health Administration.

[FR Doc. 78-33212 Filed 11-27-78; 8:45 am]

[4110-88-M]

NATIONAL ADVISORY COUNCIL ON DRUG ABUSE

Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. Appendix I), announcement is made of the following National advisory body scheduled to assemble during the month of January 1979:

NATIONAL ADVISORY COUNCIL ON DRUG ABUSE

January 25-26, 1979, Conference Room G-H, Parklawn Building, 5600 Fishers Lane, Rockville, Md. 20857. Closed: 9:30-noon, January 25. Open: Otherwise. Contact: Ms. Mary E. Kielkopf, Room 10A-23, Parklawn Building, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-6618.

Purpose. The National Advisory Council on Drug Abuse advises and makes recommendations to the Secretary, Department of Health, Education, and Welfare, the Administrator, Alcohol, Drug Abuse, and Mental Health Administration, and the Director, National Institute on Drug Abuse, on the development of new initiatives and priorities, and the efficient administration of drug abuse research, training, demonstration, prevention, and community services programs. The Council also gives advice on policies and priorities for drug abuse grants and contracts, and reviews and makes recommendations on grant applications.

Agenda. From 9:30 a.m. to 12 Noon, January 25, the meeting shall be closed for final review of grant applications for Federal assistance in accordance with the determination by the Administrator, Alcohol, Drug Abuse, and Mental Health Administration, pursuant to the provisions of Title 5, U.S. Code 552b(c)(6), and Section 10(d) of Pub. L. 92-463 (5 U.S.C. Appendix I).

The remainder of the meeting from 1:30 p.m. on January 25 until adjournment on January 26 will be open to the public for a discussion of issues in the field of drug abuse, and administrative announcements. Discussions around drug paraphernalia, priority scores for grant applications, and a report from the National Association of State Alcohol and Drug Abuse Directors are planned. Agenda items are subject to change as priorities dictate.

Substantive program information, summaries of the meeting, and roster of the Council members may be obtained from the contact person listed above.

Dated: November 21, 1978.

ELIZABETH A. CONNOLLY,
Committee Management Officer,
Alcohol, Drug Abuse, and
Mental Health Administration.

[FR Doc. 78-33213 Filed 11-27-78; 8:45 am]

[1505-01-M]

Food and Drug Administration

[Docket No. 78N-0263]

ANTACID DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Final Classification of Category III Antacid Ingredients and Labeling Claims

Correction

In FR Doc. 78-24914 appearing on page 39427 in the issue of Tuesday, September 5, 1978, in the 1st column under SUPPLEMENTARY INFOR-

MATION, the 9th line in paragraph (i) in small type should read as follows:

". . . directions for use, prescription or OTC . . .".

[4110-03-M]

Food and Drug Administration

CONAGRA, INC.

Boost-O-Iron; Withdrawal of Approval of New Animal Drug Application

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The agency withdraws approval of new animal drug application (NADA) providing for use of Boost-O-Iron (20 percent ferrous fumarate), a product intended for use in the prevention of iron deficiency anemia in infant pigs. This action is taken in response to a request by ConAgra, Inc., the sponsor.

EFFECTIVE DATE: November 28, 1978.

FOR FURTHER INFORMATON CONTACT:

David N. Scarr, Bureau of Veterinary Medicine (HRV-214), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1846.

SUPPLEMENTARY INFORMATION: ConAgra, Inc., 3801 Harney St., Omaha, NE 68131, is the sponsor of NADA 31-876 providing for Boost-O-Iron (20 percent ferrous fumarate), which is intended for use in the prevention of iron deficiency anemia in infant pigs. The application was originally approved on February 14, 1967.

The sponsor informed the agency that the product was never manufactured, requested withdrawal of approval of the application, and waived opportunity for a hearing by letter of April 17, 1978.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345-347 (21 U.S.C. 360b(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA 31-876 and all supplements for Boost-O-Iron is hereby withdrawn, effective November 28, 1978.

Published elsewhere in this issue of the FEDERAL REGISTER is a final order revoking § 558.258 *Ferrous fumarate* (21 CFR 558.258) to reflect withdrawal of approval of this application.

Dated: November 17, 1978.

LESTER M. CRAWFORD,
Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 78-33090 Filed 11-27-78; 8:45 am]

[4110-03-M]

[Docket No. 78N-0306; DESI 10670]

TOLBUTAMIDE

Drugs for Human Use; Drug Efficacy Study Implementation; Followup Notice

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice states the conditions for marketing tolbutamide for the indication for which it is regarded as effective, allowing for the submission of abbreviated new drug applications (ANDA's). The drug is an oral hypoglycemic agent.

DATE: Supplements to approved new drug applications (NDA's) due on or before January 29, 1978.

ADDRESSES: Communications forwarded in response to this notice should be identified with the reference number DESI 10670, directed to the attention of the appropriate office named below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Supplements to full new drug applications (identify with NDA number): Division of Metabolism and Endocrine Drug Products (HFD-130), Rm. 14B-04, Bureau of Drugs.

Original abbreviated new drug applications of supplements thereto (identify as such): Division of Generic Drug Monographs (HFD-530), Bureau of Drugs.

Requests for the report of the National Academy of Sciences-National Rsearch Council: Public Records and Document Center (HFI-35), Rm. 4-62.

Requests for opinion of the applicability of this notice to a specific product: Division of Drug Labeling Compliance (HFD-310), Bureau of Drugs.

Other communications regarding this notice: Drug Efficacy Study Implementation Project Manager (HFD-501), Bureau of Drugs.

FOR FURTHER INFORMATION CONTACT:

Herbert Gerstenzang, Bureau of Drugs (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: In a notice (DESI 10670) published in the FEDERAL REGISTER of September 27, 1968 (33 FR 14551), the Food and Drug Administration, having evaluated the drug described below, announced its conclusion that tolbutamide is effective for its labeled indication.

NDA 10-;670; Orinase TAblets containing tolbutamide; The Upjohn Co., 7171 Portage Rd., Kalamazoo, MI 49002.

The following new drug application was not included in the initial notice, but is affected by this notice.

NDA 12-678; Tolbutamide Tablets; Premo Pharmaceutical Laboratories, Inc., 111 Leuning St., South Hackensack, NJ 07606.

The September 27, 1968 notice also stated that an approved new drug application is required for marketing the drug product. At that time the new drug application had to contain full information as required by the new drug application form FD-356H (21 CFR 314.1(c)). Upon reevaluating the requirement of full new drug applications for tolbutamide, the director of the Bureau of Drugs concludes that abbreviated new drug applications (21 CFR 314.1(f)) are appropriate for the drug.

Labeling for oral hypoglycemic drugs is presently undergoing revision. Proposed labeling was published in the FEDERAL REGISTER of July 7, 1975 (40 FR 28587). The September 27, 1968 notice contained full labeling for tolbutamide. As the full labeling is now under review, only the indications section is included in this notice. The current indication is as follows: "Tolbutamide is indicated in uncomplicated diabetes mellitus of the stable, mild, or moderately severe, nonketotic, naturity-onset type that cannot be completely controlled by diet alone." When the review of the labeling for oral hypoglycemic drugs is finalized, revision of the indication may be required.

Accordingly, the September 27, 1968 notice is amended to read as follows:

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). Supplemental new drug applicatons are required to revise the labeling in and to update previously approved applications providing for such drugs. An approved new drug application is a requirement for marketing such a drug product.

In addition to the product specifically named above, this notice applies to any drug product that is not the subject of an approved new drug application and is identical to a similar or related drug product that is not the subject of an approved new drug application. It is the responsibility of every drug manufacturer or distributor to review this notice to determine whether it covers any drug product that the person manufactures or distributes.

Such person may request an opinion of the applicability of this notice to a specific drug product by writing to the Division of Drug Labeling Compliance (address given above).

A. *Effectiveness classification.* The Food and Drug Administration has reviewed all available evidence and concludes that the drug is effective for the indication in the labeling conditions below.

B. *Conditions for approval and marketing.* The Food and Drug Administration is prepared to approve abbreviated new drug applications and abbreviated supplements to previously approved new drug applications under condition described herein.

1. *Form of drug.* Tolbutamide is in tablet form suitable for oral administration.

2. *Labeling conditions.* a. The label bears the statement, "Caution: Federal law prohibits dispensing without prescription."

b. The drug is labeled to comply with all requirements of the act and regulations, and the labeling bears adequate information for safe and effective use of the drug. The Indication is as follows:

For use in uncomplicated diabetes mellitus of the stable, mild or moderately severe, nonketotic, maturity-onset type that cannot be completely controlled by diet alone.

3. *Marketing status.* a. Marketing of such a drug product that is now the subject of an approved or effective new drug application may be continued provided that, on or before January 29, 1978, the holder of the application has submitted (i) a supplement for revised labeling as needed to be in accord with the labeling conditions described in this notice, and complete container labeling if current container labeling has not been submitted, and (ii) a supplement to provide updating information with respect to items 6 (components), 7 (composition), and 8 (methods, facilities, and controls) of new drug application form FD-356H (21 CFR 314.1(c)) to the extent required in abbreviated new drug applications (21 CFR 314.1(f)).

b. Approval of an abbreviated new drug application (21 CFR 314.1(f)) must be obtained prior to marketing such products. Bioavailability regulations (21 CFR 320.21) published in the FEDERAL REGISTER of January 7, 1977 (42 FRf 1638), require any person submitting an abbreviated new drug application after July 7, 1977, to include either evidence demonstrating the in vivo bioavailability of the drug or information to permit waiver of the requirement. No waiver will be granted for tolbutamide as it is included in the list of effective drugs (21 CFR 320.22(c)) having a known or potential bioequivalence problem published in the FEDERAL REGISTER of January 7, 1977. Marketing prior to approval of a new drug application will subject such products, and those persons who caused the products to be marketed, to regulatory action.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-1053, as amended (21 U.S.C. 352, 355)) and under the authority delegated to the Director of the Bureau of Drugs (21 CFR 5.70).

Dated: November 17, 1978.

J. RICHARD CROUT,
Director, Bureau of Drugs.

[FR Doc. 78-33091 Filed 11-27-78; 8:45 am]

[4110-03-M]

Food and Drug Administration

[Docket No. 78D-0322]

OTC COMBINATION DRUG PRODUCTS

Availability of Guideline

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This document announces the availability of a guideline that states in detail the agency policy for combining two or more safe and effective over-the-counter (OTC) active drug ingredients. The agency will use this guideline, in addition to the existing regulatory requirements for OTC combination drugs, in evaluating the safety and effectiveness of all OTC combination drug products.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: The regulatory requirements for OTC combination drug products, set forth in § 330.10(a)(4)(iv) (21 CFR 300.10(a)(4)(iv)), are sufficiently general that they allow various interpretations. The OTC drug advisory review panels have been encouraged to exercise their own scientific judgment in developing all aspects of their reports, and different panels have, in fact, variously interpreted the OTC combination regulations. The Commissioner of Food and Drugs is therefore making available a guideline entitled "General Guidelines for OTC Drug Combination Products September 1978" that specifically sets forth acceptable criteria for combining Category I active ingredients in certain situations that are not covered by the broad regulation. For example, the guidelines explain the Food and Drug Administration's position regarding combinations of ingredients from: different therapeutic categories and which are intended to treat different symptoms; the same therapeutic category but with different mechanisms of action; and the same therapeutic category and with the same mechanism of action. The agency will apply the criteria in the guideline, in addition to the regulatory requirements in § 330.10(a)(4)(iv) in determining the safety and effectiveness of all OTC combination drug products.

The Division of OTC Drug Evaluation (HFD-510), Bureau of Drugs is responsible for maintaining the guideline.

A copy of the guideline is available for public examination between 9 a.m. and 4 p.m., Monday through Friday, in the office of the Hearing Clerk. Requests for single copies of the guideline may be submitted to the office of the Hearing Clerk, identifying the guideline with the Hearing Clerk docket number found in brackets in the heading of this document.

Interested persons may submit written comments on the guideline to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857 (preferably in four copies, identified with the Hearing Clerk docket number). Such comments will be considered in determining whether amendments or revisions to the guideline are warranted. Received comments will be incorporated into the public file on the guideline and may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday, except holidays.

Dated: November 21, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-33215 Filed 11-27-78; 8:45 am]

[4110-84-M]

Health Services Administration

FEDERAL ADVISORY COMMITTEES

Filing of Annual Reports

Notice is hereby given that pursuant to section 13 of Pub. L. 92-463, the Annual Report for the following Health Services Administration Federal Advisory Committee has been filed with the Library of Congress:

MATERNAL AND CHILD HEALTH RESEARCH GRANTS REVIEW COMMITTEE

Copies are available to the public for inspection at the Library of Congress, Special Forms Reading Room, Main Building, or weekdays between 9:00 a.m. and 4:30 p.m. at the Department of Health, Education, and Welfare, Department Library, North Building, Room 1436, 330 Independence Avenue SW., Washington, D.C. 20201, Telephone (202) 245-6791. Copies may be obtained from Gontran Lamberty, Dr. P. H., Bureau of Community Health Services, Room 7-15, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-2190.

Dated: November 17, 1978.

WILLIAM H. ASPDEN, Jr.,
Associate Administrator For Management.

[FR Doc. 78-33250 Filed 11-27-78, 8:45 am]

[4110-08-M]

National Institutes of Health

REPORT ON BIOASSAY OF PARATHION FOR POSSIBLE CARCINOGENICITY

Availability

Parathion (CAS 56-38-2) has been tested for cancer-causing activity with rats and mice in the Bioassay Program, Division of Cancer Cause and Prevention, National Cancer Institute. A report is available to the public.

Summary: A bioassay for possible carcinogenicity of technical-grade parathion was conducted by administering the test chemical in the diet to Osborne-Mendel rats and B6C3F1 mice. Applications of the chemical include use as a pesticide.

It is concluded that under the conditions of this bioassay, parathion was not carcinogenic to B6C3F1 mice. In the male and female Osborne-Mendel rats receiving parathion in their diet, there was a higher incidence of cortical tumors of the adrenal than in pooled or historical controls, suggesting that parathion is carcinogenic to this strain of rat.

Single copies of the report are available from the Office of Cancer Communications, National Cancer Institute, Building 31, Room 10A21, National Institutes of Health, Bethesda, Maryland 20014.

(Catalogue of Federal domestic Assistance Program Number 13.393, Cancer Cause and Prevention Research.)

Dated: November 1, 1978.

THOMAS E. MALONE,
Acting Director, National Institutes of Health.

[FR Doc. 78-33105 Filed 11-27-78; 8:45 am]

REPORT ON BIOASSAY OF PHOSPHAMIDON FOR POSSIBLE CARCINOGENICITY

Availability

Phosphamidon (CAS 13171-21-6) has been tested for cancer-causing activity with rats and mice in the Bioassay Program, Division of Cancer Cause and Prevention, National Cancer Institute. A report is available to the public.

Summary: A bioassay of technical-grade phosphamidon for possible carcinogenicity was conducted using Osborne-Mendel rats and B6C3F1 mice. Applications of the chemical include use as an insecticide. The test material was administered in feed to 50 rats and 50 mice of each sex at one of two doses.

It is concluded that under the conditions of this bioassay, technical-grade phosphamidon was not carcinogenic for B6C3F1 mice. The data obtained in this bioassay with Osborne-Mendel rats are insufficient to allow the interpretation that technical-grade phosphamidon is carcinogenic in this species.

Single copies of the report are available from the Office of Cancer Communications, National Cancer Institute, Building 31, Room 10A21, National Institutes of Health, Bethesda, Maryland 20014.

(Catalogue of Federal Domestic Assistance Program Number 13.393, Cancer Cause and Prevention Research.)

Dated: November 1, 1978.

THOMAS E. MALONE,
Acting Director, National Institutes of Health.

[FR Doc. 78-33106 Filed 11-27-78; 8:45 am]

REPORT ON BIOASSAY OF PIPERONYL BUTOXIDE FOR POSSIBLE CARCINOGENICITY

Availability

Piperonyl butoxide (CAS 51-03-6) has been tested for cancer-causing activity with rats and mice in the Bioassay Program, Division of Cancer Cause and Prevention, National Cancer Institute. A report is available to the public.

Summary: A bioassay of technical-grade piperonyl butoxide for possible carcinogenicity was conducted by administering the test chemical in feed to Fischer 344 rats and B6C3F1 mice. Applications of the chemical include use as an insecticide enhancer.

It is concluded that under the conditions of this bioassay, piperonyl butoxide was not carcinogenic for Fischer 344 rats or B6C3F1 mice.

Single copies of the report are available from the Office of Cancer Communications, National Cancer Institute, Building 31, Room 10A21, National Institutes of Health, Bethesda, Maryland 20014.

(Catalogue of Federal Domestic Assistance Program Number 13.393, Cancer Cause and Prevention Research.)

Dated: November 1, 1978.

THOMAS E. MALONE,
Acting Director, National Institutes of Health.

[FR Doc. 78-33107 Filed 11-27-78; 8:45 am]

[4110-02-M]

Office of Education

ADVISORY COMMITTEE ON ACCREDITATION AND INSTITUTIONAL ELIGIBILITY

Meeting

AGENCY: Department of Health, Education, and Welfare, Office of Education.

ACTION: Notice of public meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of the next public meeting of the Advisory Committee on Accreditation and Institutional Eligibility. It also describes the functions of the Committee. Notice of these meetings is required under the Federal Advisory Committee Act (5 U.S.C. Appendix 1, 10(a)(2)). This document is intended to notify the general public of its opportunity to attend and to participate.

DATES: December 12, 1978, 1 p.m. to 6 p.m., local time; December 13, 8:30 to 6 p.m.; December 14, 8:30 a.m. to 5:30 p.m.; and December 15, 9 a.m. to 3 p.m. Requests for oral presentations before the Committee must be received on or before December 8, 1978. All written material which a party wishes to file may be submitted at any time and will be considered by the Advisory Committee.

ADDRESS: Sheraton National Motor Hotel, Columbia Pike and Washington Boulevard, Arlington, Va.

FOR FURTHER INFORMATION CONTACT:

John R. Proffitt, Director, Division of Eligibility and Agency Evaluation, Office of Education, Room 3030, ROB 3, 400 Maryland Avenue, SW., Washington, D.C. 20202, 202-245-9873.

The Advisory Committee on Accreditation and Institutional Eligibility is established pursuant to Section 253 of the Veterans' Readjustment Assistance Act (Chapter 33, Title 38, U.S.

Code). The Committee advises the Commissioner of Education regarding his responsibilities to publish lists of nationally recognized accrediting agencies and associations; State agencies recognized for the approval of public postsecondary vocational education; and accrediting and State agencies recognized for the approval of nurse education. The Committee also advises the Commissioner regarding policy affecting accreditation and institutional eligibility for participation in Federal funding programs.

The meeting on December 12, 13, 14, and 15 will be open to the public. This meeting will be held at the Sheraton National Motor Hotel, Arlington, Va. The Committee will review petitions and reports by accrediting and State approval agencies relative to initial or continued recognition by the U.S. Commissioner of Education. The Committee also will hear presentations by representatives of the petitioning agencies and interested third parties. Agencies having petitions and reports pending before the Committee are:

American Medical Association, Committee on Allied Health, Education and Accreditation, in cooperation with the Review Committee for Physical Therapy Education, which is sponsored by the American Medical Association.
American Society of Landscape Architects, Landscape Architectural Accreditation Board.
California Board of Registered Nursing.
Council on Education for Public Health.
Iowa Board of Nursing.
Joint Commission on Dance and Theater Accreditation, sponsored by the National Association of Schools of Art and the National Association of Schools of Music.
Kansas State Board of Education.
Liaison Committee on Medical Education.
Louisiana State Board of Nursing.
Missouri State Board of Nursing.
National Association of Private, Nontraditional Schools and Colleges.
National Association of Schools of Music.
National Association of Trade and Technical Schools, Accrediting Commission.
New Jersey State Board of Education.
New York State Board of Regents (Nursing Education Unit).
Utah State Board for Vocational Education.

The Advisory Committee also will review a request by Flaming Rainbow University, Talequah, Okla., for a determination of satisfactory assurance that it will meet the accrediting standards of a nationally recognized agency within a reasonable period of time.

The Advisory Committee will review the following policy matters during its meeting:

1. Proposed revisions to the Criteria for Recognition of National Accrediting Bodies and State Agencies.
2. Issues regarding reauthorization of the Higher Education Act of 1965:
a. Should the present Federal eligibility system, placing dominant reliance upon accreditation, be retained unchanged?
b. Should the Office of Education undertake efforts to develop a dominant role in its eligibility system by either:
i. State legal authorizing agencies; or
ii. State approval/accrediting agencies?
c. Should the Office of Education consider establishing its own Federal approval/accrediting system for purposes of eligibility?
d. Should the Office of Education revise its eligibility system to effect a more balanced reliance upon accrediting agencies and State legal authorizing agencies?

Requests for oral presentation before the Committee should be submitted in writing to the Director, Division of Eligibility and Agency Evaluation, Office of Education, Room 3030, ROB 3, 400 Maryland Avenue, SW., Washington, D.C. 20202. Requests should include the names of all persons seeking an appearance, the party or parties which they represent (if applicable), and the purpose for which the presentation is requested. Requests must be received by the Division of Eligibility and Agency Evaluation on or before December 8, 1978. Time constraints may limit oral presentations. However, all additional written material that a party wishes to file will be considered by the Advisory Committee.

Records shall be kept of all Committee proceedings and shall be available for public inspection at the Division of Eligibility and Agency Evaluation.

Signed at Washington, D.C. on November 22, 1978.

JOHN R. PROFFITT,
Director, Division of Eligibility, and Agency Evaluation, Office of Education.

[FR Doc. 78-33280 Filed 11-27-78; 8:45 am]

[4110-02-M]

NATIONAL ADVISORY COUNCIL ON EXTENSION AND CONTINUING EDUCATION

Meeting

AGENCY: National Advisory Council on Extension and Continuing Education.

ACTION: Notice of Meeting.

SUMMARY: This notice set forth the schedule and proposed agenda of a forthcoming meeting of the National Advisory Council on Extension and Continuing Education and its ad hoc committees. It also describes the functions of the Council. Notice of this meeting is required under the Federal Advisory Committee Act (5 U.S.C. Appendix 1, 10(a)(2)). This document is intended to notify the general public of their opportunity to attend the meeting.

DATE: Meetings: December 13, 14, and 15, 1978.

ADDRESS: The St. Francis Hotel, Union Square, San Francisco, California.

FOR FURTHER INFORMATION:

William G. Shannon, Executive Director, National Advisory Council on Extension and Continuing Education, 425 13th Street, NW., Suite 529, Washington, D.C. 20004, telephone 202-376-8888.

The National Advisory Council on Extension and Continuing Education is authorized under Public Law 89-329. The Council is required to report annually to the President, the Congress, the Secretary of HEW, and the Commissioner of Education in the preparation of general regulations and with respect to policy matters arising in the administration of Part A of Title I (HEA) including policies and procedures governing the approval of State plans under section 105; and to advise the Assistant Secretary of HEW on Part B (Lifelong Learning activities) of the title. The Council is required to review the administration and effectiveness of all Federally supported extension and continuing education programs.

The meetings of the Council are open to the public beginning with the meeting of the ad hoc committees on Wednesday, December 13, from 6:00 to 8:00 p.m.; and the meetings of the full Council on Thursday, December 14, from 9:00 a.m. to 5:00 p.m.; and on Friday, December 15, from 8:30 a.m. until 1:00 p.m.

The agenda for the Council meeting is summarized as follows:

A. WEDNESDAY, DECEMBER 13 (6-8 P.M.)

1. Meeting of the Ad Hoc Committee on Adult Learners and Federal Financial Aid.
2. Meeting of the Ad Hoc Committee on the Reformulation of Title I, HEA.
3. Meeting of the Ad Hoc Committee on Private Funding Alternatives for Postsecond- ary Education.
4. Meeting of the Ad Hoc Committee on International Dimensions of Continuing Education.

B. THURSDAY, DECEMBER 14 (9 A.M.-5 P.M.) AND FRIDAY, DECEMBER 15 (8:30 A.M.-1 P.M.)

a. Report of the Chairperson.
b. Report of the Executive Director.
c. Action on previous meeting minutes.
d. Community Service and Continuing Education Program Report.
e. Budget Review.
f. Election of Officers and Executive Committee.
g. Report of Ad Hoc Committees and briefing about Federal programs.
h. Discussion of Special Report to the President.
i. Review of status of Congressional reauthorization of the Higher Education Act.

All records of the Council proceedings are available for public inspection at the Council's staff office, located in

Suite 529, 425 13th Street, NW., Washington, D.C.

Due to limited space, guests will be seated during the public meeting on a first-come basis by calling the Council office 202-376-8888.

Dated: November 22, 1978.

WILLIAM G. SHANNON,
Executive Director.

[FR Doc. 78-33233 Filed 11-27-78; 8:45 am]

[4110-02-M]

NATIONAL ADVISORY COUNCIL ON BILINGUAL EDUCATION

Meeting

AGENCY: National Advisory Council on Bilingual Education.

ACTION: Notice.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the National Advisory Council on Bilingual Education. Notice of this meeting is required under the Federal Advisory Committee Act (5 U.S.C. Appendix 1, 10(a)(2)). This document is intended to notify the general public of their opportunity to attend.

The Council had previously planned a series of hearings throughout the nation from December through March for the purpose of advising on the preparation of regulations. The schedule and procedures for promulgating regulations has been changed subsequent to those plans, therefore the Council will only have one hearing.

In order for the Council to participate effectively in the regulatory process, the required public notice of fifteen days is not being met.

DATES: December 6, 1978 Public Hearing 9:30 A.M.-4:30 P.M. December 7, 1978 Business Meeting 9:00 A.M.-4:00 P.M. December 8, 1978 Business Meeting 9:00 A.M.-4:00 P.M.

ADDRESS: Public Hearings will be held in Room 100, Home Economics Building Seventh Street, San Jose State University, San Jose, California 95192. Business Meetings will be held in the Associated Student Council Chambers, Student Union Building, San Jose State University, San Jose, California 95192.

FOR FURTHER INFORMATION CONTACT:

Mr. Louis J. Serpa Office of Bilingual Education, Reporters' Bldg., Room 421, Office of Education, 400 Maryland Avenue, SW., Washington, D.C. 20202, (202—245-2600).

The National Advisory Council on Bilingual Education is established under Section 732(a) of the Bilingual Education Act (20 U.S.C. 880b-11) to advise the Secretary of Health, Education, and Welfare and the Commissioner of Education concerning matters arising in the administration of the Bilingual Education Act.

On *December 6, 1978,* in consonance with the Council's mission to advise in the preparation of regulations under the Bilingual Education Act, testimony will be heard on the following topics:

(1) Parental Participation;

(2) Adequate Training for Basic Programs;

(3) Priorities for Training under the Bilingual Education Act;

(4) Requirements for Fellowship Recipients to pay back or work;

(5) Definition of Limited English Proficiency as basis for participation in Basic Program;

(6) Follow-up services to sustain academic achievement;

(7) Gradual assumption of costs;

(8) Measurable goals to determine when children no longer need the program;

(9) Capacity Building;

(10) Use of bilingual personnel to the extent possible;

(11) The extent and manner which English proficient students should participate;

(12) Historically underserved;

(13) Services to non-public schools;

(14) Meaning of supplement/supplant clause in the Bilingual Education Act;

(15) Participation of private nonprofit organizations in the training activities.

The following procedures shall be observed during the public hearings:

(1) Witnesses shall be heard on a first come basis;

(2) Witnesses shall limit their testimony to fifteen minutes: ten minutes of formal presentation followed by five of questioning from Council mambers;

(3) Two or more persons from the same organization shall designate one person to speak for the group;

(4) Witnesses shall present an oral synopsis of their written testimony. Witnesses who do not provide such a testimony will be heard after all who have written testimony are heard;

(5) Witnesses shall provide fifteen copies of their written testimony;

(6) Witnesses may address the Council in English or in their native language. The written testimony must be submitted in English;

(7) All testimony shall be tape recorded;

(8) Exceptions to the aforementioned procedures shall be at the discretion of the Chairman of the Public Hearings Committee.

December 7, 1978: The proposed agenda for the Business Meeting includes:

(1) Old Business: Dissertation Award Procedures, Discussion on Coordination among bilingual programs, and Participation in national conferences.

(2) New Business: Digest of Testimony.

December 8, 1978: The proposed agenda includes the following:

(1) Digest of testimony (continued).

(2) Recommendations on the development of regulations.

Records will be kept of all Council proceedings and shall be available for public inspection 14 days after the meeting in Room 421, Reporter's Building, 300 7th Street, SW., Washington, D.C. 20202. In the event that the proposed agenda is completed prior to the projected date or time, the Council will adjourn the meeting.

Signed at Washington, D.C., on November 22, 1978.

DEAN BISTLINE,
Acting Director,
Office of Bilingual Education.

[FR Doc. 78-33279 Filed 11-27-78; 8:45 am]

[4110-87-M]

Public Health Service

INDUSTRYWIDE OCCUPATIONAL HEALTH RESEARCH STUDIES

Request for Information

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Center for Disease Control, Public Health Service, HEW.

ACTION: Request for Information.

SUMMARY: This notice requests information concerning certain substances and industries for which NIOSH is planning to conduct industrywide occupational health research studies during fiscal year 1979. Of particular interest to NIOSH is information that is not published or would not be found during routine literature searches. The information will aid NIOSH in developing protocols and background data for the studies.

DATES: Information concerning this notice should be submitted by January 29, 1979.

ADDRESSES: Information should be submitted in writing to Dr. Bobby F. Craft, Director, Division of Surveillance, Hazard Evaluations and Field Studies, (DSHEFS), NIOSH, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

FOR FURTHER INFORMATION CONTACT:

F. Sutton Kay, Operations Management Officer, DSHEFS, NIOSH, 513-684-3616.

SUPPLEMENTARY INFORMATION: Section 20(a)(7) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 669(a)(7)) provides that the Sec- retary of Health, Education, and Welfare shall conduct and publish industrywide studies of the effect of chronic or low-level exposure to industrial materials, processes, and stresses on the potential for illness, disease, or loss of functional capacity in aging adults. To carry out this responsibility, NIOSH plans to initiate certain industrywide studies during fiscal year 1979. These studies will be of workers in the leather industry and of workers in other industries with specific exposure to manganese, toluene, urethane, and adrenocortical steroids. The public is invited to submit information that would aid NIOSH in developing protocols and background data for the studies. Such information would include, but not be limited to, (1) human epidemiologic studies, (2) animal studies, (3) methods for air sampling and analyses, (4) data on engineering controls, work practices and industrial hygiene practices, and (5) potential industrial and/or commercial establishments, occupational groups, etc., that could be studied by NIOSH.

Trade secret information will be held confidential under section 15 of the Act (29 U.S.C. 654) and HEW regulations (45 CFR Part 5.71(c)). Personal information concerning living individuals will be held confidential under section 3 of the Privacy Act (5 U.S.C. 552(a)) and HEW regulations (45 CFR Part 5b). All other information received in response to this notice will be available for public inspection at the foregoing address.

Dated: November 21, 1978.

EDWARD J. BAIER,
Acting Director, National Institute for Occupational Safety and Health.

[FR Doc. 78-33214 Filed 11-27-78; 8:45 am]

[4110-92-M]

INTERAGENCY COMMITTEE FOR THE INTERNATIONAL YEAR OF THE CHILD

APPROVAL OF DEVELOPMENT OF PORTABLE CUMULATIVE CHILD HEALTH RECORD CARD AS AN ACTIVITY FOR IYC

The Interagency Committee for the International Year of the Child (IYC) has approved the development of a portable cumulative child health record card as an activity for IYC. Those persons wishing to receive further information regarding this proposal may do so by contacting:

Secretariat for IYC, P.O. Box 1182, Room 5044 Donohoe Building, Washington, D.C. 20013.

Dated: November 13, 1978.

CHESTER E. NORRIS, Jr.,
Co-Chairperson, Interagency Committee on the International Year of the Child.

[FR Doc. 78-33242 Filed 11-27-78; 8:45 am]

[4310-55-M]

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

ENDANGERED SPECIES PERMIT

Receipt of Application

Applicant: Ringling Bros.-Barnum & Bailey Combined Shows, Inc., 1015 18th Street NW., Washington, D.C. 20036.

The applicant requests a permit to import from Hungary, reexport to Canada and reimport to the United States, and reexport to Hungary, nine (9) tigers (*Panthera tigris*) for the purpose of enhancement of propagation and survival of the species. All tigers involved in the activity are captive-born. the purpose of the activity will be achieved in conjunction with circus exhibition.

Humane care and treatment during transport has been indicated by the applicant.

Documents and other information submitted with this application are available to the public during normal business hours in Room 601, 1000 N. Glebe Road, Arlington, Virginia, or by writing to the Director, U.S. Fish and Wildlife Service, (WPO), Washington, D.C. 20240.

This application has been assigned file number PRT 2-3433. Interested persons may comment on this application by submitting written data, views, or arguments to the Director at the above address on or before December 28, 1978. Please refer to the file number when submitting comments.

Dated: November 22, 1978.

DONALD G. DONAHOO,
Chief, Permit Branch, Federal Wildlife Permit Office, U.S. Fish and Wildlife Service.

[FR Doc. 78-33290 Filed 11-27-78; 8:45 am]

[4310-03-M]

Heritage Conservation and Recreation Service

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 Heritage Conservation and Recreation Service before November 17, 1978. Pursuant to section 60.13(a) of 36 CFR Part 60, published in final form on January 9, 1976, written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the Keeper of the National Register, Office of Archeology and Historic Preservation, U.S. Department of the Interior, Washington, D.C. 20240. Written comments or a request for additional time to prepare comments should be submitted by December 7, 1978.

WILLIAM J. MURTAGH,
Keeper of the National Register.

CALIFORNIA

Orange County

Anaheim, *Anaheim Colony Multiple Resource Area*, roughly bounded by RR tracks, Harbor Blvd., Sycamore and Santa Ana Sts.

CONNECTICUT

New Haven County

New Haven, *Blackman, Elisha, Building*, 176 York St.

GEORGIA

Richmond County

Augusta, *Wilson, Woodrow, Boyhood Home*, 419 7th St.

LOUISIANA

East Baton Rouge Parish

Baton Rouge vicinity, *Santa Maria Planation House*, S of Baton Rouge on Perkins Rd.

Lafayette Parish

Lafayette, *St. John's Cathedral*, St. John St.

Orleans Parish

New Orleans, *Napoleon Street Branch Library*, Napoleon St.
New Orleans, *Sommerville-Kearney House*, 1401 Delachise St.

Rapides Parish

Pineville, *Post of Rapides*, Hardtner and Main St.

Tangipahoa Parish

Hammond, *Oaks Hotel (Casa de Fresa)* Railroad Ave. SW.

Washington Parish

Franklinton, *Knight Cabin*, Washington Parish Fairgrounds.
Franklinton, *Sylvest House*, Washington Parish Fairgrounds.

West Feliciana Parish

St. Francisville vicinity, *Greenwood Plantation*, N of St. Francisville on U.S. 61.

MONTANA

Jefferson County

Boulder vicinity, *Boulder Hot Springs Hotel*, SE of Boulder on MT 281.

NEBRASKA

Saline County

Wilber, *Mann-Zwonecek House*, 524 W. 1st.

NEW HAMPSHIRE

Merrimack County

Concord, *Merrimack County Bank (Old Historical Society Building)* 214 N. Main St.

Strafford County

Milton vicinity, *Plumer-Jones Farm*, N of Milton on NH 16.

NEW MEXICO

Catron County

Glenwood vicinity, *Whitewater Canyon Pipeline*, 4 mi. NE of Glenwood.

Colfax County

Eagle West vicinity, *Eagle Nest Dam*, 3 mi. SE of Eagle Nest off U.S. 64.

Socorro County

Magdalena, *Atchison, Topeka and Santa Fe Railway Depot*, off U.S. 60.

NORTH CAROLINA

Martin County

Hamilton, *Conoho Lodge*, Liberty St.

OHIO

Athens County

Nelsonville, *Stuart's Opera House*, Public Sq. and Washington St.

Delaware County

Galena vicinity, *Keeler, Diadatus, House*, SE of Galena at 4567 Red Bank Rd.

Erie County

Snadusky, *Melville-Milne, William Gordon, House*, 319 Lawrence St.

Hamilton County

Cincinnati, *Beech Avenue Houses*, 1120 and 1128 Beech Ave.
Cincinnati, *Columbia-Tusculum Multiple Resource Area*, East End neighborhood.
Cincinnati, *Immaculate Conception Church, School, and Rectory*, Pavilion and Guido Sts.

Jackson County

Wellston, *Morgan Mansion*, Broadway and Pennsylvania Aves.

Lake County

Kirtland Hills, *Hanna, Leonard C., Jr., Estate*, Little Mountain Rd.
Unionville, *Unionville District School* 3480 West St.

Lawrence County

Ironton, *Rankin Historic District*, roughly bounded by Vernon, 7th, Monroe and 4 Sts.

Lorain County

Lorain, *Lorain Lighthouse*, Lorain Harbor.
Wellington vicinity, *Wellington-Huntington Road Multiple Resource Area*, S of Wellington along OH 58.

Mercer County

Maria Stein, *Gast, Matthias, House and General Store*, OH 119. Mendon, *Mendon Town Hall*, S. Main St.

Montgomery County

Centerville vicinity, *Belville-Maxwell House*, W of Centerville off OH 725.

Muskingum County

Zanesville, *Kearns, George and Edward, Houses*, 306 and 320 Luck Ave.

Richland County

Mansfield, *Ritter, William, House*, 181 S. Main St.

Ross County

Chillicothe, *Mountain House*, Highland Ave.
Hopetown, *Wesley Chapel*, off U.S. 23.

Scioto County

Portsmouth, *Boneyfiddle Commercial District*, roughly bounded by Front, Washington, 3rd and Scioto Sts.

Seneca County

Bellevue vicinity, *Heter Farm*, NW of Bellevue on SR 29.
Tiffin, *Miami Street Grade School*, 155 Miami St.

Shelby County

Sidney, *Sidney Waterworks and Electric Light Building*, 121 N. Brooklyn Ave.

Stark County

Canton, *Timken, Henry H., Barn*, 13th St. NW., and I 77.
Canton vicinity, *Bair, Jacob H., House*, N of Canton at 7225 N. Market Ave.

OKLAHOMA

Garvin County

Paulis Valley, *Pauls Valley Historic District*, roughly bounded by RR tracks, Joy and Walnut, Sts., and Grant Ave.

OREGON

Marion County

Salem, *Lee Mission Cemetery*, D St.

Mulnomah County

Portland, *Lloyd, Frank M., Estate*, 0615 Palatine hill Rd. SW.

Washington County

North Plains vicinity, *Jackson, John Wesley, House*, E of North Plains on W. Union Rd.

[FR Doc. 8-33082 Filed 27-78: 8:45 am]

[3210-10-M]

Office of the Secretary

ALASKA NATIONAL INTEREST LANDS PROPOSAL

Availability of Final Supplement to Final Environmental Statement

Notice is hereby given that the Department of the Interior is making available for information, a Final Supplement to the environmental evaluation made in 1974 on the Alaska National Interest Lands proposed under Section 17(d)(2) of the Alaska Native Claims Settlement Act of 1971. These actions were described in the Final Environmental Impact Statement issued in 1974 (28 volumes) and covering proposed legislative authorization to establish new units or expand existing units of the National Park System, the National Wildlife Refuge System, and the National Wild and Scenic Rivers System. This supplement updates that environmental statement and includes revisions due to available new study information. It also assesses the potential impacts of alternatives not previously discussed in the original evaluation. For reference to the earlier statement, a complete listing of government offices and public libraries throughout the Nation where the 28-volume EIS and this supplement may be studied is published in the FEDERAL REGISTER of Thursday, October 26, 1978 (Vol. 43, No. 208) at pages 50050 through 50055. (However, on page 50051 of the aforementioned FEDERAL REGISTER, the list is amended to show the following three address corrections.

U.S. Fish and Wildlife Service

USFWS, 500 N.E. Multnomah Street, Suite 1692, Portland, Oregon 97232.
USFWS, 500 Gold Street, S.W.K 10th Floor, Albuquerque, New Mexico 87103.

National Park Service

NPS, Southwest Regional Office, 1100 Old Santa Fe Trail, Santa Fe, New Mexico 87501.

Copies of this final supplement will be mailed to recipients of the draft supplement. Individual copies may be secured or examined upon request at the following Government offices.

Anchorage

National Park Service, Alaska Area Office, 540 W. 5th Avenue, Anchorage, Alaska 995701.

Fairbanks

U.S. Fish and Wildlife Service, 1412 Airport Way, Fairbanks, Alaska 99701.

Juneau

U.S. Fish and Wildlife Service, Federal Building, Juneau, Alaska 99701.

Honolulu

Hawaii State Director's Office, National Park Service, 300 Ala Moana Boulevard, Box 50165, Honolulu, Hawaii 96850.

Seattle

Pacific Northwest Regional Office, National Park Service, 601 Fourth and Pike Building, Seattle, Washington 98101.

Spokane

Mines and Minerals, Pacific Northwest Region, National Park Service, Room 580, U.S. Courthouse, West 920 Riverside, Spokane, Washington 99201.

San Francisco

Western Regional Office, National Park Service, 450 Golden Gate Avenue, San Francisco, California 94102.

Los Angeles

Bureau of Land Management, Outer Continental Shelf Office, 300 N. Los Angeles Street, Los Angeles, California 90012.

Denver

Rocky Mountain Regional Office, National Park Service, 655 Pardet Street, P.O. Box 25287, Denver, Colorado 80225.

Albuquerque

Heritage Conservation and Recreation Service, 5000 Marble Avenue, N.E., Albuquerque, New Mexico 87110.

Phoenix

Southern Arizona Group Office, National Park Service, 1115 N. first Street, Phoenix, Arizona 85004.

Billings

Bureau of Land Management, Granite Tower Building, 222 N. 32nd Street, Billings, Montana 59101.

Salt Lake City

Assistant to the Regional Director (Utah), National Park Service, 125 S. State Street, Room 2208, Salt Lake City, Utah 84138.

Dallas

U.S. Geological Survey, 1045 Federal Building, 1100 Commerce Street, Dallas, Texas 75242.

Chicago

Federal Information Center, Room 250, 219 South Dearborn, Chicago, Illinois.

Ann Arbor

Heritage Conservation and Recreation Service, Federal Building, Ann Arbor, Michigan 48107.

Omaha

Midwest Regional Office, National Park Service, 1709 Jackson Street, Omaha, Nebraska 68102.

St. Louis

Jefferson National Expansion Memorial, National Park Service, 11 North Fourth Street, St. Louis, Missouri 63102.

Minneapolis-St. Paul

U.S. Fish and Wildlife Service, Federal Building, fort Snelling, Twin Cities, Minnesota 63102.

Philadelphia

Mid-Atlantic Regional Office, National Park Service, 143 S. 3rd Street, Philadelphia, Pennsylvania 19106.

Boston

U.S. Fish and Wildlife Service, One Gateway Center, Newton Corner, Massachusetts 02158.

New York

Bureau of Land Management, Outer Continental Shelf Office, Federal Building, 26 Federal Plaza, New York, New York 10014.

Atlanta

Southeast Regional Office, National Park Service, 1895 Phoenix Boulevard, Atlanta, Georgia 30349.

Louisville

Federal Information Center, 600 Federal Place, Louisville, Kentucky 40202.

Memphis

U.S. Geological Survey, Water Resources Division, Federal Office Building, 167 N. Main, Memphis, Tennessee 38103.

Miami

U.S. Geological Survey, Water Resources Division, 901 S. Main Avenue, Miami, Florida 33130.

New Orleans

Bureau of Land Management, Outer Continental Shelf Office, Hale Boggs Federal Building, 500 Camp Street, New Orleans, Louisiana 70130.

Dated: November 22, 1978.

LARRY E. MEIEROTTO,
Deputy Assistant Secretary of the Interior.

[FR Doc. 78-32848 Filed 11-27-78; 8:45 am]

[7020-02-M]

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-51]

CERTAIN CIGARETTE HOLDERS

Commission Hearing on Presiding Officer's recommendation, Relief, Bonding and the Public Interest

Recommendation of "no violation" issued. In connection with the Commission's investigation, under Section 337 of the Tariff Act of 1930, of alleged unfair methods of competition and unfair acts in the importation and sale of certain cigarette holders in the United States, the Presiding Officer recommended on October 23, 1978, that the Commission determine that there is no violation of Section 337. The Presiding Officer certified the hearing record to the Commission for its consideration. Copies of the Presiding Officer's recommendation may be obtained by interested persons by contacting the office of the Secretary to the Commission, 701 E Street, N.W., Washington, D.C. 20436, telephone (202) 523-0161.

Commission hearing scheduled. The Commission will hold a hearing beginning at 10:00 a.m., e.s.t., Wednesday, February 21, 1979, in the Commission's Hearing Room (Room 331), 701 E Street, N.W., Washington, D.C. 20436, for two purposes. First, the Commission will hear oral argument on the Presiding Officer's recommendation that there is no violation of Section 337 of the Tariff Act of 1930. Second, the Commission will receive oral presentations concerning appropriate relief, bonding, and the public interest in the event that the Commission determines that there is a violation of Section 337. These matters are being heard on the same day in order to facilitate the completion of this investigation within time limits under law and to minimize the burden of this hearing upon the parties to the investigation. The procedure of each portion of the hearing follows.

Oral argument on Presiding Officer's recommendation. A party to the Commission's investigation or an interested agency wishing to present to the Commission an oral argument concerning the Presiding Officer's recommendation will be limited to no more than 30 minutes. A party or interested agency may reserve 10 minutes of its time for rebuttal. The oral arguments will be held in this order: complainant, respondents, interested agencies, and Commission investigative staff. Any rebuttals will be held in this order: respondents, complainants, interested agencies, and Commission investigative staff.

Oral presentations on relief, bonding, and the public interest. Following the oral arguments on the Presiding Officer's recommendation, a party to the investigation, an interested agency, a public interest group, or any interested member of the public may make an oral presentation on relief, bonding, and the public interest.

1. *Relief.* In the event that the Commission were to find a violation of Section 337, it would issue (1) an order which could result in the exclusion from entry of certain cigarette holders into the United States or (2) an order which could result in requiring respondents to cease and desist from alleged unfair methods of competition or unfair acts in the importation and sale of these cigarette holders. Accordingly, the Commission is interested in what relief should be ordered, if any.

2. *Bonding.* In the event that the Commission were to find a violation of

Section 337 and order some form of relief, that relief would not become final for a 60-day period during which the President would consider the Commission's report. During this period, the certain cigarette holders would be entitled to enter the United States under a bond determined by the Commission and prescribed by the Secretary of the Treasury. Accordingly, the Commission is interested in what bond should be determined, if any.

3. *The public interest.* In the event that the Commission were to find a violation of Section 337 and order some form of relief, the Commission must consider the effect of that relief upon the public interest. Accordingly, the Commission is interested in the effect of any exclusion order or cease and desist order upon (1) the public health and welfare, (2) competitive conditions in the United States economy, (3) the production of like or directly competitive articles in the United States, and (4) United States consumers.

A party to the Commission's investigation, an interested agency, a public interest group, or any interested person wishing to make an oral presentation concerning relief, bonding, and the public interest will be limited to no more than 15 minutes. Participants will be permitted an additional 5 minutes each for summation after all presentations have been made. Participants with similar interests may be required to share time. The order of oral presentations will be as follows: complainant, respondents, interested agencies, public interest groups, other interested members of the public, and Commission investigative staff. Summations will follow the same order.

How to participate in the hearing. If you wish to appear at the Commission's hearing, you must file a written request to appear with the Secretary to the Commission, United States International Trade Commission, 701 E Street, N.W., Washington, D.C. 20436, no later than the close of business (5:15 p.m., e.s.t.) on Wednesday, February 7, 1979. Your written request must indicate whether you wish to present an oral argument concerning the Presiding Officer's recommendation or an oral presentation concerning relief, bonding and the public interest, or both. While only parties to the Commission's investigation, interested agencies, and the Commission investigative staff may present an oral argument concerning the Presiding Officer's recommendation, public interest groups and other interested members of the public are encouraged to make an oral presentation concerning the public interest.

Written submissions to the Commission. The Commission requests that written submissions of two types be filed prior to the hearing in order to focus the issues and facilitate the orderly conduct of the hearing.

1. *Briefs on the Presiding Officer's recommendation.* Parties to the Commission's investigation, interested agencies, and the Commission investigative staff are encouraged to file briefs concerning exceptions to the Presiding Officer's recommendation. Prehearing briefs must be filed with the Secretary to the Commission by no later than the close of business on Wednesday, February 7, 1979. Briefs must be served on all parties of record to the Commission's investigation on or before the date they are filed with the Secretary. Statements made in briefs should be supported by references to the record. Persons with the same positions are encouraged to consolidate their briefing, if possible.

2. *Written comments and information concerning relief, bonding, and the public interest.* Parties to the Commission's investigation, interested agencies, public interest group, and any other interested members of the public are encouraged to file written comments and information concerning relief, bonding, and the public interest. These written submissions will be very useful to the Commission in the event it determines that there is a violation of Section 337 and that relief should be granted.

Written comments and information concerning relief, bonding, and the public interest shall be submitted in this order. First, complainant shall file a detailed proposed Commission action, including a proposed determination of bonding, a proposed remedy, and a discussion of the effect of its proposals on the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, with the Secretary to the Commission by no later than the close of business on Wednesday, January 31, 1979. Second, other parties, interested agencies, public interest groups, and other interested members of the public shall file written comments and information concerning the action which complainant has proposed, any available alternatives, and the advisability of any Commission action in light of the public interest considerations listed above by no later than the close of business on Wednesday, February 14, 1979.

Additional information. The original and 19 true copies of all written submissions must be filed with the Secretary to the Commission. If you wish to submit a document (or a portion thereof) to the Commission in confidence, you must request *in camera* treatment. Your request should be directed to the Chairman of the Commission and must include a full statement of the reasons for granting *in camera* treatment. The Commission will either accept such submission in confidence, or it will return the submission to you. All nonconfidential written submissions will be open to public inspection at the Secretary's Office.

Notice of the Commission's investigation was published in the FEDERAL REGISTER of March 29, 1978 (43 FR 13104).

By order of the Commission:

Issued: November 22, 1978.

KENNETH R. MASON,
Secretary.

[FR Doc. 78-33294 Filed 11-27-78; 8:45 am]

[4410-01-M]

DEPARTMENT OF JUSTICE

THIRD CIRCUIT PANEL UNITED STATES CIRCUIT JUDGE NOMINATING COMMISSION

Meeting

United States Circuit Judge Nominating Commission, Third Circuit Panel, Chairman: John McLean, Jr.

The first meeting of the nominating panel for the Third Circuit of the United States Circuit Judge Nominating Commission will be held on December 20, 1978, at 10:00 a.m., in the Third Circuit Judical Council Conference Room, 20th Floor, Room 20321, United States Court House, 6th and Market Streets, Philadelphia, Pennsylvania 19160.

The purpose of the meeting is to provide the panel members with a history of the Circuit Court system; an explanation of the merit selection process; and, the qualifications to be sought in nominating candidates for Circuit Court Judgeships.

This meeting will be open to the public.

JOSEPH A. SANCHES,
Advisory Committee Management Officer.

NOVEMBER 21, 1978.

[FR Doc. 78-33251 Filed 11-27-78; 8:45 am]

[4510-43-M]

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[Docket No. M-78-117-C]

BETHLEHEM MINES CORP.

Petition for Modification of Application of Mandatory Safety Standard

Bethlehem Mines Corporation, Room 1871, Martin Tower, Bethlehem, Pennsylvania 18016, has filed a petition to modify application of 30 CFR

75.305 (weekly examination of return airways) to its Mine No. 51 in Washington County, Pennsylvania. The petition is filed under Section 101(c) of the Federal Mine Safety and Health Act of 1977, Pub. L. 95-164.

The substance of the petition is as follows:

(1) Certain return air courses in the petitioner's mine (designated on a map supplied by the petitioner) have deteriorated in the 68 years since they were driven. Roof falls are common.

(2) As a result of the deteriorated condition, these air courses cannot be safely examined in their entirety.

(3) As an alternative to weekly examinations or attempting a hazardous rehabilitation of the air courses, the petitioner proposes a three station air quality monitoring system and outlines its use.

(4) The petitioner states that this alternative will achieve no less protection than that provided by the standard.

REQUEST FOR COMMENTS

Persons interested in this petition may furnish written comments on or before December 28, 1978. Comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available at that address.

Dated: November 20, 1978.

ROBERT B. LAGATHER,
Assistant Secretary for Mine Safety and Health.

[FR Doc. 78-33332 Filed 11-27-78; 8:45 am]

[4510-43-M]

[Docket No. M-78-112-C]

CONSOLIDATION COAL CO.

Petition for Modification of Application of Mandatory Safety Standard

Consolidation Coal Company, Consol Plaza, Pittsburgh, Pennsylvania 15241, has filed a petition to modify application of 30 CFR 75.1103 (automatic fire sensors) at its Amonate No. 31 Mine in Amonate, West Virginia. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977, Pub. L. 95-164.

The substance of the petition is as follows:

(1) A rail strike has delayed the petitioner's plan to join a section of the mine designated as the P-left belt with the mine's main fire sensor system by 2½ to 3 months.

(2) In order to join a fire sensor system on P-left with the main system during the interim, the petitioner would have to temporarily install a cable over 5,800 feet in length.

(3) As an alternative, the petitioner outlines the current fire protection measures on the belt and proposes a monitoring system for the interim.

(4) The petitioner states that this alternative will achieve no less protection than that provided by the standard.

REQUEST FOR COMMENTS

Persons interested in this petition may furnish written comments on or before December 28, 1978. Comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available at that address.

Dated: November 20, 1978.

ROBERT B. LAGATHER,
Assistant Secretary for Mine Safety and Health.

[FR Doc. 78-33333 Filed 11-27-78; 8:45]

[4510-43-M]

[Docket No. M-78-113-C]

CONSOLIDATION COAL CO.

Petition for Modification of Application of Mandatory Safety Standard

Consolidation Coal Company, Consol Plaza, Pittsburgh, Pennsylvania 15241, has filed a petition to modify application of 30 CFR 75.305 (weekly examinations) to its Bishop Mine No. 34 in McDowell County, West Virginia. The petition is filed under Section 101(c) of the Federal Mine Safety and Health Act of 1977, Pub. L. 95-164.

The substance of the petition is as follows:

(1) Major roof falls in the Daniel Mains and Pine Ridge sections of the mine have made the return entries in these sections impassable.

(2) Rehabilitation of those return entries would be impractical and dangerous.

(3) As an alternative to weekly examinations of the return entries, the petitioner outlines the proposed use of an air quality monitoring system using five checking stations.

(4) The petitioner states that the alternative will provide at all times a measure of protection equal to that provided by the standard.

REQUEST FOR COMMENTS

Persons interested in this petition may furnish written comments on or before December 28, 1978. Comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available at that address.

Dated: November 17, 1978.

ROBERT B. LAGATHER,
Assistant Secretary for Mine Safety and Health.

[FR Doc. 78-33334 Filed 11-27-78; 8:45 am]

[4510-43-M]

[Docket No. M-78-118-C]

CONSOLIDATION COAL CO.

Petition for Modification of Application of Mandatory Safety Standard

Consolidation Coal Company, Consol Plaza, Pittsburgh, Pa. 15241, has filed a petition to modify application of 30 CFR 75.305 (weekly examination of return air courses) to its Amonate No. 31 Mine in Amonate, Virginia. The petition is filed under Section 101(c) of the Federal Mine Safety and Health Act of 1977, Pub. L. 95-164.

The substance of the petition is as follows;

(1) This petition pertains to return air courses designated on a map of the mine supplied by the petitioner.

(2) Timbers have deteriorated in these sections of the mine and roof falls have resulted, leaving the air courses virtually impassable and extremely hazardous to travel and examine.

(3) The existing falls have had no effect on the velocity or quantity of air passing through the air courses.

(4) The return air courses are not designated as escapeways.

(5) As an alternative to weekly examinations or attempting a hazardous rehabilitation of the air courses, the petitioner proposes to install and maintain a two station air quality monitoring system.

(6) The petitioner states that this alternative will achieve no less protection than that provided by the standard.

REQUEST FOR COMMENTS

Persons interested in this petition may furnish written comments on or before December 28, 1978. Comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available for inspection at that address.

Dated: November 20, 1978.

ROBERT B. LAGATHER,
Assistant Secretary for Mine Safety and Health.

[FR Doc. 78-33335 Filed 11-27-78; 8:45 am]

[4510-43-M]

[Docket No. M-78-116-C]

MARROWBONE DEVELOPMENT CO.

Petition for Modification of Application of Mandatory Safety Standard

Marrowbone Development Company, P.O. Box 119, Naugatuck, West Virginia 25685, has filed a petition to modify application of 30 CFR 75.1700 (oil and gas well barriers) to its Western Mingo Coal Company No. 1 Mine in Mingo County, West Virginia. The petition is filed under Section 101(c) of the Federal Mine Safety and Health Act of 1977, Pub. L. 95-164.

The substance of the petition is as follows:

(1) The petitioner wishes to mine through Columbia Gas Transmission Corporation's gas well #8817.

(2) If the petitioner were required to establish and maintain barriers around the well in accordance with the standard, roof control in the mine would be adversely affected, and the mine's ventilation plan would be unduly complicated.

(3) In lieu of a barrier around gas well #8817, the petitioner proposes to plug the well by a technique outlined in the petition and which has been approved by the State of West Virginia.

(4) The plugged well would then be mined through following a list of safeguards stated in the petition.

(5) The petitioner states that this alternative will provide no less protection than that provided by the standard.

REQUEST FOR COMMENTS

Persons interested in this petition may furnish written comments on or before December 28, 1978. Comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available for inspection at that address.

Dated: November 20, 1978.

ROBERT B. LAGATHER,
Assistant Secretary for Mine Safety and Health.

[FR Doc. 78-33336 Filed 11-27-78; 8:45 am]

[4510-43-M]

[Docket No. M-78-53-M]

PORTLAND-MONSON SLATE CO.

Petition for Modification of Application of Mandatory Safety Standard

The Portland-Monson Slate Co., Monson, Maine 04464, has filed a petition to modify application of 30 CFR 57.19-102 (shaft guides) to its No. 5 Mine in Piscataquis County, Maine. The petition is filed under Section 101(c) of the Federal Mine Safety and Health Act of 1977, Pub. L. 95-164.

The substance of the petition is as follows:

(1) The vertical shaft of the mine measures approximately 20 feet by 20 feet square and 375 feet deep. There is a lateral drift in two directions from the bottom landing.

(2) The petitioner uses a guy derrick which allows for both vertical and horizontal movement of the conveyance and hoist hook. The horizontal movement is necessary:

(a) To service air, water, electrical and ventilation lines in the shaft;

(b) To service pumping stations on the shaft wall at the 150 and 300 foot levels;

(c) To hoist large, irregular blocks of slate from any point on the shaft bottom and to swing them laterally from the mine opening for truck loading.

(3) The horizontal movement makes the installation of guides impractical.

(4) The possibility of large rocks entangling in guides will constitute an extreme hazard to miners underground.

(5) Guides of any kind will interfere with the operation and placement of a wall mounted shaft mucker hung at the bottom of the shaft.

(6) For these reasons, the petitioner states that guides will not result in any net gain in safety in the mine and will constitute a hazard to miners and equipment when hoisting large rock.

REQUEST FOR COMMENTS

Persons interested in this petition may furnish written comments on or before December 28, 1978. Comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available at that address.

Dated: November 17, 1978.

ROBERT B. LAGATHER,
Assistant Secretary for Mine Safety and Health.

[FR Doc. 78-33337 Filed 11-27-78; 8:45 am]

[4510-43-M]

[Docket No. M-78-58-M]

RIO ALGOM CORP.

Petition for Modification of Application of Mandatory Safety Standard

The Rio Algom Corp., P.O. 610, Moab, Utah 84532, has filed a petition to modify application of 30 CFR 57.21-1 (gassy mines) to its Lisbon Mine in San Juan County, Utah. The petition is filed under Section 101(c) of the Federal Mine Safety and Health Act of 1977, Pub. L. 95-164.

The substance of the petition is as follows:

(1) MESA classified the mine as gassy in 1973 following ignition of a gas which included acetylene leaking from a compressed gas cylinder.

(2) The mine does not connect to any mine that has been classified as gassy.

(3) Since the initial classification of the mine as gassy, no ignition of flammable gas emanating from the ore body or the strata surrounding the ore body has occurred nor has the concentration of flammable gas ever been found in excess of .06 percent.

(4) The petitioner states that the mine was erroneously classified as gassy and that reclassification of the mine as non-gassy will in no fashion diminish the safety of miners in the mine.

REQUEST FOR COMMENTS

Persons interested in this petition may furnish written comments on or before December 28, 1978. Comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Va. 22203. Copies of the petition are available at that address.

Dated: November 20, 1978.

ROBERT B. LAGATHER,
Assistant Secretary for Mine Safety and Health.

[FR Doc. 78-33338 Filed 11-27-78; 8:45 am]

[4510-43-M]

[Docket No. M-78-60-M]

RIO BLANCO SHALE CO.

Petition for Modification of Application of Mandatory Safety Standard

Rio Blanco Oil Shale Co., 9725 East Hampden Avenue, Denver, Colo. 80231, has filed a petition to modify application of 30 CFR 57.19-3 (hoists) to its mine in Larimer County, Colo. The petition is filed under Section 101(c) of the Federal Mine Safety and Health Act of 1977, Pub. L. 95-164.

The substance of the petition is as follows:

(1) The petitioner plans to install a roller chain hoist for emergency escape at its shale mine.

(2) The hoist drive uses two independent chains, either of which is adequate to drive the unit. If one of the chains is defective, the other serves as complete backup.

(3) The hoist would serve during the four-year life of the mine's modular development phase and would be

eliminated should the mine go on to commercial production.

(4) For these reasons, the petitioner requests relief from the standard.

REQUEST FOR COMMENTS

Persons interested in this petition may furnish written comments on or before December 28, 1978. Comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Va. 22203. Copies of the petition are available for inspection at that address.

Dated: November 20, 1978.

ROBERT B. LAGATHER,
Assistant Secretary for Mine Safety and Health.

[FR Doc. 78-33339 Filed 11-27-78; 8:45 am]

[4510-43-M]

[Docket No. M-78-103-C]

UNITED POCAHONTAS COAL CO.

Petition for Modification of Application Mandatory Safety Standard

United Pocahontas Coal, Crumpler, W. Va. 24825, has filed a petition to modify application of 30 CFR 75.305 (weekly examination of return airways) to its Rolfe No. 6-A Mine in McDowell County, W. Va. The petition is filed under Section 101(c) of the Federal Mine Safety and Health Act of 1977, Pub. L. 95-164.

The substance of the petition is as follows:

(1) The top of entries serving as return airways in the 005 section of the petitioner's mine is not supported and has deteriorated in a number of areas.

(2) Although the entries are open and function efficiently as return airways, weekly examinations of them as well as attempts to rehabilitate them would be hazardous.

(3) The entries are not designated as escapeways.

(4) As an alternative to weekly examinations of the airways, the petitioner proposes to establish monitoring points specified on a map supplied with the petition. The roof in these areas is supported or will be supported.

(5) The petitioner states that these monitoring points will enable air quality and quantity to be measured in a safe manner on a daily basis.

REQUEST FOR COMMENTS

Persons interested in this petition may furnish written comments on or before December 28, 1978. Comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Va. 22203. Copies of the petition are available for inspection at that address.

Dated: November 20, 1978.

ROBERT B. LAGATHER,
Assistant Secretary for Mine Safety and Health.

[FR Doc. 78-33340 Filed 11-27-78; 8:45 am]

[4510-28-M]

Office of the Secretary

[TA-W-3760]

ALLSTATE LAWN PRODUCTS, INC., DULUTH, MINN.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3760: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on May 24, 1978 in response to a worker petition received on April 25, 1978 which was filed on behalf of workers and former workers producing women's and children's raincoats at the Duluth, Minnesota plant of Allstate Lawn Products, Incorporated.

the Notice of Investigation was published in the FEDERAL REGISTER on June 6, 1978 (43 FR 24634-35). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Allstate Lawn Products, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative detrmination and issue a certification of eligibility to apply for adjustment assitance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

that increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Allstate Lawn Products produced rainwear under a licensing agreement with a Duluth manufacturer between September 1976 and May 1977. In May 1977 this manufacturer's two plants, in Duluth and Chisholm, Minnesota, were closed and Allstate began to manufacture rainwear in another facility in Chisholm. Very little production occurred in Duluth in 1977—by the second quarter of 1977 the plant was closed. Most workers of Allstate Lawn Products, Duluth, were laid off by May 1977.

Since April 1977, the earliest possible impact date, sales at Allstate have increased. Sales of Allstate including its predecessor corporation increased from 1976 to 1977 and in the first six months of 1978 compared to the same period in 1977. Sales and production are approximately equal.

In the period following the closure of the Duluth plant, total employment, as well as sales, at Allstate increased. The shutdown of the Duluth plant resulted in a consolidation of business into the Chisholm plant of Allstate Lawn Products.

CONCLUSION

After careful review, I determine that all workers of the Duluth, Minnesota plant of Allstate Law Products, Incorporated, are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 20th day of November 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-33295 Filed 11-27-78; 8:45]

[4510-28-M]

[TA-W-4163]

AMERICAN PILLOW COMPANY, INC., LOWELL, MASS.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4163: Investigation regarding certification of eligibility to apply for adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on September 19, 1978 in response to a worker petition received on September 18, 1978 which was filed on behalf of workers and former workers producing down-filled outerwear at the American Pillow Co., Inc., Lowell, Massachusetts.

The Notice of Investigation was published in the FEDERAL REGISTER on October 27, 1978 (43 FR 50270). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the American Pillow Co., Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

On March 24, 1978, the U.S. Department of Commerce issued a certification of eligibility for firm adjustment assistance for the American Pillow Co. (F-226)

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Trade Act of 1974 must be met. It is concluded that all of the requirements have been met.

U.S. imports of feather products, including down-filled outerwear, increased 201 percent in value from the 1975 level of $9.4 million to $28.3 million in 1976. Imports increased 366 percent from 1976 to $132 million in 1977.

The investigation revealed that retail customers of the American Pillow Company reduced their purchases of down-filled outerwear from the company from 1976 to 1977. During the same period, these customers increased their import purchases of that product.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with down-filled outerwear produced at the American Pillow Co., Inc. contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of the American Pillow Co., Inc., Lowell, Massachusetts, who became totally or partially separated from employment on or after September 11, 1977 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 20th day of November 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-33296 Filed 11-27-78, 8:45 am]

[4510-28-M]

[TA-W-3923]

ANDREX INDUSTRIES CORP., NEW YORK, N.Y.

Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on July 5, 1978 in response to a worker petition received on July 5, 1978 which was filed on behalf of workers and former workers at the New York, New York sales office of Andrex Industries Corporation engaged in employment related to the production of knitted fabrics.

The Notice of Investigation was published in the FEDERAL REGISTER on July 18, 1978 (43 FR 30928-29). No public hearing was requested and none was held.

On July 5, 1978, a petition was filed on behalf of the same group of workers (TA-W-3940).

Notice of Investigation was published in the FEDERAL REGISTER on July 18, 1978 (43 FR 30928-29). No public hearing was requested and none was held.

Since the identical group of workers is the subject of the ongoing investigation TA-W-3940, a new investigation would serve no purpose. Consequently, the investigation has been terminated.

Signed at Washington, D.C., this 17th day of November 1978.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 78-33297 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-4033]

CENTRAL SLIPPER COMPANY OF NEW YORK, INC., NEW YORK, N.Y.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein present the results of TA-W-4033: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on August 3, 1978 in response to a worker petition received on July 31, 1978 which was filed on behalf of workers and former workers producing slippers and sneakers at Central Slipper, New York, N.Y. The investigation revealed that the plant stitched uppers for slippers and sneakers produced at affiliated plants.

The investigation also revealed that Central Slipper's official corporate name was Central Slipper Company of New York, Incorporated.

The Notice of Investigation was published in the FEDERAL REGISTER on September 1, 1978 (43 FR 39193). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Frier Industries, Incorporated, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

The ratio of imports of rubber/canvas footwear (sneakers) to domestic production of rubber/canvas footwear increased from 100.0 percent in 1976 to 119.1 percent in 1977, and increased from 127.1 percent in the first half of 1977 to 238.8 percent in the first half of 1978.

Central Slipper Company of New York stitched uppers for slippers and sneakers produced at two affiliated plants: Fashion Footwear Company, Incorporated, Rutherford, N.J. (TA-W-2083) and Frier Industries Distribution Corporation, Carlstadt, N.J. (TA-W-2087). These two companies were certified for trade adjustment assistance on December 20, 1977.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with canvas/rubber footwear (sneakers), the uppers of which were produced at Central Slipper Company of New York, Incorporated, New York, N.Y., contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certifications:

All workers of Central Slipper Company of New York, Incorporated, New York, New York who became totally or partially separated from employment on or after November 26, 1977 and before August 31, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 20th day of November 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc. 78-33299 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-3706]

CHEMICAL METALLURGICAL DIVISION, SCM CORP., LAKEHURST, N.J.

Negative Determination Regarding Application for Reconsideration

On October 14, 1978, the petitioner requested administrative reconsideration of the Department of Labor's Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance in the case of workers and former workers of the Lakehurst mine of the Chemical Metallurgical Division of the SCM Corporation, Lakehurst, New Jersey. The determination was published in the FEDERAL

REGISTER on September 26, 1978, (43 FR 43576).

Pursuant to 29 CFR 90.18(c), reconsideration may be granted under the following circumstances:

(1) If it appears, on the basis of facts not previously considered, that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts previously considered; or

(3) If, in the opinion of the certifying officer, a misinterpretation of facts or of the law justifies reconsideration of the decision.

The petitioner claims that the Glidden Pigments Group of the Chemical Metallurgical Division of SCM imported ilmenite ore as late as March 1978.

The Department's investigation revealed that the entire output of ilmenite ore from the Lakehurst mining site of the Chemical Metallurgical Division of SCM was used by the Glidden Pigments Group. The Lakehurst mining site, which was acquired in 1960, originally had a life expectancy of 15 years and closed in March, 1978 because the supply of ilmenite ore had been effectively exhausted and the strip mining operation was no longer economically feasible. The property has subsequently been sold to a domestic firm in the construction industry. SCM has not imported ilmenite for at least the past three years. Just before the Lakehurst mine closed, SCM had stockpiled about two years supply of ilmenite ore from the Lakehurst site. After the Lakehurst mining site closed, SCM made a substantial purchase of ilmenite ore from the stockpile of a domestic firm which stated that the ilmenite ore it sold to SCM had originally been imported from India between 1956 and 1960.

Thus, workers laid off at the Lakehurst mining site were laid off because the supply of ilmenite had been effectively exhausted and the mine had fully lived out its life expectancy.

CONCLUSION

After review of the application and the investigative file, I conclude that there has been no error or misinterpretation of fact or misinterpretation of the law which would justify reconsideration of the Department of Labor's prior decision. The application is, therefore, denied.

Signed at Washington, D.C., this 17th day of November 1978.

JAMES F. TAYLOR,
Director, Office of Management Administration and Planning.

[FR Doc. 78-33300 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-3990]

COBLENTZ BAGS CO., NEW YORK, N.Y.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3990: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on July 25, 1978 in response to a worker petition received on July 17, 1978 which was filed by the Leather Goods, Plastics, and Novelty Workers Union, on behalf of workers and former workers producing ladies leather and vinyl handbags at the Coblentz Bags Company, Incorporated, New York, New York.

The Notice of Investigation was published in the FEDERAL REGISTER on August 1, 1978 (43 FR 33840). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of The Coblentz Bags Company, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

U.S. imports of ladies handbags increased both absolutely and relative to domestic production for each year from 1974 through 1977 when compared to the previous year. Imports continued to increase absolutely in the first three months of 1978 as compared to the same period in 1977.

Results of a Department of Labor survey indicated that customers of the Coblentz Bags Company increased purchases of imported handbags and decreased purchases from Coblentz in 1977 compared to 1976 and in the first six months of 1978 compared to the first six months of 1977.

CONCLUSIONS

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with ladies handbags produced at the Coblentz Bags Company, New York, New York contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of The Coblentz Bags Company New York, New York, who became totally or partially separated from employment on or after July 11, 1977 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of November 1978.

JAMES F. TAYLOR,
Director, Office of Management Administration and Planning.

[FR Doc. 78-33301 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-3816]

CRAIG BYRON CO., FALL RIVER, MASS.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3816: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on June 7, 1978 in response to a worker petition received on June 2, 1978 which was filed on behalf of workers and former workers producing women's dresses, three piece suits and pant suits at Craig Byron Company, Fall River, Massachusetts.

The Notice of Investigation was published in the FEDERAL REGISTER on June 20, 1978 (43 FR 26499). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Craig Byron Company, its customers, the National Cotton Council of America, the U.S. International Trade Commission, the U.S. Department of Commerce, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Act must be met. Without regard to whether any of the other criteria have been met. The following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

In 1977, total sales both quantity and dollar value were above 1976 levels. In the first six months of 1978, quantity of sales were above January-June 1977 levels.

Total production in 1977 increases compared to 1976 production levels. January-June 1978 production levels

were above the January-June 1977 production levels.

Customers of the Craig Byron Company who were surveyed and who reduced purchases from the manufacturer did not increase purchases of imported dresses, suits, or pantsuits.

CONCLUSION

After careful review, I determine that all workers of Craig Byron Company, Fall River, Massachusetts are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 17th day of November 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-33302 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-3839]

DAVID HOBER AND COMPANY, INC., NEW YORK, N.Y.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3839: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on June 14, 1978 in response to a worker petition received on June 12, 1978 which was filed on behalf of workers formerly producing ladies' tailored sportswear at David Hober and Company, Incorporated, New York, New York.

The Notice of Investigation was published in the FEDERAL REGISTER on June 27, 1978 (43 FR 27924). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of David Hober and Company, Incorporated, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

U.S. imports of women's, misses' and children's blouses and shirts increased from 30,273,000 dozen in 1976 to 30,849,000 dozen in 1977. For the first half of 1978, imports increased to 19,854,000 dozen, compared to 16,829,000 dozen in the first half of 1977.

U.S. imports of women's, misses', and children's skirts increased to 568,000 dozen in the first half of 1978 compared to 220,000 dozen in the first half of 1977.

U.S. imports of women's, misses', and children's slacks and shorts increased from 11,040,000 dozen in 1976 to 11,622,000 dozen in 1977. For the first half of 1978, imports increased to 8,233,000 dozen, compared to 6,393,000 dozen in the first half of 1977. The ratio of imports to domestic production increased from 36.8 percent in 1976 to 38.0 percent in 1977.

U.S. imports of women's, misses', and children's coats and jackets increased from 2,252,000 dozen in 1976 to 2,723,000 dozen in 1977. The ratio of imports to domestic production increased from 48.3 percent in 1976 to 54.9 percent in 1977.

A Department survey, conducted with customers who purchased ladies' sportswear produced by David Hober and Company, Incorporated, revealed that customers increased imports of ladies' sportswear from 1976 to 1977 and in the first half of 1978 compared to the first half of 1977, while decreasing purchases from David Hober and Company, Incorporated.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with ladies' sportswear produced by David Hober and Company, Incorporated, New York, New York contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of David Hober and Company, Incorporated, New York, New York, who became totally or partially separated from employment on or after May 31, 1977 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of November 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-33303 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-3555, 4067, 4069, 4070, 4073, 4076, 4078]

DOREL GROUP CO., NORTH QUINCY, MASS.

Negative Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

TA-W-3555, Dorel Steel Corporation,

TA-W-4067, Angle Iron and Steel Corporation,

TA-W-4069, Dorel Crane and Equipment Rental Company,

TA-W-4070, W. P. Griffin Company,

TA-W-4073, Metro Steel Company,

TA-W-4076, Quinfield Steel Fabrication Company,

TA-W-4078, The Quincy Corporation.

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3555, 4067, 4069, 4070, 4073, 4076, 4078; Investigations regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigations were initiated on August 17, 1978 in response to worker petitions received on August 15, 1978 which were filed on behalf of workers and former workers fabricating and erecting buildings at the Dorel Group companies listed in the appendix. Petition TA-W-3555 was received on April 14, 1978 and the investigation was initiated on April 27, 1978.

Notices of investigation were published in the FEDERAL REGISTER on September 1, 1978 (43 FR 39194).[1] No public hearing was requested, and none was held.

The information upon which the determination was made was obtained principally from officals of the Dorel Group companies, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In the order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the separations, or threats thereof, and to the absolute decline in sales or production.

Evidence developed during the course of the investigation revealed that the absolute and relative levels of imports of fabricated structural steel

[1] Notice of Investigation of TA-W-3555 was published on May 16, 1978 (43 FR 21069).

decreased over the period of time when employment declines occurred at the Dorel Group companies. Imports of fabricated structural steel, in absolute terms, decreased from 1975 to 1976, increased from 1976 to 1977 and decreased 28 percent in the first six months of 1978 compared to the first six months of 1977. The ratios of imports to domestic production and consumption decreased from 5.6 percent and 5.5 percent, respectively, in the first six months of 1977 to 3.9 percent and 3.9 percent, respectively in the first six months of 1978.

Sales, production and employment levels at each Dorel Group company increased significantly from 1976 to 1977, decreasing only in the first half of 1978 compared to the first half of 1977. Production and employment declines in the first half of 1978 at these companies are attributable to inclement weather conditions in February and March 1978 in the Boston, Massachusetts region.

CONCLUSION

After careful review, I determine that all workers at the Dorel Group companies listed in the appendix are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 15th day of November 1978.

JAMES F. TAYLOR,
Director, Office of Management Administration, and Planning.

APPENDIX

TA-W-Number and

3555, Dorel Steel Corporation; 4067, Angle Iron and Steel Corporation; 4069, Dorel Crane and Equipment Rental Company; 4070, W. P. Griffin Company; 4073, Metro Steel Company; 4076, Quinfield Steel Fabrication Company; 4078, The Quincy Corporation.

[FR Doc. 78-33304 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-4060]

DUVAL CORP., BATTLE MOUNTAIN, NEV.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4060: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on August 15, 1978 in response to a worker petition received on August 10, 1978 which was filed by the International Union of Operating Engineers on behalf of workers and former workers mining and milling copper at the Battle Mountain, Nevada mine of Duval Corporation.

The Notice of Investigation was published in the FEDERAL REGISTER on August 29, 1978 (43 FR 38635). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Duval Corporation, *American Metal Market*, the American Bureau of Metal Statistics, the U.S. Department of Interior, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

U.S. imports of refined copper increased from 147 thousand short tons in 1975 to 384 thousand short tons in 1976 and increased again to 391 thousand short tons in 1977. In the first six months of 1978, imports increased to 327 thousand short tons compared with 164 thousand short tons in the same period in 1977. The ratio of imports to domestic production increased from 8.6 percent in 1975 to 21.0 percent in 1976 and increased again to 22.2 percent in 1977. In the first six months of 1978, the ratio increased to 35.9 percent compared with 15.0 percent in the same period in 1977.

The level of imports of copper is affected by the differential between the domestic producers price for copper and the price established by the LME (London Metal Exchange). When the LME price drops more than the estimated transportation cost of 5 cents per pound below the domestic producers price, the demand for imported copper increases. During the last nine months of 1977 and the first six months of 1978, the average LME price had fallen almost 8 cents per pound below the average domestic producers price.

The major factor contributing to depressed prices has been an oversupply of imported and domestic copper, as evidenced by U.S. inventory levels for refined copper. U.S. inventories of refined copper were higher in every month of 1977, except December, when compared to the same month in 1976. Inventories in December 1977 were less than one percent below December 1976 levels. Duval Corporation's inventory of copper at the end of 1977 was 38 percent higher than at the end of 1976. In the first six months of 1978, U.S. inventories surpassed levels in the same months of 1977, with the exception of March which was only marginally below the same month in the previous year. The abundant supply of copper stocks in the foreseeable future provides no reason for domestic consumers of copper to maintain ties with domestic producers for purposes of a guarantee against copper shortages. Consequently, in 1977 and in the first half of 1978, when many domestic copper producers curtailed production because of the depressed market price for copper, imports of refined copper increased in 1977 compared to 1976 and doubled in the first half of 1978 compared to the same period in 1977.

Duval Corporation's decision to lay off workers and reduce its mining operations beginning in June, 1977 and culminating in the six week shutdown in August, 1977 of all Duval properties including the Battle Mountain mine, was based mainly on an attempt to minimize losses which the company could not avoid were it to run at normal production levels at the current market prices for copper.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with the copper which is mined and milled at the Battle Mountain, Nevada mine of Duval Corporation contributed importantly to the decline in sales or production and to the total or partial separation of workers of that mine. In accordance with the provisions of the Act, I make the following certification:

All workers of the Battle Mountain, Nevada mine of Duval Corporation who became totally or partially separated from employment on or after August 7, 1977 and before October 1, 1977 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974. All workers separated on or after October 1, 1977 are denied eligibility.

Signed at Washington, D.C., this 20th day of November 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc. 78-33305 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-3961]

ERIE TECHNOLOGICAL PRODUCTS, INC., NORTH AND SOUTH PLANTS, ERIE, PA.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3961: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on July 11, 1978 in response to a worker petition received on July 6, 1978, in response to a worker petition received on July 6, 1978 which was filed by the International Union of Electrical Workers on behalf of workers and former workers producing electronic component parts at Erie Technological Products, Incorporated, Erie, Pennsylvania. The investigation revealed that the petition is intended to cover workers and former workers producing capacitors at the North and south plants of Erie Technological Products, Incorporated, Erie, Pennsylvania.

The Notice of Investigation was published in the FEDERAL REGISTER on July 25, 1978 (43 FR 32199). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Erie Techological Products, Incorporated, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

The value of U.S. imports of ceramic capacitors increased from 27.5 million dollars in 1976 to 37.8 million dollars in 1977. The ratio of imports to domestic production increased from 20.0 percent in 1976 to 22.1 percent in 1977. The value of imports increased from 7.9 million dollars in the first three months of 1977 to 11.1 million dollars in the first three months of 1978. The ratio of imports to domestic production increased from 18.5 percent in the first three months of 1977 to 24.9 percent in the first three months of 1978.

Erie Technological Products, Incorporated transferred production of some capacitors from its North and south plants in Erie, Pennsylvania to an offshore company facility during the first quarter of 1978. The transfer was completed and production at the offshore facility began in April 1978.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with capacitors produced at the North and South plants of Erie Technological Products, Incorporated, Erie, Pennsylvania contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of the North and South plants of Erie Technological Products, Incorporated, Erie, Pennsylvania engaged in employment related to the production of capacitors who became totally or partially separated from employment on or after June 23, 1977 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 20th day of November 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-33306 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-3685]

FLORA FASHIONS, INC., STANHOPE, N.J.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3685: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on May 8, 1978 in response to a worker petition received on April 28, 1978 which was filed by the International Ladies' Garment Worker's Union on behalf of workers and former workers producing ladies' coats and raincoats at Flora Fashions, Incorporated, Stanhope, N.J.

The Notice of Investigation was published in the FEDERAL REGISTER on May 26, 1978 (43 FR 22793). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Flora Fashions, Incorporated, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated.

Subsequent to the earliest impact date that could be set under the law—April 25, 1977—there were no significant layoffs until December 1977 when the usual seasonal layoffs occur. Employment increased from July-December of 1977 compared to the same period in 1976. Employment increased in the first five months of 1978 compared to the same period in 1977.

CONCLUSION

After careful review of the facts obtained in the investigation, I determine all workers of Flora Fashions, Stanhope, N.J. are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of November 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-33307 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-3027]

FORT PITT STEEL CASTING DIVISION, CONVAL PENN, INC., McKEESPORT, PA.

Negative Determination Regarding Application for Reconsideration

By application dated October 12, 1978, the petitioner for workers requested administrative reconsideration of the Department of Labor's Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance in the case of workers and former workers of Conval Penn, Incorporated's, Fort Pitt Steel Casting Division located in McKeesport, Pennsylvania. The determination was published in the FEDERAL REGISTER on September 26, 1978, (43 FR 43578).

Pursuant to 29 CFR 90.18(c), reconsideration may be granted under the following circumstances:

(1) If it appears, on the basis of facts not previously considered, that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts previously considered; or

(3) If, in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justifies reconsideration of the decision.

In his application, the petitioner claims that the Department did not fully consider all of the facts regarding the subject firm and its primary customers indicating that the Department should have emphasized in its survey of customers the so-called noncaptive firms. Further, the petitioner points to the increase in absolute imports of steel castings in 1977.

In its investigation, the Department conducted a survey of both captive and non-captive customers of subject firm. Included in its survey were three of the six firms cited in the application for administrative reconsideration. The results of the Department's

customer survey were in accord with the aggregate import data which while showing an increase in absolute terms of imports of steel castings in 1977 nonetheless showed that the ratio of such imports to domestic production was only 1.3 percent, just slightly higher than the 1.1 percent recorded the previous year. While the customer survey indicated that some customers increased purchases of imported steel castings, none of the customers increased such purchases while at the same time decreasing purchases of steel castings from Fort Pitt Steel Casting Division.

CONCLUSION

After review of the application and the investigative file, I conclude that there has been no error or misinterpretation of fact or misinterpretation of the law which would justify reconsideration of the Department of Labor's prior decision. The application is, therefore, denied.

Signed at Washington, D.C., this 22d day of November 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-33308 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-4061]

GTE SYLVANIA, INC., ALTOONA RECEIVING TUBE PLANT, ALTOONA, PA.; EMPORIUM RECEIVING TUBE PLANT, EMPORIUM, PA.; WILLIAMSPORT RECEIVING TUBE FINISHING WAREHOUSE, WILLIAMSPORT, PA.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4061: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on August 15, 1978 in response to a worker petition received on August 10, 1978 which was filed by the United Electrical, Radio and Machine Workers of America on behalf of workers and former workers producing electron receiving tubes at the Emporium Receiving Tube Plant, GTE Sylvania, Inc., Emporium, Pennsylvania. The investigation ws expanded to include workers and former workers producing electron receiving tubes at the GTE Sylvania, Inc., Altoona Receiving Tube Plant, Altoona, Pennsylvania and the Williamsport Receiving Tube Finishing Warehouse, Williamsport, Pennsylvania.

The Notice of Investigation was published in the FEDERAL REGISTER on August 29, 1978 (43 FR 38635-38636). No public hearing was requested and none was held.

On February 28, 1976, the Department issued a certification of eligibility to apply for adjustment assistance applicable to workers at GTE Sylvania, Altoona and Emporium, Pennsylvania (TA-W-392). That certification expired on February 28, 1978, two years from its date of issuance.

The determination was based upon information obtained principally from officials of GTE Sylvania, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

Imports of electron receiving tubes and mounts increased both absolutely and relative to domestic production during the first half of 1978 compared to the same period of 1977. Further, mounts imported by the major domestic firms for assembly onto domestically produced tubes are comprising an increasing share of the tube and mount import category, increasing from 67 percent of the category in 1974 to 75 percent in 1977.

Since a small number of domestic producers account for most of the production of electron receiving tubes, industry figures directly reflect the situation of the individual firms.

A major domestic tube manufacturer is relying increasingly upon imported mounts for assembly onto tubes. The intensified competition for the declining electron receiving tube market has resulted in production cutbacks at GTE Sylvania in the third quarter of 1978.

CONCLUSION

After careful review of the facts obtained in the investigation, I conlcude that increases of imports of articles like or directly competitive with electron receiving tubes produced at the Altoona Receiving Tube Plant, the Emporium Receiving Tube Plant and the Williamsport Receiving Tube Finishing Warehouse of GTE Sylvania, Inc. contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance wth the provisions of the Act, I make the following certification:

All workers of the Altoona Receiving Tube Plant, Altoona, Pennsylvania the Emporium Receiving Tube Plant, Emporium, Pennsylvania and the Williamsport Receiving Tube Finishing Warehouse, Williamsport, Pennsylvania of GTE Sylvania, Inc. who became totally or partially separated from employment on or after February 28, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of November 1978.

JAMES F. TAYLOR,
Director, Office of Management Administration and Planning.

[FR Doc. 78-33309 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-4203]

GALETON PRODUCTION CO., GALETON, PA.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4203: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on September 21, 1978 in response to a worker petition received on September 21, 1978 which was filed on behalf of workers and former workers producing electron receiving tubes at the Galeton Production Company, Galeton, Pennsylvania.

The Notice of Investigation was published in the FEDERAL REGISTER on October 10, 1978 (43 FR 46591). No public hearing was requested and none was held.

On June 28, 1976 the Department of Labor issued a certification of eligibility to apply for adjustment assistance applicable to all workers of Galeton Production Company (TA-W-817). That certification expired on June 28, 1978, two years from its date of issuance.

The determination was based upon information obtained principally from officials of Galeton Production Company, its customers, the Electronics Industry Association, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

Imports of electron receiving tubes increased both absolutely and relative to domestic production in the first half of 1978 compared to the same period of 1977. The ratio of imports to domestic production during the first half of 1978 was 75.7 percent.

Galeton Production Company's customer for tube mounts decreased pur-

chases from the subject firm and increased purchases of imported tube mounts in the second quarter of 1978 compared to the previous quarter.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with electron receiving tube mounts produced at Galeton Production Company, Galeton, Pennsylvania contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm.

In accordance with the provisions of the Act, I make the following certification:

"All workers engaged in employment related to the production of electronic receiving tube mounts at Galeton Production Company, Galeton, Pennsylvania who became totally or partially separated from employment on or after June 28, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974."

Signed at Washington, D.C., this 20th day of November 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-33310 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-4169]

GENESCO INC., GENERAL SHOE DIVISION, TULLAHOMA, TENN.

Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on September 19, 1978 in response to a worker petition received on September 13, 1978 which was filed on behalf of workers and former workers producing footwear for men, women and children at the Tullahoma, Tennessee plant of Genesco Incorporated, General Shoe Division.

The Notice of Investigation was published in the FEDERAL REGISTER on October 27, 1978 (43 FR 50270). No public hearing was requested and none was held.

On November 25, 1977, the Department certified as eligible to apply for adjustment assistance all workers at the Tullahoma, Tennessee plant of Genesco, Incorporated (TA-W-2131). Since all workers separated, totally or partially, from the Tullahoma, Tennessee plant of Genesco Incorporated, General Shoe Division on or after June 6, 1976 (impact date) and before November 25, 1979 (expiration date of the certification) are covered by the existing certification a new investigation would serve no purpose. Consequently, the investigation has been terminated.

Signed at Washington, D.C., this 17th day of November 1978.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 78-33311 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-4170]

GENESCO INC., GENERAL SHOE DIVISION, COWAN, TENN.

Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on September 19, 1978 in response to a worker petition received on September 13, 1978 which was filed on behalf of workers and former workers producing footwear for men, women and children at the Cowan, Tennesse plant of Genesco Incorporated, General Shoe Division.

The Notice of Investigation was published in the FEDERAL REGISTER on October 27, 1978 (43 FR 50270). No public hearing was requested and none was held.

On October 31, 1977, the Department certified as eligible to apply for adjustment assistance all workers of the Cowan, Tennessee plant of Genesco, Incorporated, General Shoe Division (TA-W-2174). Since all workers separated, totally or partially, from the Cowan, Tennessee plant of Genesco Incorporated, General Shoe Division on or after June 15, 1976 (impact date) and before October 31, 1979 (expiration date of the certification) are covered, a new investigation would serve no purpose. Consequently, the investigation has been terminated.

Signed at Washington D.C. this 17th day of November 1978.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 78-33312 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-3989]

IGUALDAD TRACTOR SHOP, MAYAGUEZ, P.R.

Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on July 25, 1978 in response to a worker petition received on July 17, 1978 which was filed on behalf of workers and former workers producing raw sugar at the Aquadilla, Puerto Rico plant of Central Coloso. The Department's investigation revealed that the petitioning group of workers were employed at the Igualdad Tractor Shop, located at the Igualdad Sugar Mill, Mayaguez, Puerto Rico.

The Notice of Investigation was published in the FEDERAL REGISTER on August 1, 1978 (43 FR 33840). No public hearing was requested and none was held.

On May 19, 1978, the Department certified as eligible to apply for adjustment assistance all workers of the Igualdad Sugar Mill, Mayaguez, Puerto Rico (TA-W-2793). Since all workers separated, totally or partially, from the Igualdad Tractor Shop, Mayaguez, Puerto Rico on or After May 6, 1978 (impact date) and before May 19, 1980 (expiration date of the certification) are covered under the certification in TA-W-2793, a new investigation would serve no purpose. Consequently, the investigation has been terminated.

Signed at Washington, D.C., this 17th day of November 1978.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 33313 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-4182]

INTERCONTINENTAL PETROLEUM CORP., INC., HOUSTON, TEX., TEXAS CITY, TEX., PAWHUSKA, OKLA.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4182: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on September 19, 1978 in response to a worker petition received on September 19, 1978 which was filed on behalf of workers and former workers producing crude oil at Intercontinental Petroleum Corporation, Inc., Houston Texas. The investigation revealed that workers at Intercontinental Petroleum Corporation, Inc., are engaged in transporting crude oil, gasoline, and diesel fuel, at three locations: Houston, Texas; Texas City, Texas; and Pawhuska, Oklahoma.

The Notice of Investigation was published in the FEDERAL REGISTER on October 27, 1978 (43 FR 50270). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Intercontinental Petroleum Corporation, Inc., and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. The Department has determined that services are not "articles" within the meaning of section 222 of the Act.

Intercontinental Petroleum Corporation, a wholly-owned subsidiary of Intercontinental Oil Company, Inc., was incorporated in Texas in 1975. Both companies are engaged in transporting crude oil, gasoline and diesel fuel. Intercontinental Petroleum (IPC) operates in three locations—corporate offices are located in Houston, Texas, a maintenance yard for trucks is located in Pawhuska, Oklahoma, and a storage terminal is located in Texas City, Texas.

Prior to April 1978, trucks owned by IPC transported crude oil from the well to receiving stations. In April 1978, IPC discontinued this trucking operation. In 1978, IPC leased a storage terminal in Texas City, Texas. IPC now transports diesel fuel and gasoline from storage tanks to local gas stations. The parent company continues to truck crude oil from the well to the receiving stations.

Workers of the Intercontinental Petroleum Corporation, Inc., are engaged in the transporting and storage of crude oil, gasoline, and diesel fuel, and do not produce an article within the meaning of Section 222(3) of the Act.

CONCLUSION

After careful review, I determine that all workers of Intercontinental Petroleum Corporation, Inc., Houston, Texas, Texas City, Texas, and Pawhuska, Oklahoma, are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 20th day of November 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-33314 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-4162]

J. P. STEVENS CO., ROCK HILL INDUSTRIAL PLANT, ROCK HILL, S.C.

Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on September 14, 1978 in response to a worker petition received on September 13, 1978 which was filed by the Amalgamated Clothing and Textile Workers Union on behalf of workers and former workers producing denim fabric at the J. P. Stevens Company, Rock Hill Industrial Plant, Rock Hill, South Carolina.

The Notice of Investigation was published in the FEDERAL REGISTER on September 26, 1978 (43 FR 43587-88). No public hearing was requested and none was held.

Section 221 (a) of the Trade Act of 1974 states that a petition for certification of eligibility to apply for adjustment assistance may be filed with the Secretary of Labor by a group of workers or by their certified or recognized union or other duly authorized representative. During the course of the investigation, it was established that the Amalgamated Clothing and Textile Workers Union is not an authorized representative of the workers at the Rock Hill, South Carolina plant of J. P. Stevens Company. Consequently, the investigation has been terminated.

Signed at Washington, D.C., this 20th day of November 1978.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 78-33315 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-3971]

MORRIS WHITE FASHIONS, SCRANTON, PA.

Certification Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3971: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on July 13, 1978 in response to a worker petition received on July 13, 1978 which was filed by the International Leather Goods, Plastic and Novelty Workers' Union on behalf of workers and former workers producing ladies' handbags at Morris White Fashions, Scranton, Pennsylvania. The investigation revealed that the U.S. Department of Commerce certified Morris White Fashions on September 2, 1977 (F-118).

The Notice of Investigation was published in the FEDERAL REGISTER on July 28, 1978 (43 FR 32885,6). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Morris White Fashions, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

U.S. imports of handbags increased each year from 54.4 million units in 1974 to 92.8 million units in 1977 and from 22.1 million units in the first quarter of 1977 to 34.0 million units in the first quarter of 1978.

The ratio of imports to domestic production increased each year from 66.7 percent in 1974 to 116.6 percent in 1977.

The Department conducted a survey of major customers purchasing ladies' handbags from Morris White Fashions during 1976, 1977, and 1978. The majority of customers that responded indicated decreases in purchases from Morris White in favor of purchases of imported products.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with ladies' handbags produced at Morris White Fashions, Scranton, Pennsylvania contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

"All workers of Morris White Fashions, Scranton, Pennsylvania who became totally or partially separated from employment on or after July 10, 1977 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974."

Signed at Washington, D.C., this 17th day of November 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-33317 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-3780]

NORTHERN OHIO SUGAR CO., FINDLAY, OHIO

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3780: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on May 25, 1978 in response to a worker petition received on May 24, 1978 which was filed by the American Federation of Grain Millers on behalf of workers and former workers processing sugar beets into refined sugar at

the Findlay, Ohio, plant of Nothern Ohio Sugar Company.

The Notice of Investigation was published in the FEDERAL REGISTER on June 29, 1978 (43 FR 25197). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Northern Ohio Sugar Company, Great Western Sugar Company, the U.S. Department of Commerce, the U.S. Department of Agriculture, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

Imports of cane and beet sugar (raw value) increased from 3.9 million short tons in 1975 to 4.7 million short tons in 1976 and to 6.1 million short tons in 1977. The ratio of imports to domestic production increased from 59 percent in 1975 to 66 percent in 1976 and to 96 percent in 1977.

Imports of raw sugar into the United States were subject to quotas from 1935 to December 31, 1974. Since December 31, 1974, when the Sugar Act expired, imported sugar has entered the U.S. free of quantity restrictions. Removal of quotas occurred about the time per capita sugar consumption declined in the U.S.

The resultant surplus of sugar severely depressed sugar prices. World prices fell from 57.3 cents a pound in November 1974 to 11.5 cents a pound in January 1976 and to a level of 11.0 cents a pound in 1977. World sugar supply presently outstrips world demand by four million tons; consequently world prices are not expected to rise in the near future.

The U.S. Department of Agriculture (U.S.D.A.) considering depressed conditions in the domestic sugar market, instituted a price support program in an effort to guarantee a floor price level paid to sugar producers.

In 1977, the U.S.D.A. price support program guaranteed producers $13.50 per hundred weight (13.50¢ per lb.) of raw sugar. The support price has been raised to $14.65 per hundred weight for the 1978 harvest. However, the support price has not been sufficient to protect domestic producers from the increased volume of imports.

The U.S. International Trade Commission conducted an investigation under Section 201 of the Trade Act of 1974 and in March 1977 issued a finding that sugar was being imported into the United States in such quantities as to be a substantial cause of the threat of serious injury to the domestic sugar industry.

The Commission also conducted an investigation under Section 22 of the Agriculture Adjustment Act and in April 1978 issued a finding that sugar was being imported in such quantities as to render, or tend to render, ineffective the price support program conducted by the U.S. Department of Agriculture for sugar cane and sugar beets.

Sugar beet growers contracted with the Findlay plant of Northern Ohio Sugar Company for less acreage in 1977 than in 1976. Depressed sugar prices result in low profitability for growers, which leads the growers to devote less acreage to beets and switch to other crops. The Findlay refinery was closed in May 1978.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with the refined sugar processed from sugar beets produced at Findlay, Ohio, plant of Northern Ohio Sugar Company contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

"All workers of the Findlay, Ohio plant of Northern Ohio Sugar Company who became totally or partially separated from employment on or after May 21, 1977 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974."

Signed at Washington, D.C. this 17th day of November 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-33318 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-4054]

PROGRESSIVE UNIFORM MANUFACTURING CORP., PHILADELPHIA, PA.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4054: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on August 10, 1978 in response to a worker petition received on August 10, 1978 which was filed by the Amalgamated Clothing and Textile Workers Union on behalf of workers and former workers producing men's and women's jeans and related sports wear at Progressive Uniform Manufacturing Corporation, Philadelphia, Pennsylvania.

The Notice of Investigation was published in the FEDERAL REGISTER on August 29, 1978 (43 FR 38634). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Progressive Uniform Manufacturing Corporation, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

United States imports of women's misses', and children's slacks and shorts increased absolutely and relative to domestic production from 1974 through 1977. Imports increased from 11.0 million dozen in 1976 to 11.6 million dozen in 1977. U.S. imports increased from 6.3 million dozen in the first half of 1977 to 8.2 million dozen in the first half of 1978. The import to domestic production ratio of slacks and shorts increased from 36.8 percent in 1976 to 38.0 percent in 1977.

United States imports of men's and boys' woven cotton man-made jeans and dungarees increased to 23 million units in 1977 compared to 14 million units in 1976. Imports increased to 17 million units in the first six months of 1978 compared to 6.7 million units in the same period of 1977. The import to domestic production ratio was 5.4 percent in 1976 and increased to 8.5 percent in 1977.

Major customers of Progressive who were surveyed decreased purchases from Progressive and increased purchases from foreign sources.

On August 12, 1976, the Department issued a certification of eligibility to apply for adjustment assistance applicable to workers of Progressive Uniform Manufacturing Company (TA-W-919). That certification expired on August 12, 1978—two years from its date of issuance.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with men's and women's jeans and related sportswear produced at Progressive Uniform Manufacturing Corporation, Philadelphia, Pennsylvania contributed importantly to the decline in sales or production and to the total or partial sep-

aration of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

"All workers of Progressive Uniform Manufacturing Corporation, Philadelphia, Pennsylvania who become totally or partially separated from employment on or after August 12, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974."

Signed at Washington, D.C., this 20th day of November 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-33319 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-4183]

RITE COAT, INC., COPIAGUE, N.Y.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4183: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on September 19, 1978, in response to a worker petition received on September 15, 1978, which was filed by the International Ladies' Garment Workers Union on behalf of workers and former workers producing ladies' rainwear and wintercoats at Rite Coat, Inc., Copiague, N.Y.

The Notice of Investigation was published in the FEDERAL REGISTER on October 27, 1978 (43 FR 50270). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Rite Coat, Inc., its manufacturer, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files. In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

U.S. imports of women's, misses and children's raincoats increased from 191 thousand dozen in 1975 to 261 thousand dozen in 1976 and decreased to 242 thousand dozen in 1977. Imports increased to 210 thousand dozen in the first half of 1978 compared to 116 thousand dozen in the first half of 1977. The ratio of imports to domestic production increased from 36.8 percent in 1975 to 45.0 percent in 1976 and decreased to 40.3 percent in 1977.

U.S. imports of women's, misses' and children's coats and jackets increased from 1,517 thousand dozen in 1975 to 2,252 thousand dozen in 1976 to 2,723 thousand dozen in 1977. Imports decreased to 1,132 thousand dozen in the first half of 1978 compared to 1,231 thousand dozen in the first half of 1977.

Rite Coat, Inc., was engaged in contract work for one manufacturer during the period under investigation. This manufacturer, which accounted for 100 percent of the company's business, increased its purchases from Rite Coat, Inc., in each of the last 3 years and in the first 9 months of 1978 compared to the first 9 months of 1977. During the same period the manufacturer, whose own sales increased, did not import or contract with foreign sources for the production of ladies' rainwear.

CONCLUSION

After careful review, I determine that all workers of Rite Coat, Inc., Copiague, N.Y. are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 20th day of November 1978.

JAMES F. TAYLOR,
Director, Office of Management Administration and Planning.

[FR Doc. 78-33321 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-3882]

ROSEMER MANUFACTURING CO., HACKENSACK, N.J.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3882: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on June 22, 1978 in response to a worker petition received on April 28, 1978 which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing ladies' coats and sportswear at Rosemer Manufacturing Hackensack, N.J. The investigation revealed that the correct name of the firm is Rosemer Manufacturing Co.

The Notice of Investigation was published in the FEDERAL REGISTER on June 30, 1978 (43 FR 28579). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Rosemer Manufacturing Co., its manufacturers, the National Cotton Council of America, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the total or partial separations, or threat thereof, and to the absolute decline in sales or production.

Rosemer Manufacturing Co. produces primarily ladies' and children's coats. A survey of the manufacturers who purchased the majority of ladies' and children's coats produced by Rosemer Manufacturing Co. in 1976 and 1977 indicated that none of these manufacturers increased purchases of imported coats while decreasing purchases from the subject firm. Only one manufacturer surveyed reduced purchases from Rosemer Manufacturing Co. in 1977 compared to 1976. This manufacturer does not purchase imports or use foreign contractors and sales by this manufacturer increased in 1977 compared to 1976 and increased in the first half of 1978 compared to the first half of 1977.

CONCLUSION

After careful review, I determine that all workers of Rosemer Manufacturing Co., Hackensack, N.J. are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 20th day of November 1978.

JAMES F. TAYLOR,
Director, Office of Management Administration and Planning.

[FR Doc. 78-33322 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-4108]

SKF INDUSTRIES, INC., ALTOONA, PA.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department

of Labor herein presents the results of TA-W-4108: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on August 22, 1978, in response to a worker petition received on August 15, 1978 which was filed on behalf of workers and former workers producing ball bearings at the Altoona, Pennsylvania plant of SKF Industries, Incorporated.

The Notice of Investigation was published in the FEDERAL REGISTER on September 5, 1978 (43 FR 39458/9). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of SKF Industries, Inc., the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

United States imports of ball bearings increased from 111.9 million units in 1976 to 127.9 million units in 1977 and from 65.7 million units in the first six months of 1977 to 84.6 million units in the same period in 1978.

The imports to domestic production ratio for ball bearings increased from 45.6 percent in 1976, to 49.2 percent in 1977 and from 50.5 percent in the first six months of 1977 to 60.7 percent in the same period in 1978.

Imports of ball bearings by the Altoona plant increased absolutely and relative to plant production in 1976, 1977 and the first nine months of 1978. Imports of ball bearings have replaced, in some instances totally, in others partially, production of smaller ball bearings formerly produced at the plant.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with ball bearings produced at the Altoona, Pa., plant of SKF Industries, Inc., contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of the Altoona, Pa., plant of SKF Industries, Inc., who became totally or partially separated from employment on or after December 25, 1977, and before September 9, 1978, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 20th day of November 1978.

JAMES F. TAYLOR,
Director, Office of Management Administration and Planning.

[FR Doc. 78-33323 Filed 11-27-78; 8:45 am]

[4510-23-M]

[TA-W-3015]

SARAJO MANUFACTURING CO., PIERCE CITY, MO.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3015: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on February 2, 1978 in response to a worker petition received on January 25, 1978 which was filed on behalf of workers and former workers producing boys' sport and dress shirts at Sarajo Manufacturing Company, Pierce City, Missouri. During the course of the investigation it was established that boys' vests, jackets and suit tops were also produced.

The notice of investigation was published in the FEDERAL REGISTER on February 17, 1978 (43 FR 7066). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Sarajo Manufacturing Company, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, The National Cotton Council, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

United States imports of men's and boys' woven dress, business, sport and uniform shirts increased from 91,808 thousand units in 1975 to 144,103 thousand units in 1976 and then decreased to 139,720 thousand units in 1977. Imports increased from 30,875 thousand units in the first quarter of 1977 to 34,583 thousand units in the first quarter of 1978. Imports of men's and boys' woven dress, business, sport and uniform shirts relative to domestic production increased from 36.8 percent in 1975 to 53.9 percent in 1976 and to 54.7 percent in 1977.

United States imports of men's and boys' knit sport and dress shirts, excluding T-shirts, increased from 66.2 million units in 1975 to 74.0 million units in 1976 and to 75.2 million units in 1977. Imports increased from 20.0 million units in the first quarter of 1977 to 26.1 million units in the first quarter of 1978. The import to domestic production ratio remained constant at 22.9 percent from 1975 to 1976 and decreased to 19.7 percent in 1977.

United States imports of men's and boys' tailored dress coats and sportcoats increased from 5,465 thousand units in 1975 to 6,965 thousand units in 1976 and then decreased to 6,269 thousand units in 1977. Imports increased from 1,323 thousand units in the first quarter of 1977 to 1,776 thousand units in the first quarter of 1978. The imports to domestic production ratio increased from 28.2 percent in 1975 to 30.0 percent in 1976 and decreased to 26.5 percent in 1977.

United States imports of men's and boys' tailored suits increased from 3,106 thousand units in 1975 to 3,562 thousand units in 1976 and to 4,091 thousand units in 1977. Imports decreased from 1,834 thousand units in the first quarter of 1977 to 1,132 thousand units in the first quarter of 1978. Imports of men's and boys' tailored suits relative to domestic production increased from 19.0 percent in 1976 to 20.0 percent in 1977.

A survey of customers of Sarajo Manufacturing Company indicated that a major customer decreased purchases of boys' leisure jackets and suits from Sarajo and increased purchases of imports in 1977 compared to 1976. Another major customer ceased purchases of boys' shirts from Sarajo in the first quarter of 1978 while continuing to purchase imported boys' shirts.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with boys' shirts, vests, jackets and suit tops produced at Sarajo Manufacturing Company, Pierce City, Missouri contributed importantly to the decline in sales and production and to the total or partial separations of workers at the firm.

In accordance with the provisions of the Act, I make the following certification:

"All workers at Sarajo Manufacturing Company, Pierce City, Missouri who became totally or partially separated from imployment on or after September 30, 1977 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974."

Signed at Washington, D.C., this 17th day of November 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-33324 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-3796]

SPEED TEX CORP., FAIR LAWN, N.J.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3796: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on May 31, 1978 in response to a worker petition received on May 15, 1978 which was filed on behalf of workers and former workers producing finished knit polyester fabric at Speed Tex Corporation, Fair Lawn, New Jersey.

The Notice of Investigation was published in the FEDERAL REGISTER on June 20, 1978 (43 FR 26497). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Speed Tex Corporation, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

that increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Imported garments are not considered like or directly competitive with finished fabric. Imports of finished fabric must be considered in this case.

U.S. imports of finished fabric decreased from 464 million yards in 1976 to 453 million square yards in 1977. Imports increased from 187 million square yards in the first half of 1977 to 255 million square yards in the first half of 1978. The ratio of imports to domestic production was 2.2 percent or less from 1973 through 1977. The ratio increased from 1.8 percent in 1976 to 1.9 percent in 1977.

The Department surveyed the major textile mills and converters who reduced their value of contract work with Speed Tex. None of the respondents indicated that they purchased imported fabric in 1977 or in the first quarter of 1978. A survey of the customers of these mills and converters also indicated insignificant import penetration. These results are consistent with industry data, which show negligible imports of finished fabric during the past four years.

CONCLUSION

After careful review, I determine that all workers of Speed Tex Corporation, Fair Lawn, New Jersey are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 17th day of November 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-33325 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-4019]

U.S. STEEL CORP., TEXAS WORKS, BAYTOWN, TEX.

Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on July 31, 1978 in response to a worker petition received on July 27, 1978 which was filed by the United Steelworkers of America on behalf of workers and former workers producing carbon steel pipe at the Baytown, Texas works of the U.S. Steel Corporation.

The Notice of Investigation was published in the FEDERAL REGISTER on August 8, 1978 (43 FR 35130-31). No public hearing was requested and none was held.

Due to the short term of operation of the pipe mill at the Baytown, Texas plant of the U.S. Steel Corporation, there is not sufficient information in this case upon which to base a determination. Consequently, the investigation has been terminated.

Signed at Washington, D.C., this 17th day of November 1978.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 78-33326 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-4036]

U.S. STEEL CORP., AMERICAN BRIDGE DIVISION, COMMERCE (LOS ANGELES), CALIF.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4036: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on August 3, 1978 in response to a worker petition received on July 31, 1978 which was filed by the United Steelworkers of America on behalf of workers and former workers producing fabricated structural steel at the Commerce (Los Angeles), California plant of the American Bridge Division of the U.S. Steel Corporation.

The Notice of Investigation was published in the FEDERAL REGISTER on September 1, 1978 (43 FR 39193). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of the U.S. Steel Corporation, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

that increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

All of the plant's business is obtained through competitive bids. An examination of the bids lost by the Commerce plant in 1977 and in the frst half of 1978 was made by the Department. Only a minor percentage of the bids lost by the Commerce plant in both periods was lost to foreign fabricators. The demand for fabricated structural steel is dependent upon the activity in the construction industry. Both the value of construction and the value of fabricated structural steel shipments declined in each year compared to the preceding year from 1974 to 1977.

Imports of fabricated structural steel increased from 94,400 tons in 1976 to 142,100 tons in 1977 before declining from 94,000 tons in the first

half of 1977 to 67,300 tons in the first half of 1978. The ratio of imports to the domestic shipments of fabricated structural steel increased from 2.5 percent in 1976 to 4.1 percent in 1977 before declining from 5.6 percent in the first half of 1977 to 3.9 percent in the first half of 1978.

CONCLUSION

After careful review, I determine that all workers of the Commerce (Los Angeles), California plant of the American Bridge division of the U.S. Steel Corp. are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of November 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-33327 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-4055]

UNIVERSAL DATA SERVICES, BOYERTOWN, PENNA.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-4055: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on August 10, 1978 in response to a worker petition received on August 9, 1978 which was filed on behalf of workers and former workers engaged in employment related to data processing at Universal Data Services, Boyertown, Pennsylvania. The investigation revealed that Universal Data Services was a division of Universal Container Corporation.

The Notice of Investigation was published in the FEDERAL REGISTER on August 29, 1978 (43 FR 38634). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Universal Container Corporation and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

Universal Data Services, Boyertown, Pennsylvania was a wholly owned division of Universal Container Corporation until it closed in September, 1978. Universal provided a signficant proportion of data processing services during 1976, 1977 and 1978 for the Faith Shoe Company, a subsidiary of Universal Container Corporation. All employees of the Faith Shoe Company who became totally or partially separated from employment on or after February 17, 1976 have previously been certified eligible to apply for adjustment assistance benefits in a determination issued on May 27, 1977 (TA-W-1695). The Faith Shoe Company closed in May, 1978.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with the women's and children's shoes produced at the Faith Shoe Company, Wilkes Barre, Pennsylvania contributed importantly to the decline in sales or production and to the total or partial separation of workers of Universal Data Services, Boyertown, Pennsylvania. In accordance with the provisions of the Act, I make the following certification:

All workers of Universal Data Services, Boyertown, Pennsylvania who became totally or partially separated from employment on or after January 1, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of November 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-33328 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-3998]

WHITE PINE COPPER DIVISION, OF COPPER RANGE CO., WHITE PINE, MICH.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3998: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on July 26, 1978 in response to a worker petition received on July 24, 1978 which was filed by the United Steelworkers of America on behalf of workers and former workers producing refined copper at the White Pine Copper Division of the Copper Range Company, White Pine, Michigan.

The Notice of Investigation was published in the FEDERAL REGISTER on August 4, 1978 (43 FR 34562). No public hearing was requested and none was held.

On August 6, 1976, the Department issued a certification of eligibility to apply for worker adjustment assistance applicable to workers at the White Pine Copper Company. (TA-W-788) That certification expired on August 6, 1978, two years from its date of issuance.

The determination was based upon information obtained principally from officials of White Pine Copper Division, its customers, the U.S. Department of the Interior, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

U.S. imports of refined copper increased from 384 thousand short tons in 1976 to 391 thousand short tons in 1977 and rose from 164 thousand short tons in January-June 1977 to 327 thousand short tons in January-June 1978. The ratio of imports to domestic copper production increased from 21.0 percent in 1976 to 22.2 percent in 1977 and rose from 15.0 percent in January-June 1977 to 35.9 percent in January-June 1978.

Price competition from imports of refined copper has adversely affected production and employment at White Pine. Imports of copper are affected by the differential between the domestic price for copper and the price established by the LME (London Metal Exchange). When the LME price drops more than the estimated transportation cost of 5 cents per pound below the domestic producers price, the demand for imported copper increases. During the last nine months of 1977 and the first six months of 1978, the average LME price had fallen almost 8 cents per pound below the average domestic producers price.

The major factor contributing to depressed prices is an oversupply of domestic and imported copper as evidenced by U.S. inventory levels for refined copper. U.S. inventories of refined copper were higher in every month of 1977, except December, when compared to the same month in 1976. Inventories in December 1977 were less than one percent below December 1976 levels. In the first nine months of 1978, inventory levels surpassed levels in the same months of 1977, except for March which was only marginally below March 1977.

The abundant supply of copper stocks in the forseeable future provides no reason for domestic consumers of copper to maintain ties with do-

mestic producers for purposes of a guarantee against copper shortages. Consequently, in 1977 and in the first half of 1978, when many domestic copper producers curtailed production because of the depressed market price for copper, imports of refined copper increased in 1977 compared to 1976 and doubled in the first half of 1978 compared to the same period in 1977. A Departmental survey revealed that customers of White Pine decreased purchases from the subject firm and increased purchases of imported copper in the first half of 1978 compared to the first half of 1977.

Price pressure from imported copper has reduced the ability of domestic producers to profitably mine domestic ore and convert it to copper concentrate and refined copper. Estimated costs of production at White Pine during the period January-August 1978 were above the price which White Pine received for its copper. As a result the company lost money and was forced to reduce production and employment levels at its copper division.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with refined copper produced at the White Pine Copper Division of Copper Range Company, White Pine, Michigan contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the act, I make the following certification:

All workers of the White Pine Copper Division of Copper Range Company, White Pine, Michigan and workers of the Copper Range Company employed at the White Pine Copper Division, White Pine, Michigan who became totally or partially separated from employment on or after August 6, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 17th day of November 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-33329 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-4118]

WHITMO HANDBAGS, INC., NEWBURGH, N.Y.

Certification Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3843: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on August 28, 1978 in response to a worker petition received on August 25, 1978 which was filed by the International Leather Goods, Plastics and Novelty Workers' Union on behalf of workers and former workers producing handbags at Whitmo Handbags, Incorporated, Newburgh, New York.

The Notice of Investigation was published in the FEDERAL REGISTER on September 8, 1978 (43 FR 40071). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Whitmo Handbags, Incorporated its customers, the National Handbag Association, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. It is concluded that all of the requirements have been met.

Aggregate U.S. imports of handbags increased absolutely and relative to domestic production in each year from 1974 to 1977 and increased absolutely in the first quarter of 1978 compared to the same period in 1977. Imports increased from 90.2 million units in 1976 to 92.8 million units in 1977. Imports relative to domestic production increased from 111.1 percent in 1976 to 116.6 percent in 1977.

Customers of Morris White Fashions, Inc., Whitmo's parent corporation and the firm for which Whitmo produced exclusively under contract, were surveyed by the Department and by the U.S. Department of Commerce. Most customers who were surveyed who reduced purchases from Morris White increased purchases of imported handbags.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with ladies' handbags produced at Whitmo Handbags, Incorporated, Newburgh, New York contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

"All workers of Whtimo Handbags, Incorporated, Newburgh, New York who became totally or partially separated from employment on or after August 23, 1977 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974."

Signed at Washington, D.C., this 17th day of November 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-33330 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-4165]

BRENTWOOD FABRICS CORP., NEW YORK, N.Y.

Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on September 19, 1978 in response to a worker petition received on September 14, 1978 which was filed on behalf of workers and former workers engaged in the dyeing, finishing and printing of gray goods at Brentwood Fabrics Corporation, New York, N.Y.

The Notice of Investigation was published in the FEDERAL REGISTER on October 27, 1978 (43 FR 50270). No public hearing was requested and none was held.

During the course of the investigation, it was established that all workers of Brentwood Fabrics Corporation were separated from employment in August 1977. Section 223(b) of Trade Act of 1974 states that a certification under this section may not apply to any worker whose last total or partial separation from the firm or appropriate subdivision of the firm occurred more than one year before the date of the petition under Title II, Chapter 2 of the Trade Act of 1974.

The date of the petition in this case is September 8, 1978. Since workers separated from employment at Brentwood Fabrics Corporation prior to September 8, 1977 are not eligible for program benefits under Title II, Chapter 2, Subchapter B of the Trade Act of 1974, continuation of this investigation would serve no purpose. Consequently, the investigation has been terminated.

Signed at Washington, D.C. this 20th day of November 1978.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 78-33298 Filed 11-27-78; 8:45 am]

[4510-28-M]

[TA-W-3699]

RIDDELL, INC., CHICAGO, ILL.

Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3699: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on May 11, 1978 in response to a worker petition received on May 5, 1978 which was filed by the United Shoe Workers of America on behalf of workers and former workers producing men's leather athletic and athleisure shoes at Riddell, Incorporated, Chicago, Illinois. The investigation revealed that the plant produces football helmets and athletic footwear.

The Notice of Investigation was published in the FEDERAL REGISTER on May 30, 1978 (43 FR 23036). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Riddell, Incorporated, its customers, the Sporting Goods Manufacturers Association, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met. With respect to workers engaged in employment related to the production of football helmets, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Imports of football helmets are not separately identifiable in the official trade statistics. Industry sources indicate, however, that imports of football helmets are negligible.

With respect to workers engaged in employment related to the production of athletic footwear all of the group eligibility requirements have been met.

U.S. imports of athletic footwear increased both absolutely and relative to domestic production during 1977 compared to 1976.

Several customers surveyed who purchased football and baseball shoes from Riddell either reduced purchases from Riddell while increasing purchases of imports or reduced purchases from Riddell relative to their purchases of imported football and baseball shoes.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with athletic footwear produced at Riddell, Incorporated, Chicago, Illinois contributed importantly to the decline in sales or production and to the total or partial separation of workers engaged in employment related to such production at that firm.

In accordance with the provisions of the Act, I make the following certification:

"All workers engaged in employment related to the production and distribution of athletic footwear at Riddell, Incorporated, Chicago, Illinois who became totally or partially separated from employment on or after April 27, 1977 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974."

I further determine that workers engaged in employment related to the production of football helmets at Riddell, Incorporated, Chicago, Illinois are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 20th day of November 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc 78-33320 Filed 11-27-78; 8:45 am]

[7510-01-M]

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 78-65]

IMPROVING GOVERNMENT REGULATIONS

Final Report

AGENCY: National Aeronautics and Space Administration.

ACTION: Final Report.

SUMMARY: NASA is issuing this notice to implement Executive Order 12044 and to publish its Final Report. The Report describes procedures for developing new regulations, criteria for defining a significant agency regulation, criteria for defining regulations requiring regulatory analysis and criteria for selecting existing regulations for review.

Because of the nature of NASA's work, few significant regulations are anticipated and only an occasional regulation will require a regulatory analysis. NASA is a research and development agency and generally does not issue regulations with any significant impact on the public.

A process for reviewing NASA regulations, both internal and those published in 14 CFR Chapter V, is in place and predates the Executive Order. For this reason, the agency believes that development of a new plan for reviewing existing regulations is unnecessary and not required by the Executive Order.

EFFECTIVE DATE: November 28, 1978.

ADDRESS: Director, Information Systems Division (Code NSM-12), Office of Management Operations, NASA Headquarters, Washington, D.C. 20546.

FOR FURTHER INFORMATION CONTACT:

Richard Reeves, 202-755-3924 or Joan Cavanaugh, 202-755-3219.

SUPPLEMENTARY INFORMATION: On May 22, 1978, NASA published in the Federal Register (43 FR 21981) its First Report implementing Executive Order 12044. The public was invited to send written comments on this Report by July 21, 1978. The only comments received by NASA were from the Task Force on Sex Discrimination, Department of Justice. Two comments from the Task Force concerned review of existing and future regulations to eliminate gender-specific language. NASA is committed to eliminating the use of such language not only in public regulations but also in internal management directives. NASA Handbook 1410.12 (currently in final coordination) on preparation of directives and regulations requires the use of sex-neutral terminology and a review procedure ensures the elimination of such language. Many regulations have already been reviewed and revised to eliminate such language. To reinforce this commitment the paragraph on "Policy" in this Report is revised to add a sentence on the subject.

NASA's recently revised management directives system, which consists of both internal directives and regulations published in 14 CFR Chapter V, in our judgment includes the underlying policy expressed in EO 12044. It also requires initiating offices to review annually all regulations and revise or cancel them if appropriate.

NASA's First Report stated that 14 CFR Subparts 1204.4 and 1204.508 were being reviewed. A revision of 14 CFR Subpart 1204.4 correcting organizational titles is scheduled for completion by December 31, 1978. A revision to NASA's enforcement plan for Title VI, Civil Rights Act of 1964, was sent to the Department of Justice. When that plan is approved by the Depart-

ment of Justice, NASA will revise 14 CFR 1204.508.

A review of all other NASA regulations in 14 CFR Chapter V was completed during the summer of 1978. Regulations no longer necessary are being canceled. Those requiring revision were identified and scheduled for updating. Revisions are now in process or scheduled for action. Another annual review of all regulations in 14 CFR Chapter V is scheduled for completion in August 1979. Based on this review, unnecessary regulations will be canceled and those requiring revision will be scheduled for update.

Because reviews are now required on an annual basis, and have recently been done, NASA does not propose to establish an additional review. Written comments concerning existing regulations in 14 CFR Chapter V are invited at any time and will be considered during the annual review.

PROCESS FOR DEVELOPING REGULATIONS

NASA is revising its internal directive on development of CFR regulations to comply with Executive Order 12044. The revised directive (NASA Management Instruction 1410.10B) should be finalized in the near future and will include the following provisions implementing Executive Order 12044.

POLICY

Regulations will be written clearly and concisely. Sex-neutral terminology will be used in all regulations. A regulation will be issued or continued only if it is necessary for the effective and efficient performance of an agency function. Before adopting a regulation, meaningful alternatives and costs of compliance, paperwork and other burdens on those affected will be considered.

SIGNIFICANT AGENCY REGULATIONS

Any regulation that meets one or more of the following criteria will be considered significant:

(1) It is a matter of major concern to the public, especially if substantial public comments are anticipated;

(2) It may impose heavy compliance and reporting burdens on the public, especially on small business;

(3) It may substantially affect the quality of the environment, and the public health and safety; and

(4) It involves important NASA policy which will require substantial resources to develop and enforce.

REGULATIONS REQUIRING REGULATORY ANALYSIS

A draft Regulatory Analysis shall be prepared for each proposed significant regulation which:

(1) could have an annual effect on the economy of $100 million or more;

(2) Could cause a major increase in costs or prices for individual industries, levels of government or geographic regions; or

(3) The Administrator determines deserves such analysis.

Each draft Regulatory Analysis shall contain:

(1) A succinct statement of the problem or policy objective;

(2) A description of the major alternative ways of dealing with the problem that were considered by the agency;

(3) An analysis of the economic consequences of each of these alternatives;

(4) A detailed explanation of the reasons for choosing one alternative over the others; and

(5) The urban and community analyses required by Office of Management and Budget Circular A-116.

Each advance notice or notice of proposed rulemaking on a proposal requiring a Regulatory Analysis shall contain an explanation of the regulatory approach that has been selected or is favored, a short description of the other alternatives considered, and a statement of how the public may obtain a copy of the draft Regulatory Analysis.

A final Regulatory Analysis shall be prepared and made available when the final regulations are published.

DETERMINATIONS REQUIRED

(1) When the need for a regulation is identified, the initiating office (the office having the need) immediately will determine, in consultation with the Office of General Counsel, whether the regulation:

Would have external impact requiring that it be published in 14 CFR Chapter V;

(b) Meets the criteria for a significant regulation;

(c) Requires a regulatory analysis or is one that may require such analysis and therefore must be referred to the Administrator for a determination.

(2) If an affirmative determination is made under (1) (b) or (c), the initiating office will submit a written report to the Administrator after coordination with the Directives System Manager and the Office of General Counsel. The report will describe the nature of the required regulations, the issues to be considered, the alternative approaches to be explored, a tentative plan for obtaining public comment, target dates for completion of steps in the development of the regulations, the responsible official, proposed coordination and the determinations made under (1). Subsequent changes in this information will be reported in a timely fashion.

(3) For those regulations requiring a regulatory analysis, the initiating office will submit a draft analysis to the Administrator as part of the report required in (2). The draft regulatory analysis will incorporate the urban and community analyses required by Office of Management and Budget Circular A-116.

DOCUMENTATION FOR APPROVAL OF SIGNIFICANT REGULATIONS

The initiating office shall insure that each proposed or final "significant" regulation submitted to the Administrator includes sufficient documentation to establish the following:

(1) The proposed regulation is needed;

(2) The direct and indirect effects of the regulation have been adequately considered;

(3) Alternative appraches have been considered and the least burdensome of the acceptable alternatives has been chosen;

(4) Public comments have been considered and an adequate response has been prepared;

(5) The regulation is written in plain English and is understandable to those who must comply with it;

(6) An estimate has been made of the new reporting burdens or recordkeeping requirements necessary for compliance with the regulation;

(7) The name, address and telephone number of a knowledgeable agency official is included in the publication; and

(8) A plan for evaluating the regulation after its issuance has been developed.

COORDINATION

Federal Register regulations will be coordinated in the same manner as other NASA directives (see NASA Handbook 1410.12). The procedure for consultation with state and local government officials, or their representatives, established by the March 23, 1978, Memorandum from the President will be followed.

APPROVAL

The Administrator will approve all proposed and final rules to be published in the FEDERAL REGISTER. If the regulation is "significant," the Administrator will consider the 8 factors described above before approving the regulations.

OPPORTUNITY FOR PUBLIC PARTICIPATION

(1) *Policy.* NASA shall give the public an early and meaningful opportunity to participate in its rulemaking activities.

(2) *Significant Regulations*

(a) To give the public an early opportunity to participate in the devel-

opment of NASA's significant regulations, initiating offices will consider the following:

(i) Publishing an advance notice of proposed rulemaking;

(ii) Holding open conferences or public hearings;

(iii) Sending notices of proposed rules to publications likely to be read by those affected; and

(iv) Notifying interested parties directly.

(b) Public comment period for proposed significant regulations will be at least 60 days unless the Administrator determines in a given case that this is not possible. Should this occur a brief statement of the reasons for a shorter period will be included in the preamble to the regulation.

(3) *Other Regulations.* In keeping with the spirit of Executive Order 12044, other proposed rules for which a public comment period is required will provide a 60-day public comment period whenever possible. If this is not possible, at least a 30-day comment period will be provided unless the Administrator authorizes a shorter time period.

(4) *Consideration of Comments.* Relevant comments will be considered and incorporated into the final regulations as appropriate.

SEMIANNUAL AGENDA OF SIGNIFICANT REGULATIONS

Each Program and Staff Office, through its Directives Manager, will submit a report (RCS 10000000774) to the Directives System Manager (Code NSM) by the second Monday of September and the second Monday of March. The report will describe the significant regulations being considered by that office, the need and legal basis for the action being considered, the name and phone number of a knowledgeable official, whether a regulatory analysis is required and the status of regulations previously reported. The report will be submitted in the format depicted in an attachment to NASA Management Instruction 1410.10B; negative responses are required. Reports will be consolidated by the Directives System Manager into a semiannual agenda of significant regulations for publication in the FEDERAL REGISTER on the first Monday of October and the first Monday of April. In addition, the agenda will include existing regulations scheduled for review in accordance with the paragraph entitled Review. The Administrator will approve the agenda before it is published. Supplements may be issued if necessary.

REVIEW

Review of existing regulations in the Code of Federal Regulations will be accomplished through the annual review of the NASA Management Directives System. In this review initiating offices shall also consider:

(1) The continued need for the regulation;

(2) The type and number of complaints or suggestions received;

(3) The burdens imposed on those directly or indirectly affected by the regulations;

(4) The need to simplify or clarify language;

(5) The need to eliminate overlapping and duplicative regulations; and

(6) The length of time since the regulation has been evaluated or the degree to which technology, economic conditions or other factors have changed in the area affected by the regulation.

ROBERT A. FROSCH,
Administrator.

[FR Doc. 78-33117 Filed 11-27-78; 8:45 am]

[7555-01-M]

NATIONAL SCIENCE FOUNDATION

NATIONAL MAGNET LABORATORY VISITING SUBCOMMITTEE OF THE ADVISORY COMMITTEE FOR MATERIALS RESEARCH

Meeting

In accordance with the Federal Advisory Committee Act, Pub. L. 92-463, the National Science Foundation announces the following meeting.

Name: National Magnet Laboratory Visiting Subcommittee of the Advisory Committee for Materials Research.

Date and Time: December 14, 1978—9:00 a.m. to 5:00 p.m., December 15, 1978—9:00 a.m. to 5:00 p.m.

Place: Francis Bitter National Magnet Laboratory, Massachusetts Institute of Technology, 170 Albany Street, Cambridge, Massachusetts.

Type of Meeting: December 14, 1978—Open: 9:00 a.m. to 5:00 p.m., December 15, 1978—Closed: 9:00 a.m. to 5:00 p.m. Contact Person: Dr. William Bernard, Senior Staff Associate/Mathematical, Physical Sciences and Engineering, Room 307, National Science Foundation, Washington, D.C. 20550, Telephone (202) 632-7307.

Summary Minutes: May be obtained from the Committee Management Coordinator, Division of Financial and Administrative Management, Room 248, National Science Foundation, Washington, D.C. 20550.

Purpose of Subcommittee: To provide the Foundation with specific guidance as to how the National Magnet Laboratory may best serve as a national facility responsive to the needs of the scientific community.

Agenda: *December 14, 1978.* Welcome—Dr. Robert A. Alberty, Dean of Science, Massachusetts Institute of Technology. Introduction—Prof. Benjamin Lax, Director, National Magnet Laboratory (NML). Magnet Technology—Dr. D. Bruce Montgomery. Magnetism and Superconductivity—Dr. Simon Foner. Motional Stark Spectroscopy—Dr. Michael Rosenbluh. High Field Thin Film Superconductors—Prof. Malcolm R. Beasley, Stanford University. Structure and Dynamics of Proteins in Solution—Dr. Christopher M. Dobson, Harvard University. Negative Hydrogen Ions in Semiconductors—Dr. David M. Larsen. Laboratory Tour—Prof. Benjamin Lax. High Field dHvA Effects—Prof. Douglas H. Lowndes, University of Oregon. Cellular and Subcellular Effects of Magnetic Field—Dr. Richard Frankel. Magnetics and Ophthalmology—Dr. David Lobel, Tel Aviv University, Israel. Individual visits by Visiting Subcommittee Members with Laboratory Staff.

DECEMBER 15, 1978

CLOSED SESSION (9:00 A.M. TO 5:00 P.M.)

Evaluation of the management, operation, and programs of the NML.

Reason for Closing: The program being reviewed includes information of a proprietary or confidential nature, including technical information, financial data such as salaries, and personal information concerning individuals associated with the proposals. These matters are within exemption (4) and (6) of 5 U.S.C. 552b(c), Government in the Sunshine Act.

Authority To Close Meeting: This determination was made by the Committee Management Officer pursuant to provisions of Section 10(d) of Pub. L. 92-463. The Committee Management Officer was delegated the authority to make such determinations by the Acting Director, NSF, on February 18, 1977.

M. REBECCA WINKLER,
Committee Management Coordinator.

NOVEMBER 22, 1978.

[FR Doc. 78-35331 Filed 11-27-78; 8:45 am]

[7590-01-M]

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-329 and 50-330]

CONSUMERS POWER CO. (MIDLAND PLANT, UNITS 1 AND 2)

Order Extending Construction Completion Dates

Consumers Power Company is the holder of Construction Permits Nos. CPPR-81 and CPPR-82, issued by the Atomic Energy Commission* on December 15, 1972, for construction of

*Effective January 19, 1975, the Atomic Energy Commission became the Nuclear Regulatory Commission, and Permits in effects on that day were continued under the authority of the Nuclear Regulatory Commission.

the Midland Plant, Units 1 and 2, which is presently under construction at the licensee's site in Midland County, Michigan.

On August 29, 1977, Consumers Power Company filed a request for an extension of the completion dates because construction has been delayed due to:

1. Reevaluation of construction time due to changing project scope and industry experience.

2. Switching the completion sequence of Unit 1 and Unit 2,

3. Adverse financial conditions prevailing in 1974 and 1975, and

4. Initial mobilization of the architect-engineer after issuance of the construction permit.

This action involves no significant hazards consideration; good cause has been shown for delay; and the extension is for a reasonable period, the bases for which are set forth in an NRC staff evaluation dated November 17, 1978.

A negative declaration and an environmental impact appraisal have been prepared and are available, as are the above stated documents, for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C. 20555, and at the Grace Dow Memorial Library, 1710 W. St. Andrews Road, Midland, Michigan 48640.

It is hereby ordered that the latest completion dates for Construction Permits Nos. CPPR-81 and CPPR-82 are extended from December 1, 1978, and December 1, 1979, to October 1, 1982, and October 1, 1981 for Units 1 and 2, respectively.

Date of Issuance: November 17, 1978.

For the Nuclear Regulatory Commission.

ROGER S. BOYD,
Director, Division of Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 78-33201 Filed 11-27-78; 8:45 am]

[7590-01-M]

NUCLEAR REGULATORY COMMISSION

EXPORTATION OF NUCLEAR FACILITIES OR MATERIALS

Applications For Licenses

Pursuant to 10 CFR 110.70, "Public Notice of Receipt of an Application", please take notice that the Nuclear Regulatory Commission has received the following applications for export licenses. A copy of each application is on file in the Nuclear Regulatory Commission's Public Document Room located at 1717 H Street, N.W., Washington, D.C.

Dated this day, November 17, 1978, at Bethesda, Maryland.

For the Nuclear Regulatory Commission.

JAMES R. SHEA,
Director, Office of International Programs.

Name of applicant, date of application, date received, application number	Material type	Quantity—Special nuclear material in kilograms		End-use	Country of ultimate destination
		Total element	Total isotope		
Edlow International Oct. 20, 1978, Nov. 1, 1978, XSNM01403	3.55 pct enriched uranium	61,750	2,190	First and second reload fuel for Forsmark I.	West Germany.
Edlow International, Oct. 30, 1978, Nov. 1, 1978, XU08436	Natural uranium	10,000		For research and lab studies at Korea Nuclear Fuel Institute.	South Korea.
Mitsubishi International, Oct. 30, 1978, Nov. 7, 1978, XSNM01404	3.25 pct enriched uranium	15,247	496	Reload fuel for Ohi Unit I	Japan.
Mitshbishi International, Oct. 31, 1978, Nov. 7, 1978, XSNM01405	2.85 pct enriched uranium	11,983	342	Reload fuel for Mihama 3	Do.
Nissho-Iwai Corp., Nov. 3, 1978, Nov. 8, 1978, XSNM01408	93.30 pct enriched uranium	47.162	44.003	Fuel for JMTR, JRR-2 and JRR-4.	Do.

[FR Doc. 78-33206 Filed 11-27-78; 8:45am]

[7590-01-M]

[Dockets Nos. 50-250 and 50-251]

FLORIDA POWER & LIGHT CO.

Issuance of Amendments to Facility Operating Licenses

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendments Nos. 42 and 34 to Facility Operating Licenses Nos. DPR-31 and DPR-41, respectively, issued to Florida Power & Light Co. These amendments revise the Appendix A Technical Specifications for operation of the Turkey Point Plant Unit Nos. 3 and 4, located in Dade County, Florida. The amendments are effective 60 days after the date of issuance.

The amendments revise the Technical Specifications to incorporate limiting conditions for operation and surveillance requirements for existing fire protection systems and administrative controls.

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 these amendments was not required since the amendments do not involve a significant hazards consideration.

The Commission has determined that the issuance of these amendments will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) and environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of these amendments.

For further details with respect to this action, see (1) the application for amendments dated December 22, 1977, (2) Amendments Nos. 42 and 34 to Licenses Nos. DPR-31 and DPR-41 and (3) the Commission's letter of November 25, 1977 transmitting proposed fire protection Technical Specifications and the related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room 1717 H Street NW., Washington, D.C. and at the Environmental & Urban Affairs Library, Florida International University, Miami, Florida 33199. 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 Operating Reactors.

Dated at Bethesda, Maryland this 8th day of November 1978.

For the Nuclear Regulatory Commission.

A. SCHWENCER,
Chief, Operating Reactors Branch No. 1, Division of Operating Reactors.

[FR Doc. 78-33203 Filed 11-27-78; 8:45 am]

[7590-01-M]

[Docket No. 50-219]

JERSEY CENTRAL POWER & LIGHT CO.

Issuance of Amendment to Provisional Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 33 to Provisional Operating License No. DPR-16, issued to Jersey Central Power & Light Company (the licensee), which revised the Technical Specifications for operation of the Oyster Creek Nuclear Generating Station (the facility) located in Ocean County, New Jersey. The amendment is effective as of its date of issuance.

The amendment revises the MAPLHGR limits for Exxon Fuel types III E, III F, V, and V B, and adds a MAPLHGR multiplier.

The application for 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.

Notice of Proposed Issuance of Amendment to Provisional Operating License in connection with this action was published in the FEDERAL REGISTER on September 11, 1978 (43 FR 40329). No request for a hearing or petition for leave to intervene was filed following notice of the proposed action.

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 May 30, 1978, and supplements thereto dated June 6, 1978 and October 3, 1978, (2) Amendment No. 33 to License No. DPR-16, 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 NW., Washington, D.C., and at the Ocean County Library, Brick Township Branch, 401 Chambers Bridge Road, Brick Town, New Jersey 08723. 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 Operating Reactors.

Dated at Bethesda, Maryland, this 11th day of November, 1978.

For the Nuclear Regulatory Commission.

DENNIS L. ZIEMANN,
Chief, Operating Reactors Branch No. 2, Division of Operating Reactors.

[FR Doc. 78-33204 Filed 11-27-78, 8:45 am]

[7590-01-M]

[Docket Nos. 50-329 and 50-330]

MIDLAND PLANT, UNIT NOS. 1 AND 2

Negative Declaration Supporting: Extension of Construction Permits No. CPPR-81 and CPPR-82 Expiration Dates

The U.S. Nuclear Regulatory Commission (the Commission) has reviewed the Consumers Power Company (permittee) request to extend the expiration date of the construction permits for the Midland Plant, Unit Nos. 1 and 2 (CPPR-81 and CPPR-82) which is located in Midland County in the State of Michigan. The permittee requested a forty-six month extension to permit CPPR-81 through October 1, 1982 and a twenty-two month extension to permit CPPR-82, through October 1, 1981, to allow for completion of construction of the plant.

The Commission's Division of Site Safety and Environmental Analysis has prepared an environmental impact appraisal relative to these changes to CPPR-81 and CPPR-82. Based on this appraisal, the Commission has concluded that an environmental impact statement for this particular action is not warranted because there will be no environmental impact attributable to the proposed action other than that which has already been described in the Commission's Final Environmental Statement—Construction Permit stage.

The environmental impact appraisal is available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C. and at the Grace Dow Memorial Library, 1710 W. St. Andrews Road, Midland, Mich.

Dated at Bethesda, Md., this 17th day of November 1978.

For the Nuclear Regulatory Commission.

WM. H. REGAN, Jr.,
Chief, Environmental Projects Branch 2, Division of Site Safety and Environmental Analysis.

[FR Doc. 78-33202 Filed 11-27-78; 8:45 am]

[7590-01-M]

REGULATORY GUIDE

Notice of Issuance and Availability

The Nuclear Regulatory Commission has issued a new guide in its Regulatory Guide Series. 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.

Regulatory Guide 8.24, "Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication," specifies the types and frequencies of surveys that are acceptable to the NRC staff for the protection of workers in plants licensed by the NRC for processing enriched uranium and for the fabrication of uranium fuel. This guide provides guidance to applicants in preparing license applications and to licensees in establishing acceptable survey programs to detect radiation exposure in accordance with the "as low as is reasonably achievable" (ALARA) philosophy.

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. Public comments on Regulatory Guide 8.24 will, however, be particularly useful in evaluating the need for an early revision if received by January 25, 1979.

Comments should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

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 the latest revision of issued guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future 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 20th day of November 1978.

For the Nuclear Regulatory Commission.

RAY G. SMITH,
Acting Director, Office, of Standards Development.

[FR Doc. 78-33207 Filed 11-27-78; 8:45 am]

[7590-01-M]

[Docket Nos. 50-259, 50-260 and 50-296]

TENNESSEE VALLEY AUTHORITY

Issuance of Amendments to Facility Operating License

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 44 to Facility Operating License No. DPR-33, Amendment No. 40 to Facility Operating License No. DPR-52, and Amendment No. 17 to Facility Operating License No. DPR-68 issued to Tennessee Valley Authority (the licensee), which revised the Technical Specifications for operation of the Browns Ferry Nuclear Plant, Unit Nos. 1, 2, and 3 (the facility) located in Limestone County, Alabama. The amendments are effective as of the date of issuance.

These amendments change the Technical Specifications to (1) permit the average power range monitor system to be inoperable in the refuel mode, provided the source range monitors are connected to give a noncoincidence, high flux scram; (2) permit less than three intermediate range monitors (IRMs) per trip channel to be operable in the shutdown or refuel modes, provided at least four IRMs (one in each core quadrant) are connected to give a non-coincidence, high flux scram; (3) clarifies ambiguous portions of the Technical Specifications related to the rod block monitor system; (4) removes reference to an obsolete 1968 version of an ASTM procedure; (5) modifies the list of snubbers that are required to be operable; (6) removes a specification for additional tests of secondary containment that only applied during the first fuel cycle for each Browns Ferry Unit, and (7) changes one of the four locations where milk samples are collected.

The applications for the amendments comply 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. Prior public notice of these amendments was not required since the amendments do not involve a significant hazards consideration.

The Commission has determined that the issuance of these amendments 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 these amendments.

For further details with respect to this action, see (1) the applications for amendments dated August 2, 1978 and August 11, 1978, (2) Amendment No. 44 to License No. DPR-33, Amendment No. 40 to License No. DPR-52, and Amendment No. 17 to License No. DPR-68, 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 NW., Washington, D.C., and at the Athens Public Library, South and Forrest, Athens, Alabama 35611. 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 Operating Reactors.

Dated at Bethesda, Maryland, this 16th day of November 1978.

For the Nuclear Regulatory Commission.

THOMAS A. IPPOLITO,
Chief, Operating Reactors Branch No. 3, Division of Operating Reactors.

[FR Doc. 78-33205 Filed 11-27-78; 8:45 am]

[7905-01-M]

RAILROAD RETIREMENT BOARD

RAILROAD RETIREMENT SUPPLEMENTAL ANNUITY PROGRAM

Determination of quarterly rate of excise tax

In accordance with directions in Section 3221(c) of the Railroad Retirement Tax Act (26 U.S.C. § 3221(c)), the Railroad Retirement Board has determined that the excise tax imposed by such Section 3221(c) on every employer, with respect to having individuals in his employ, for each man-hour for which compensation is paid by such employer for services rendered to him during the quarter beginning January 1, 1979, shall be at the rate of twelve and one-half cents.

In accordance with directions in Secton 15(a) of the Railroad Retirement Act of 1974, the Railroad Retirement Board has determined that for the quarter beginning January 1, 1979, 17.4 percent of the taxes collected under Sections 3211(b) and 3221(c) of the Railroad Retirement Tax Act shall be credited to the Railroad Retirement Account and 82.6 percent of the taxes collected under such Sections 3211(b) and 3221(c) plus one hundred percent of the taxes collected under Section 3221(d) of the Railroad Retirement Tax Act shall be credited to the Railroad Retirement Supplemental Account.

Dated: November 20, 1978.

By Authority of the Board.

R. F. BUTLER,
Secretary of the Board.

[FR Doc. 78-33232 Filed 11-27-78; 8:45 am]

[8010-01-M]

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. 20770; 70-6082]

APPALACHIAN POWER CO., ET AL.

Proposed Issuance and Sale of Notes to Banks by Holding Company and Capital Contributions by Holding Company to Subsidiaries

NOVEMBER 14, 1978.

In the matter of Appalachian Power Company, 40 Franklin Road, Roanoke, Virginia 24009, Indiana & Michigan Electric Company, 2101 Spy Run Avenue, Fort Wayne, Indiana 46801, Kentucky Power Company, 15th Street and Carter Avenue, Ashland, Kentucky 41101, Ohio Power Company, 301 Cleveland Avenue SW., Canton, Ohio 44701, and American Electric Power Company, Inc., 2 Broadway, New York, New York 10004.

Notice is hereby given that American Electric Power Company, Inc. ("AEP"), a registered holding company, and Appalachian Power Company ("Appalachian"), Indiana and Michigan Electric Company ("I&M"), Ohio Power Company ("Ohio Power"), and Kentucky Power Company ("KPCO"), AEP's subsidiary electric utility companies, have filed a post-effective amendment to an application-declaration previously filed with this Commission pursuant to the Public Utility Holding Company Act of 1935 ("Act") designating Section 6(b) and 12 of the Act and Rule 50 promulgated thereunder as applicable to the following proposed transactions. All interested persons are referred to the application-declaration, as amended by the post-effective amendment, summarized below, for a complete statement of the proposed transactions.

By prior order in this proceeding (HCAR No. 20365, January 5, 1978), AEP was authorized to issue and sell from time to time, prior to January 1, 1979, short-term notes and commercial paper, to banks, and to a dealer in commercial paper respectively, in an amount of up to $165,000,000, such notes maturing no later than June 30, 1979. AEP was also authorized to make cash capital contributions, prior to January 1, 1979, to its public utility

subsidiary companies in the following aggregate amounts: Appalachian, $95,000,000; I&M, $60,000,000; and Ohio Power, $35,000,000.

AEP, by post-effective amendment, requests that it be permitted to issue and sell from time to time, prior to January 1, 1980, as funds may be required, short-term notes (including commercial paper) in an aggregate amount not to exceed $165,000,000 outstanding at any one time. None of such notes or commercial paper shall mature no later than June 30, 1980. The notes to be sold to banks will be dated as of the date of the borrowing which it evidences, will mature not more than 270 days from the date of issue or reissue thereof, and will be prepayable at any time without premium or penalty. AEP proposes to issue and sell such short-term notes to 11 banks with lines of credit in an aggregate amount of $179,000,000. The banks and their respective lines of credit which AEP has established at such banks are as follows:

Name	Amount
Chemical Bank, New York, N.Y.	$45,000,000
The Chase Manhattan Bank (National Association), New York, N.Y.	40,000,000
Manufacturers Hanover Trust Co., New York, N.Y.	25,000,000
Morgan Guaranty Trust Co. of New York, New York, N.Y.	22,000,000
Bankers Trust Co., New York, N.Y.	9,000,000
Irving Trust Co., New York, N.Y.	8,000,000
The Bank of New York, New York, N.Y.	4,000,000
The Cleveland Trust Co., Cleveland, Ohio	8,000,000
First Pennsylvania Bank & Trust Co., Philadelphia, Pa.	9,000,000
Mellon Bank, N.A., Pittsburgh, Pa.	6,000,000
United Virginia Bank, Richmond, Va.	3,000,000
Total	179,000,000

AEP will be required to either (1) maintain compensating balances of 10% of the bank lines made available and additional compensating balances of 10% of the amount of any borrowings, or (2) maintain compensating balances and pay an annual fee for the availability of the line of credit, equivalent generally, in combination, to compensating balances not in excess of 10% of the line of credit made available. Where only compensating balances are required, borrowings under such lines will bear interest at an annual rate not greater than the bank's prime commercial rate in effect at the time of issuance. Where a combination of compensating balances and fees are required, borrowings under such lines would bear interest at a specified rate in excess of the bank's prime commercial rate in effect at the time of issuance, but such specified rate would not be greater than the equivalent rate of borrowings bearing interest at the prime rate with compensating balances equal to 10% of the amount borrowed. If the full amount were borrowed from the banks, the effective interest cost to AEP, based on a prime commercial rate of 10¾%, would be 13.44%.

The commercial paper will be in the form of promissory notes in denominations of not less than $50,000 nor more than $50,000,000 of varying maturities, with no such maturity more than 270 days after the date of issuance and none will be prepayable prior to maturity. The commercial paper notes will be sold directly to Lehman Commercial Paper Incorporated (the "dealer") at a discount rate not in excess of the discount rate per annum prevailing at the time of issuance for commercial paper of comparable quality and maturity. No commercial paper notes will be issued having a maturity of more than 90 days if such commercial paper notes would have an effective interest cost which exceeds the effective interest cost at which AEP could borrow from banks.

The dealer will reoffer the commercial paper notes to not more than 200 of such dealer's customers identified and designated in a non-public list prepared by the dealer in advance, at a discount rate of ⅛ of 1% per annum less than the discount rate to AEP. It is expected that such customers of the dealer will hold the commercial paper notes to maturity, but, if any such customer wishes to resell such commercial paper prior to maturity, the dealer, pursuant to a verbal repurchase agreement, will repurchase such commercial paper sold by it and reoffer it to other customers on the list.

AEP also requests authority to make cash capital contributions from time to time prior to January 1, 1980, to its public utility subsidiary companies in the following aggregate amounts: Appalachian, $100,000,000, I&M, $60,000,000, Ohio Power, $50,000,000 and KPCO, $20,000,000.

The proceeds from the sale of the short-term notes are to be applied by AEP, together with other funds, to make additional investments in its public utility subsidiary companies to assist them in financing the costs of their respective construction programs and to retire their short-term debt. The construction programs of AEP's public utility subsidiary companies for 1978 and 1979 are estimated as follows: $314,000,000 and $37,000,000 respectively, for Appalachian; $275,000,000, $252,000,000, respectively, for I&M and its generating subsidiary; $205,000,000 and $241,000,000, respectively, for Ohio Power and its generating subsidiary, and $42,000,000 and $123,000,000, respectively, for KPCO.

AEP requests an exception from the competitive bidding requirements of Rule 50 for the proposed issue and sale of its commercial paper pursuant to paragraph (a)(5) thereof.

No additional fees and expenses are expected to be incurred with this proposed transaction. It is stated that the State Corporation Commission of Virginia and the Public Service Commission of West Virginia have jurisdiction over the proposed capital contribution by AEP to Appalachian and that no other State Commission and no Federal Commission, other than this Commission, has jurisdiction over the proposed transactions.

Notice is further given that any interested person may, not later than December 7, 1978, request in writing that a hearing be held on such matter, stating the nature of his interest, the reasons for such request, and the issues of fact or law raised by the application-declaration, as amended by said post-effective amendment which he desires to controvert; or he may request that he be notified if the Commission should order a hearing thereon. Any such request should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request should be served personally or by mail upon the applicants-declarants at the above-stated addresses, and proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. At any time after said date, the application-declaration, as amended by said post-effective amendment or as it may be further amended, may be granted and permitted to become effective as provided in Rule 23 of the General Rules and Regulations promulgated under the Act, or the Commission may grant exemption from such rules as provided in Rules 20(a) and 100 thereof or take such other actions as it may deem appropriate. Persons who request a hearing or advice as to whether a hearing is ordered will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Corporate Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc. 78-33061 Filed 11-27-78; 8:45 am]

[8010-01-M]

[Release No. 10486; 811-2465]

BAYROCK CAPITAL SERIES, INC.

Application

NOVEMBER 17, 1978.

Notice is hereby given that Bayrock Capital Series, Inc. (Bayrock Capital Preservation Fund Series), 40 Wall

Street, New York, New York 10005 ("Applicant"), a Maryland corporation registered under the Investment Company Act of 1940 ("Act") as a closed-end, diversified investment company, filed an application on October 26, 1978, pursuant to Section 8(f) of the Act and Rule 8F-1 thereunder, for an order of the Commission declaring that Applicant has ceased to be an investment company as defined in the Act. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below.

Applicant asserts that on March 13, 1974, it registered under the Act and filed a registration statement under the Securities Act of 1933, which was subsequently amended on July 9, 1974. Such registration statement was later withdrawn and no public offering was made. Applicant further asserts that it has only one shareholder, no assets and no outstanding liabilities. Applicant represents that it is not now engaged, and does not propose to engage, in any business activities other than those necessary for the winding-up of its affairs.

Section 8(f) of the Act provides, in part, that when the Commission upon application finds that a registered investment company has ceased to be an investment company, it shall so declare by order and, upon the effectiveness of such order, the registration of such company shall cease to be in effect.

Notice is further given that any interested person may, not later than December 12, 1978, at 5:30 p.m., submit to the Commission in writing a request for a hearing on the matter accompanied by a statement as to the nature of his interest, the reason for such request, and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission shall order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail upon Applicant at the address stated above. Proof of such service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed contemporaneously with the request. As provided by Rule 0-5 of the Rules and Regulations promulgated under the Act, an order disposing of the application will be issued as of course following said date unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons who request a hearing, or advice as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc. 78-33062 Filed 11-27-78; 8:45 am]

[8010-01]

[Release No. 15339]

BOSTON STOCK EXCHANGE, INC.

Applications for Unlisted Trading Privileges and of Opportunity for Hearing

NOVEMBER 16, 1978.

The Boston Stock Exchange, Inc. ("BSE") has filed applications with the Securities and Echange Commission pursuant to Section 12(f)(1)(C) of the Securities Exchange Act of 1934 (the "Act") and Rule 12f-1 thereunder for unlosted trading privileges in the securities of the companies as set forth below, which securities are registered with the Commission pursuant to Section 12 of the Act or which would be required to be so registered except for the exemption from registration provided in subsection (g)(2)(B) or (g)(2)(G) of Section 12.[1]

United Canso Oil and Gas, Ltd., Common Stock, $1.00 par value (Canadian—File No. 7-5066.

Canada Southern Petroleum, Ltd., Common Stock, $1.00 par value (Canadian) File No. 7-5067.

United Canso and Canada Southern are currntly listed on the BSE and the PSE. The BSE has filed these applications for unlisted trading privileges, however, because these companies have filed applications to withdraw from listing and registration on the BSE as well as the PSE. United Canso's and Canada Southern's applications are currently pending before the Securities and Exhange Commission.[2]

Upon receipt of a request, on or before December 15, 1978, from any interested person, the Commission will determine whether the applications with respect to the companies named shall be set down for hearing. Any such request should include a brief statement as to the title of the security in which the person is interested, the position which he proposes to take at the hearing, if ordered. In addition, any interested person may submit his views or any additional facts bearing on the said applications by means of a letter addressed to the Secretary, Securities and Exchange Commission, Washington, D.C. 20549 not later than the date specified. If no one requests a hearing with respect to the particular applications, such applications will be determined by order of the Commission on the basis of the facts therein and other information contained in the official files of the Commission pertaining thereto.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc. 78-33063 Filed 11-27-78; 8:45 am]

[8010-01-M]

[Release No. 20778; 70-6142]

THE COLUMBIA GAS SYSTEM, INC., ET AL.

Post—Effective Amendment Relating to Intrasystem Financing

NOVEMBER 15, 1978.

In the matter of The Columbia Gas System, Inc., 20 Montchanin Road, Wilmington, Delaware 19807; Columbia Gas of West Virginia, Inc., Columbia Gas of Kentucky, Inc., Columbia Gas of Virginia, Inc., Columbia Gas of Pennsylvania, Inc., Columbia Gas of New York, Inc., Columbia Gas of Maryland, Inc., Columbia Gas of Ohio, Inc., 99 North Front Street, Columbus, Ohio 43215; Columbia Gas Transmission Corporation, 1700 MacCorkle Avenue, S.E., Charleston, West Virginia 25314; Columbia Gulf Transmission company, 3805 West Alabama Avenue, Houston, Texas 77027; Columbia Hydrocarbon Corporation, Columbia Coal Gasification Corporation, The Inland Gas Company, Inc., 340—17th Street, Ashland, Kentucky 41101; Columbia Gas Development Corporation, Columbia LNG Corporation,, and Columbia Development of Canada Ltd., 20 Montchanin Road, Wilmington, Delaware 19807.

Notice is hereby given that The Columbia Gas System, Inc. ("Columbia"), a registered holding company, and its subsidiary companies named above, have filed a post-effective amendment to their application-declaration in this proceeding pursuant to Sections 6(b), 9, 10, 12(b) and 12(f) of the Public Utility Holding Company Act of 1935

---

[1] These are not the first applications for unlisted trading privileges pursuant to Section 12(f)(1)(C) of the Act to be filed with the Commission. The Commission currently has pending before it applications by the Pacific Stock Exchange Incorporated ("PSE") for unlisted trading privileges pursuant to Section 12(f)(1)(C) in the common stock of Pacific Resources, Inc. (File No. 7-4933), United Canso Oil and Gas, Ltd. ("United Canso") (File No. 7-5022) and Canada Southern Petroleum, Ltd. ("Canada Southern") (File No. 7-5023), and by the BSE in the common stock of Air Express International Corporation (File No. 7-5031).

[2] Notice of the applications was given in Securities Exchange Act Release Nos. 14484, February 16, 1978 (Canada Southern) and 14485), February 16, 1978 (United Canso).

("Act") and Rules 43, 45 and 50(a)(3) promulgated thereunder as applicable to the following proposed transactions. All interested persons are referred to the amended application-declaration, which is summarized below, for a complete statement of the proposed transaction.

By order dated April 28, 1978 (HCAR No. 20523) in this proceeding, the Commission, among other things, authorized Columbia to advance on open account to certain subsidiaries, and have outstanding from time to time, up to an aggregate amount of $260,700,000 to finance the purchase by such subsidiaries of under ground storage gas inventories, miscellaneous other inventories and for short-term seasonal purposes. The advances authorized for Columbia Gas of West Virginia, Inc. ("Columbia of West Virginia"), were limited to $24,000,000, its then estimated short-term financing requirements.

The open account advances initially bear interest at the rate in effect from time to time at the agent bank for Columbia's short-term loan line of credit. Interest charges to the subsidiaries subsequently will be adjusted, after the storage financing period, to the effective cost of money Columbia achieves on its short-term borrowing for this purpose. Substantially all of such advances are expected to be taken down by December 31, 1978, however, a portion may be taken down during the period January 1, 1978, through May 31, 1979. The funds would be advanced, repaid and reborrowed, as required from time to time for periods not exceeding one year from the date of each advance. All such advances are to be repaid on or before May 31, 1979.

Applicants-declarants now seek to increase the authorization for the proposed advances to Columbia of West Virginia to an aggregate principal amount of $31,000,000. It is stated that the $7,000,000 increase is required to provide Columbia of West Virginia with sufficient funds to finance gas purchases and other normal short-term seasonal requirements. It is further stated that the proposed increase in short-term financings has been necessitated by an unanticipated reduction in cash flow resulting from the denial by the State of West Virginia Public Services Commission ("West Virginia Commission") in its order dated June 30, 1978 in Case No. 9407 of Columbia of West Virginia's request to fully recover gas costs until completion of further hearings. In its final order in that proceeding dated October 5, 1978, the West Virginia Commission authorized the recovery of substantially all the increase in purchased gas costs. Since these costs are not recoverable immediately, but will be recovered through an actual cost adjustment provision over the next twelve months, the company is experiencing a current reduction in cash flow. In all other respects, the proposed transactions remain the same.

It is stated that the West Virginia Commission has jurisdiction over the proposed transactions. It is further stated that no other state commission and no Federal commission, other than this Commission, has jurisdiction over the proposed transactions.

Notice is further given that any interested person may, not later than December 11, 1978, request in writing that a hearing be held on such matter, stating the nature of his interest, the reasons for such request, and the issues of fact or law raised by said post-effective amendment which he desires to controvert; or he may request that he be notified if the Commission should order a hearing thereon. Any such request should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request should be served personally or by mail upon the applicants-declarants at the above-stated addresses, and proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. At any time after said date, the application-declaration, as amended or as it may be amended, may be granted and permitted to become effective as provided in Rule 23 of the General Rules and Regulations promulgated under the Act, or the Commission may grant exemption from such rules as provided in Rules 20(a) and 100 thereof or take such other action as it may deem appropriate. Persons who request a hearing or advice as to whether a hearing is ordered will receive any notices or orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Corporate Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc. 78-33064 Filed 11-27-78; 8:45 am]

[8010-01-M]

[Rel. No. 10479; 812-4365]

DEVELOPING GROWTH SHARES, INC., ET AL.

Notice of Filing of Application

NOVEMBER 15, 1978.

Notice is hereby given that Developing Growth Shares, Inc. ("New Fund") and Lord Abbett Developing Growth Fund, Inc. ("LADGF") (collectively, "Funds"), both open-end, diversified investment companies registered under the Investment Company Act of 1940 ("Act"), and Lord, Abbett & Co. ("Lord Abbett"), the investment manager and principal underwriter for the Funds (collectively referred to as "Applicants"), 63 Wall Street, New York, New York 10005, filed an application on September 5, 1978, and amendments thereto on October 16, 1978 and November 13, 1978, for an order: (1) pursuant to Section 17(b) of the Act, exempting the proposed transactions described below from Section 17(a) of the Act; (2) pursuant to Section 17(d) of the Act and Rule 17d-1 thereunder, permitting Applicants to participate in the proposed transactions; and (3) pursuant to Section 6(c) of the Act, exempting the issuance of shares of New Fund from Section 22(d) of the Act and Rule 22c-1 thereunder. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below.

Applicants state that on August 21, 1978, Lord Abbett organized New Fund under the laws of the State of Maryland as a vehicle by which LADGF can, in the manner described below, make an indirect offering of LADGF shares at a fixed and predetermined price. New Fund has, or will have, the same investment objective, policies and restrictions and the same practices, programs and management as LADGF. Applicants further state that although New Fund has not yet commenced operations, it proposes to make a public offering ("Underwritten Offering"), in January 1979, of shares of its capital stock at its present net asset value of $11.65 per share, plus an underwriting discount, through underwriters for whom Bache Halsey Stuart Shields Incorporated, E. F. Hutton & Company Inc., Paine, Webber, Jackson and Curtis, Incorporated and others will act as representatives. For purchases of less than 400 shares, the underwriting discount will be 85 cents per share, or 6.8 percent of the public offering price (7.3 percent of the amount invested). These charges will be reduced according to a schedule of decreasing percentages according to the amount invested. New Fund's schedule of sales charges is lower than that of LADGF.

Immediately after the closing of the Underwritten Offering, LADGF will merge into New Fund ("Merger"), and New Fund will change its name to Lord Abbett Developing Growth Fund, Inc. pursuant to an Agreement and Articles of Merger ("Merger Agreement"). Persons purchasing shares of New Fund's capital stock pursuant to the Underwritten Offering will not be required to make payment for such shares until the closing date of the conversion of LADGF's shares into shares of New Fund pursuant to the

Merger Agreement. Applicants represent that such closing date will be approximately five weeks after the effective date of New Fund's Registration Statement under the Securities Act of 1933 ("Securities Act") for the Underwritten Offering.

In the Merger, shares of capital stock of LADGF will be converted into full or fractional shares of capital stock of New Fund having the same aggregate net asset value as the shares being converted. No adjustments will be made to reflect potential federal income tax liabilities by reason of unrealized appreciation in LADGF's portfolio prior to the Merger. However, LADGF will be declaring a dividend of all its then undistributed investment company income and a capital gains distribution of all its then undistributed net capital gains prior to the Merger. Net asset values will be determined as of the close of business on the business date next preceding the effective date of the Merger. No sales charge will be payable upon the conversion of the shares. All expenses of the Applicants in connection with the Underwritten Offering and the Merger will be borne by Lord Abbett.

As soon as practicable after the Merger, New Fund, as the surviving fund in the Merger and renamed "Lord Abbett Developing Growth Fund, Inc.," will offer its shares in the same manner as LADGF presently does. New Fund's Board of Directors has approved the Underwritten Offering and the Merger. The initial stockholders of New Fund, who will be partners of Lord Abbett, will consent to the Merger prior to the Underwritten Offering. The Board of Directors of LADGF approved the Merger and has authorized the submission of the merger proposals to stockholders at its annual meeting.

Applicants contend that the proposed transactions have been structured in the manner described above in order to effect what amounts to an indirect public offering, through an underwriting syndicate, by LADGF of its capital stock at a fixed price and in an orderly manner. The current prospectus of LADGF has been supplemented to disclose the terms of the proposed Underwritten Offering. On the effective date of the Registration Statement of New Fund under the Securities Act for the Underwritten Offering, LADGF intends to cease offering its shares, except to its existing shareholders, who, through cumulative purchasing or statements of intention, can purchase shares at lower sales charges than they could in the Underwritten Offering.

Section 17(a) of the Act provides, in part, that it is unlawful for an affilitated person of a registerd investment company, or any affiliated person of such a person, acting as principal, knowingly to sell to or purchase from such registered investment company any security or other property. Section 2(a)(3) of the Act provides, in part, that an affiliated person of another person includes any person directly or indirectly controlling, controlled by, or under common control with, such other person. LADGF and New Fund state, without conceding, that they may be deemed to be affiliated persons of one another because each has an investment management and distribution agreement with Lord Abbett and because they have the same officers and directors. Thus, Section 17(a) of the Act may prohibit LADGF and New Fund, as affiliated persons of each other, from effectuating the Merger.

Section 17(b) of the Act, however, provides, in part, that the Commission shall exempt a proposed transaction from the provisions of Section 17(a) if evidence establishes that the terms of the proposed transaction, including the consideration to be paid or received, are fair and reasonable and do not involve overreaching on the part of any person concerned, and that the proposed transaction is consistent with the policy of each registered investment company concerned and with the general purposes of the Act.

LADGF and New Fund submit that the terms of the Merger Agreement are reasonable and fair and do not involve overreaching on the part of any person concerned and are consistent with the policies of the Funds and the general purposes of the Act. The Underwritten Offering will permit New Fund to raise funds without cost to it. In the Merger, New Fund will be issuing its shares to stockholders of LADGF on the basis of the relative net asset values of the Funds immediately prior to the Merger without the payment of any commissions. Lord Abbett will bear all of the expenses of the Funds in connection with the Underwritten Offering and the Merger.

Applicants state that the directors of LADGF concluded that the increased size of the surviving corporation, estimated to be nearly twice the size of LADGF, which presently has approximately $15 million in net assets, should be advantageous to the stockholders of LADGF for three reasons. First, an increase in assets, without cost to LADGF, will cause the fixed and semi-fixed expenses of the surviving corporation to be spread over a greater asset base, thus lowering the ratio of expenses to net assets. Second, the increase in assets will permit the surviving corporation to take advantage of investment opportunities that are not now available to LADGF because of its present size. Third, the increase in assets should enable the surviving corporation to attract favorable attention from investors and securities dealers. This could result in an increase in sales of the surviving corporation's capital stock, which could permit a further reduction in the per share expense ratio and provide additional assets for expansion of its portfolio.

Section 17(d) of the Act and Rule 17d-1 thereunder provide, in part, that it shall be unlawful for any affiliated person of, or principal underwriter for, a registered investment company, or any affiliated person of such a person or principal underwriter, acting as principal, to effect any transaction in which such registered company is a joint or a joint and several participant with such person, principal underwriter, or affiliated person, unless an order of the Commission permitting such transaction is issued. In passing upon an application for such an order, the Commission will consider whether the participation of such registered company in such enterprise on the basis proposed is consistent with the provisions, policies and purposes of the Act and the extent to which such participation is on a basis different from or less advantageous than that of other participants.

Applicants state that Lord Abbett acts as principal underwriter and investment manager for both Funds. Lord Abbett proposes to bear all of the expenses of the Funds in connection with the Underwritten Offering and the Merger. During LADGF's fiscal year ending September 30, 1977, Lord Abbett reimbursed LADGF for expenses in the amount of $45,583, which was $1,599 greater than its management fee for that period. Further, it is represented that, according to the unaudited report of LADGF's expenses for its fiscal year ending September 30, 1978, Lord Abbett would be required to reimburse LADGF for expenses in the amount of $2,409. While not conceding that the provisions of Section 17(d) of the Act and Rule 17d-1 apply to the proposed transactions, Applicants request that, to the extent that the interrelationships described herein might cause any of the proposed activities by Lord Abbett to come within the provisions of Section 17(d) of the Act, an order of the Commission permitting the participation by the Funds in the proposed transactions be issued pursuant to section 17(d) of the Act and Rule 17d-1 thereunder.

Applicants submit that the participation by each of the Funds in the proposed transactions is consistent with the provisions, policies and purposes of the Act and is not on a basis different from or less advantageous than that of the other participants.

Rule 22c-1 under the Act provides, in part, that no registered investment company shall sell, redeem or repurchase any redeemable security of which it is the issuer except at a price based on the current net asset value of such security which is next computed after receipt of a tender of such security for redemption or of an order to purchase or sell such security. Applicants state that because under the Merger Agreement, the respective net asset values of the Funds will be determined as of the close of business on the business day immediately preceding the Merger, the issuance by New Fund of shares of its capital stock in the Merger may not comply with Rule 22c-1.

Section 6(c) of the Act provides, in part, that the Commission may, upon application, conditionally or unconditionally exempt any person, security or transaction from any provision of the Act or any rule thereunder, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and with the purposes fairly intended by the policy and provisions of the Act.

Applicants submit that the timing of the determination of net asset values of the Funds is appropriate. It will allow adequate time to prepare for the closing of the Merger. It is further submitted that such timing will not give rise to the speculative activity which Rule 22c-1 was designed to prohibit. Therefore, Applicants state that the granting of the exemption is necessary and appropriate, is in the public interest and is consistent with the protection of investors and with the purposes fairly intended by the policy and provisions of the Act.

Accordingly, Applicants request that to the extent that the proposed transactions may not be in compliance with Rule 22c-1 under the Act, the Commission issue an order of exemption therefrom pursuant to Section 6(c) of the Act, to permit the transactions described in the application to be consummated.

Section 22(d) of the Act provides, in part, that no registered investment company shall sell redeemable securities of which it is the issuer except at a current public offering price described in the prospectus.

Applicants state that while the availability to certain LADGF shareholders during the Underwritten Offering of purchasing privileges they enjoy under LADGF's current schedule of sales charges may appear to constitute price discrimination which Section 22(d) is designed to prohibit, the purpose of this arrangement is to enable existing shareholders to buy at the lowest possible price. Thus, present LADGF shareholders who are able to obtain lower sales charges on purchases of shares through statements of intention or cumulative purchasing discounts, will be able to exercise these privileges with respect to LADGF shares during the Underwritten Offering. Applicants represent that Lord Abbett and the transfer agent for LADGF will take all necessary steps to avoid sales of LADGF shares to existing shareholders of LADGF who do not qualify for lower sales charges. All other investors will buy at the sales charge structure in the New Fund prospectus. Applicants further represent that the current prospectus of LADGF was supplemented to disclose the terms of the proposed Underwritten Offering and the reduced sales charges. Present LADGF shareholders will be informed of their options also by means of a letter accompanying the proxy material which will be sent to them in connection with the approval of the Merger and by the proxy statement itself.

Thus, Applicants submit that the granting of the requested exemption from Section 22(d) of the Act is necessary and appropriate, is in the public interest and is consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Notice is further given that any interested person may, not later than December 11, 1978, at 5:30 p.m., submit to the Commission in writing a request for a hearing on the matter accompanied by a statement as to the nature of his interest, the reason for such request, and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission shall order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail upon Applicants at the address stated above. Proof of such service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed contemporaneously with the request. As provided by Rule 0-5 of the Rules and Regulations promulgated under the Act, an order disposing of the application will be issued as of course following said date unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons who request a hearing, or advice as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc. 78-33065 Filed 11-27-78; 8:45 am]

[8010-01-M]

[Rel. No. 20779; 70—6227]

GENERAL PUBLIC UTILITIES CORP.

Holding Company's Proposed Capital Contributions to Subsidiaries

NOVEMBER 15, 1978.

Notice is hereby given that General Public Utilities Corporation ("GPU"), 260 Cherry Hill Road, Parisppany, New Jersey 07054, a registered holding company, has filed with this Commission a declaration pursuant to the Public Utility Holding Company Act of 1935 ("Act"), designing Section 12(b) of the Act and Rule 45 promulgated thereunder as applicable to the proposed transactions. All interested persons are referred to the declaration, which is summarized below, for a complete statement of the proposed transactions.

GPU requests authorization to make cash capital contributions from time to time commencing from the date of the order permitting this declaration to become effective through December 31, 1979, to two of its three major electric utility subsidiaries, Jersey Central Power and Electric Light Company ("Jersey Central") and Pennsylvania Electric Company ("Penelec"), of amounts aggregating up to $90,000,000. GPU does not expect that it will be necessary to make cash capital contributions to its other major electric utility subsidiary, Metropolitan Edison Company ("Met-Ed") during the year.

GPU requests permission to allocate the respective amounts of the proposed contributions (within the $90,000,000 aggregate amount) between Jersey Central and Penelec as to best match their needs as such needs develop during 1979. Those needs will be affected by the earnings and internal cash generation, rate and timing of expenditures for construction, and restrictions on the issuance of debt, preferred stock and short term debt with respect to each subsidiary.

It is stated that the cash capital contributions will be credited by Jersey Central and Penelec to their respective capital accounts and the funds used for the purpose of financing their respective businesses, including the payment of construction expenditures, which are estimated for 1979 at $305,000,000 for Jersey Central and $115,000,000 for Penelec.

The fees and expenses to be incurred in connection with the proposed transactions are estimated to $6,000, including legal fees of $3,500. It is stated that no state commission and no federal commission, other than this Commission, has jurisdiction over the proposed transactions.

Notice is further given that any interested person may, not later than December 8, 1978, request in writing that a hearing be held on such matter, stating the nature of his interest, the reasons for such request, and issues of fact or law raised by said declaration which he desires to controvert; or he may request that he be notified if the Commission should order a hearing thereon. Any such request should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request should be served personally or by mail upon the declarant at the above-stated address, and proof of service (by affidavit or, in the case of an attorney-at-law, by certificate) should be filed with the request. At any time after said date, the declaration, as filed or as it may be amended, may be permitted to become effective as provided in Rule 23 of the General Rules and Regulations promulgated under the Act, or the Commission may grant exemption from such rules as provided in Rules 20(a) and 100 thereof or take such other action as it may deem appropriate. Persons who request a hearing, or advice as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Corporate Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc. 78-33065 Filed 11-27-78; 8:45 am]

[8010-01-M]

[Rel. No. 20771, 70—6195]

INDIANA & MICHIGAN ELECTRIC CO.

Proposed Increase in Short-Term Indebtedness

NOVEMBER 14, 1978.

Notice is hereby given that Indiana & Michigan Electric Company ("I&M"), 2101 Spy Run Avenue, Fort Wayne, Indiana 46801, an electric utility subsidiary company of American Electric Power Company, Inc. ("AEP"), a registered holding company, has filed with this Commission a post-effective amendment to its application previously filed in this matter pursuant to the Public utility Holding Company Act of 1935 ("Act"), designating Section 6(b) of the Act and Rules 50(a)(2) and 50(a)(5) promulgated thereunder as applicable, as amended by said post-effective amendment, which is summarized below, for a complete statement of the proposed transaction.

By order dated September 7, 1978 (HCAR No. 20700), I&M was authorized to issue and sell short-term notes and commercial paper through January 1, 1980, in an aggregate amount not to exceed $125,000,000 outstanding at any one time, such indebtedness to mature not later than June 30, 1980. As of October 26, 1978, I&M had $102,090,000 aggregate principal amount of short-term debt outstanding.

By post-effective amendment applicant proposes that its short-term debt authorization be increased from $125,000,000 to $150,000,000. It is stated that the increase is necessary due to changes in previous plans to sell a 15% interest in its Rockport Plant to Kentucky Power Company, another electric utility subsidiary of AEP. That planned sale, which is the subject of a separate application before this Commission (File No. 70-6198), was disapproved by the Kentucky Public Service Commission on October 19, 1978.

Concerning the credit arrangements, it is stated that I&M has lines of credit with 39 banks which total $295,990,000, such banks being of three classes.

Each note to be issued to a Class I bank will mature not more than 270 days after the date of issuance or renewal thereof, and will be prepayable at any time without premium or penalty. I&M's credit arrangements with these banks require it to maintain compensating balances equal to a percentage of the line of credit made available by the bank plus a percentage of any amount actually borrowed (generally not in excess of 10 percent of the line of credit and 10 percent of the amount borrowed). In most cases I&M maintains deposit balances for its operational and financial needs in amounts sufficient to satisfy any compensating balances required with respect to borrowings from such banks. Borrowings from a Class I bank would generally bear interest at an annual rate not greater than the bank's prime commercial rate in effect from time to time.

Each note to be issued to a Class II bank will mature not more than 90 days after the date of issuance or renewal thereof, and will be prepayable at any time without premium or penalty. I&M's credit arrangements with these banks require it to maintain compensating balances of 5 percent of the line of credit and to pay a fee equal to 4 percent of the bank's prime commercial rate then in effect on the size of the line. The combination of 5 percent compensating balances and a fee is generally equivalent to compensating balances not in excess of 10 percent of the line of credit made available. In addition, I&M must pay interest at the rate of 100.5 percent of the bank's prime commercial rate then in effect on the borrowings. It is stated that if the balances maintained and the fees paid by I&M with and to the Class I and II banks were maintained and paid solely to fulfill requirements for borrowings by I&M, the effective annual interest cost under either such arrangement, assuming full use of the line of credit, would not exceed 125 percent of the prime commercial rate in effect from time to time, or not more than 13.4375 percent on the basis of a prime commercial rate of 10.75 percent.

With respect to the Class III banks, I&M has a money market facility at each of two named banks in an aggregate amount of $25,000,000. These money market facilities do not represent a formal commitment or engagement by these banks to I&M, but represent merely the ability of I&M to request unsecured borrowings, in the form of promissory notes, on a case-by-case basis. These money market facilities are available for unsecured borrowings in domestic dollars and/or in Eurodollars for periods of up to 180 days after the date of issuance, and any such borrowings will be prepayable at any time without premium or penalty. No compensating balances are required. The interest rate, which is presently to be negotitated on a case-by-case basis (using a 360 day year), is pegged to either the London Interbank Offering Rate plus a designated percent, if the borrowings are made in Eurodollars, or to a designated percent of the banks's prime rate, it the borrowings are made in domestic dollars. It is stated that interest rates on these notes will be lower than the effective interest rates for borrowings made from Class I and II banks, including the effect of any compensating balances and fees paid.

I&M also has arrangements to sell commercial paper directly to Lehman Commercial Paper Incorporated (the "Dealer"). The commercial paper will consist of promissory notes in denominations of not less than $50,000 nor more than $5,000,000, of varying maturities, with no maturity more than 270 days after the date of issue; such notes will not be repayable prior to maturity and will be sold at a discount rate not in excess of the discount rate per annum prevailing at the time of issuance for commercial paper of comparable quality and maturity. No commercial paper will be issued having a maturity of more than 90 days if such commercial paper would have an effective interest cost to I&M which ex-

ceeds the effective interest cost at which I&M could borrow from commercial banks. The Dealer will reoffer the commercial paper, at a discount rate ⅛ of 1 percent annum less than the discount rate at which such notes were purchased from I&M, to not more than 200 of the Dealer's customers designated in a non-public list prepared by the Dealer in advance. No sales of such commercial paper will be made to any customer unless that customer has received up-to-date reports as to the credit position of I&M. It is expected that the Dealer's customers will hold such commercial paper to maturity; but if any such customer wishes to resell I&M commercial paper prior to maturity, the Dealer, pursuant to a verbal repurchase agreement, will repurchase the commercial paper and reoffer it to other customers on its non-public list.

The proceeds from the issue and sale of the notes will be used by I&M to reimburse its treasury for past expenditures made in connection with its construction program and to pay part of the cost of its future construction program. I&M estimates its construction expenditures for the year 1978 and 1979 at $450,000,000 (exclusive of the expenditures of its generating subsidiary).

I&M claims exemption from the competitive bidding requirements of Rule 50 for the proposed issuance of notes to banks pursuant to paragraph (a)(2) thereof, and requests exemption from such requirements for the proposed issue and sale of its commercial paper pursuant to paragraph (a)(5) thereof.

There are no additional fees or expenses to be incurred in connection with the proposed transaction. It is stated that no state commission and no federal commission, other than this Commission, has jurisdiction over the proposed transaction.

Notice is further given that any interested person may, not later than December 7, 1978, request in writing that a hearing be held on such matter, stating the nature of his interest, the reasons for such request, and the issues of fact or law raised by the application, as amended by said post-effective amendment, which he desires to controvert; or he may request that he be notified if the Commission should order a hearing thereon. Any such request should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request should be served personally or by mail upon the applicant at the above-stated address, and proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. At any time after said date, the application, as amended by said post-effective amendment or as it may be further amended, may be granted as provided in Rule 23 of the General Rules and Regulations promulgated under the Act, or the Commission may grant exemption from such rules as provided in Rules 20(a) and 100 thereof or take such other action as it may deem appropriate. Persons who request a hearing or advice as to whether a hearing is ordered will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Corporate Regulation, pursuant to delegated authority.

GEORGE A FITZSIMMONS,
Secretary.

[FR Doc. 78-33067 Filed 11-27-78; 8:45 am]

[8010-01-M]

[Rel. No. 10484; 812—4293]

JET CAPITAL CORP.

Renotice of Application

NOVEMBER 17, 1978.

Notice is hereby given that an application was filed on April 19, 1978, and amended on July 7, 1978, by Jet Capital Corporation ("Applicant"), One Allen Center, Houston, Texas 77002, a Delaware corporation, pursuant to Section 3(b)(2) of the Investment Company Act of 1940 ("Act"), declaring that the Applicant is primarily engaged in a business or businesses other than that of investing, reinvesting, owning, holding, or trading in securities. On July 13, 1978, a notice of the application (Investment Company Act Release No. 10322) was issued. On August 30 and October 30, 1978, the Applicant filed additional amendments to its application setting forth, among other things, certain information concerning purchases by Texas International Airlines, Inc. ("TXIA"), the securities of which are Applicant's principal assets) of the common stock of National Airlines, Inc. ("National"), and the means by which TXIA financed these purchases. All interested persons are referred to the application and amendments thereto on file with the Commission for a statement of the representations and modifications made therein, which are summarized below and in the previous notice.

Section 3(a)(3) of the Act defines an investment company as any issuer which is engaged, or proposes to engage, in the business of investing, reinvesting, owning, holding, or trading in securities, and owns or proposes to acquire investment securities having, a value exceeding 40 per centum of such issuer's total assets (exclusive of Government securities and cash items) on an unconsolidated basis.

Applicant was incorporated in 1969, but during that year it had minimal assets and virtually no business. Applicant states that after a public offering of its common stock and warrants to purchase common stock increased its assets, Applicant's business became leasing jet aircraft. Applicant represents that subsequently the aircraft leasing business became unattractive and shareholder approval was obtained to explore other business opportunities in the airline field. This exploration eventually led in early 1971 to an advisory agreement with TXIA, a scheduled airline which operates primarily in the Southwest as well as in the Republic of Mexico. Applicant states that it acquired control of TXIA in 1972 as a part of a comprehensive refinancing of TXIA designed by Applicant and necessitated by losses of $20 million incurred by TXIA in the four prior years. In exchange for $1,150,000 Applicant received 2,040,000 shares of TXIA Series C convertible preferred stock and common stock purchase warrants, expiring June 30, 1982, to purchase 765,000 shares of TXIA common stock. Applicant states that the TXIA Series C convertible preferred stock enabled it to cast more than 50% of the votes at any meeting of TXIA stockholders.

As of January 31, 1978, Applicant states that it was entitled to cast 55.7% of the votes at a meeting of TXIA stockholders. However, as a result of the issuance by TXIA of 990,000 common shares on April 19, 1978, Applicant states that the percentage of such votes which Applicant would be entitled to cast declined to approximately 43.9%, and Applicant's investment securities, as defined in Section 3(a) of the Act, exceeded 40% of the value of its total assets.

Applicant states that on August 16, 1978, TXIA offered outside of the United States through a wholly-owned subsidiary $25,000,000 of debentures convertible into TXIA's common stock. Applicant states that these debentures will be convertible into an aggregate of 1,724,138 shares of common stock of TXIA. In addition, Applicant states on October 6, 1978, TXIA filed a registration statement with the Commission for the public offering and sale of 1,525,287 shares of the common stock of TXIA. Of that number, TXIA proposes to offer and sell to the public 350,000 shares, plus up to an additional 138,000 shares to the extent the underwriters of the offering exercise an option to purchase such shares from TXIA in order to cover overallotments. The remaining 1,037,287 shares are to be sold by or for the account of certain selling security holders. Applicant states that based on the number

of shares outstanding on August 31, 1978, and giving effect to the proposed public offering (including the conversions of preferred stock and exercises of warrants contemplated thereby and assuming the exercise in full of the underwriters' option), the voting interest of Applicant on votes for directors of TXIA would be 31.2%. Applicant further states that if all warrants are exercised (other than those owned by Applicant), if all debentures are converted, if all Series A and B preferred stock are converted, and if all shares reserved under a stock option plan and an employee stock purchase plan are issued, then the possible voting interest of Applicant on votes for directors of TXIA would be 21%.

Applicant states that since April 18, 1978, TXIA's business has included its purchases of the stock of National, although it is asserted that the purchases of National stock were not contemplated by Applicant on April 18, 1978. Applicant states that as of July 10 and at all times through August 21, 1978, TXIA held an aggregate of 790,700 shares of National common stock or approximately 9.2% of the outstanding shares. From August 22 to October 30, 1978, TXIA purchased an additional 1,178,300 shares, and as of the close of business on October 30, 1978, TXIA held approximately 23% of the outstanding common stock of National. Applicant states that TXIA intends to purchase up to 25% of the National common stock but is not committed to do so. Based upon estimated asset figures as of August 31, 1978, 27.5% of TXIA's assets were held in investment securities for purposes of Section 3(a)(3) of the Act.

Section 3(b)(2) of the Act exempts from the definition of an investment company in Section 3(a)(3) of the Act any issuer which the Commission finds and by order declares to be primarily engaged in a business or businesses other than that of investing, reinvesting, owning, holding, or trading in securities, either directly or (a) through majority-owned subsidiaries or (b) through controlled companies conducting similar types of businesses. Section 2(a)(9) of the Act defines control as the power to exercise a controlling interest over the management or policies of a company, unless such power is solely the result of an official position with such company. In addition, Section 2(a)(9) of the Act states that any person who owns beneficially, either directly or through one or more controlled companies, more than 25 per centum of the voting securities shall be presumed to control such company. Any person who does not so own more than 25 per centum of the voting securities of any company shall be presumed not to control such company, but any such presumption may be rebutted by evidence.

Applicant submits that it is entitled to an order of exemption under Section 3(b)(2) of the Act because it is primarily engaged and has been primarily engaged since 1972 in the air transportation business through a controlled subsidiary, TXIA. Applicant states that it has never been nor held itself out to be an investment company, that the three officers of Applicant have been principal executive officers of TXIA for more than 6 years and devote nearly all of their business time to the affairs of TXIA, and that Applicant's assets and income reflect these factors. Applicant states that in addition to having 31.2% of the vote at a meeting of shareholders, by virtue of its ownership of a majority of a combined class of TXIA's Series B and Series C preferred stock, Applicant has veto power over certain corporate action, such as any merger or consolidation of TXIA, any sale of all or substantially all of TXIA's assets, the reclassification of the capital shares of TXIA or the liquidation of TXIA. Applicant states that as a result of an amendment of TXIA's loan agreements, TXIA will not be in default if Applicant no longer controls TXIA; however, Applicant asserts that this amendment was not made in anticipation of a loss of control of TXIA by Applicant and that amendment does not indicate that any lender has questioned the lenders' earlier confirmation that Applicant controls TXIA.

Applicant asserts that it has no present intention of engaging in any business activity other than the direction and control of TXIA for the foreseeable future and that it has no present intention to sell any of its securities in TXIA. Applicant asserts that the purchases by TXIA of the common stock of National are in furtherance of TXIA's business as an airline and are not part of any intention of TXIA to engage in the business of investing or trading in securities within the meaning of the Act. Applicant states that prior to TXIA's purchases of National stock, TXIA had never purchased stock of any other corporation in any substantial amount. Applicant states that it is not the present intention of TXIA to purchase stock of National for purposes of control and then to resell after National's earnings performance has improved. Applicant contends that if TXIA gains control of National, its intention would be to participate in the airline business directly and through National either by control or consolidation.

In further support of the request for exemption, Applicant states that it has never owned a material amount of stock of any corporation other than TXIA, and that it has never sold any TXIA securities. Applicant states that subsequent to the purchase and control of TXIA by Applicant in 1972, the three officers of Applicant who are principal executive officers of TXIA moved themselves and their families from New York to Houston, Texas where TXIA's offices are located. Applicant also states that to its knowledge, no person other than Applicant is entitled to cast 5% of the votes for directors after completion of the proposed TXIA public offering.

Applicant states that it is its understanding that, other than the proposed public offering described above, TXIA has no current intention to offer or sell any equity securities or any securities convertible into or exchangeable for equity securities, although a combination of TXIA and National might involve the issuance of such securities. In this connection, however, TXIA has filed a petition with the CAB requesting permission to purchase National stock beyond the present 25% limit and expects that the financial terms of a combination of TXIA and National would require the issuance of a substantial amount of additional securities and that if may also require substantial additional financing. Applicant submits that TXIA would not be an investment company even if it acquired National stock in an amount having a value in excess of 40% of TXIA's assets. Applicant contends that TXIA would be entitled to an exemption pursuant to either Section 3(b)(1) or Section 3(b)(2) of the Act because it would continue to be primarily engaged in the airline business.

Applicant states that as a condition to an order pursuant to Section 3(b)(2) of the Act, the exemptive order will terminate 30 days after it is determined that at the end of any calendar quarter more than 40 percent of TXIA's total assets consist of investment securities as defined by Section 3(a)(3) of the Act, unless:

(1) Applicant has received an opinion of counsel to the effect that TXIA is primarily engaged in a business other than that of investing, reinvesting, owning, holding or trading in securities within the meaning of Section 3(b)(1) of the Act, or

(2) Applicant or TXIA has filed a request for a no-action letter pursuant to Section 3(b)(1) of the Act and, alternatively, an order pursuant to Section 3(b)(2) of the Act, or

(3) Applicant or TXIA has filed a request for an order pursuant to Section 3(b)(2) of the Act.

Applicant states that in the event that Applicant or TXIA shall proceed under either item (2) or item (3) above, Applicant's exemption shall cease, and it shall register in the event that the Commission shall have final-

ly denied the request from exemption and the time to appeal therefrom shall have run.

Section 3(b)(2) provides, in part, that whenever the Commission finds, upon its own motion, that the circumstances which gave rise to the issuance of an order granting an application thereunder no longer exist, the Commission shall by order revoke such order.

Notice is further given that any interested person may, not later than December 11, 1978, at 5:30 p.m., submit to the Commission in writing a request for a hearing on the matter accompanied by a statement as to the nature of his interest, the reason for such request, and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission shall order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail upon Applicant at the address stated above. Proof of such service (by affidavit, or in case of an attorney-at-law, by certificate) shall be filed contemporaneously with the request. As provided by Rule 0-5 of the Rules and Regulations promulgated under the Act, an order disposing of the application will be issued as of course following said date unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons who request a hearing, or advice as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc. 78-33068 Filed 11-27-78; 8:45 am]

[8010-01-M]

[Rel. No. 20772; 70-6224]

KENTUCKY POWER CO.

Proposed Short-Term Borrowing

NOVEMBER 14, 1978.

Notice is hereby given that Kentucky Power Company ("Kentucky"), an electric utility subsidiary company of American Electric Power Company, Inc. ("AEP"), 15th Street and Carter Avenue, Ashland, Kentucky 41101, a registered holding company, has filed with this Commission an application pursuant to the Public Utility Holding Company Act of 1935 ("Act"), designating Section 6(b) of the Act and Rule 50(a)(2) promulgated thereunder as applicable to the proposed transaction. All interested persons are referred to the application, which is summarized below, for a complete description of the proposed transaction.

Kentucky requests that from the date of the granting of this application to January 1, 1980, the exemption from the provisions of Section 6(a) of the Act afforded to it by the first sentence of section 6(b) of the Act, related to the issuance of short-term notes, be increased to the extent necessary to cover the issuance and sale of notes to banks in an aggregate amount not to exceed $35,000,000 outstanding at any one time, all such indebtedness to mature not later than March 31, 1980.

Kentucky states that such short-term financing is necessary due to a change in its plans concerning a contemplated $100,000,000 term loan involved with its proposed purchase of a 15% interest in the Rockport Plant owned by Indiana & Michigan Electric Company, another electric utility subsidiary of AEP. That proposed transaction is the subject of a separate application before this Commission (File No. 70-6198), but was disapproved by the Kentucky Public Service Commission on October 19, 1978. Kentucky expects to request a reconsideration of the decision of the Kentucky Public Service Commission or to file a new application before it. Due to the uncertainty as to when and if said state commission will approve the proposal, Kentucky requests the short-term borrowing authorization in the event such approval is not forthcoming.

Concerning the credit arrangements, it is stated that Kentucky has lines of credit with 11 banks which total $241,000,000. Each note to be issued will mature not more than 90 days after the date of issuance or renewal thereof, and will be prepayable at any time without premium or penalty. Kentucky's credit arrangements with these banks require it to maintain compensating balances of 5% of the line of credit and pay a fee equal to 4% of the bank's prime commercial rate then in effect on the size of the line of credit. The combination of a 5% compensating balance and a fee is generally equivalent to a compensating balance not in excess of 10% of the line of credit made available. In addition, Kentucky must pay interest on the borrowings at the rate of 108.5% of the bank's prime commercial rate then in effect. Interest computed at this rate would not be greater than the effective rate for borrowings bearing interest at the prime rate with compensating balances equal to 10% of the amount borrowed. If the balances maintained and fees paid by Kentucky were maintained and paid solely to fulfill requirements for borrowings by Kentucky, the effective interest cost to Kentucky, assuming full use of the line of credit, would not exceed 125% of the prime commercial rate in effect from time to time, or not more than 13.4375% on the basis of a prime commercial rate of 10.75%.

Kentucky claims exemption from the competitive bidding requirements of Rule 50 for the proposed issuance of notes to banks pursuant to paragraph (a)(2) thereof.

The fees and expenses to be incurred in connection with the proposed transaction are estimated at $2,500. It is stated that no state commission and no federal commission, other than this Commission, has jurisdiction over the proposed transaction.

Notice is further given that any interested person may, not later than December 7, 1978, request in writing that a hearing be held on such matter, stating the nature of his interest, the reasons for such request, and the issues of fact or law raised by said application which he desires to controvert; or he may request that he be notified if the Commission should order a hearing thereon. Any such request should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request should be served personally or by mail upon the applicant at the above stated address, and proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. At any time after said date, the application, as filed or as it may be amended, may be granted as provided in Rule 23 of the General Rules and Regulations promulgated under the Act, or the Commission may grant exemption from such rules as provided in Rules 20(a) and 100 thereof or take such other action as it may deem appropriate. Persons who request a hearing or advice as to whether a hearing is ordered will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Corporate Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc. 78-33069 Filed 11-27-78; 8:45 am]

[8010-01-M]

[Release No. 20780; 70—6225]

LOUISIANA POWER & LIGHT CO.

Proposed Extension of Issuance and Sale of Notes to Banks and to Dealer in Commercial Paper and Exception From Competitive Bidding

NOVEMBER 16, 1978.

Notice is hereby given that Louisiana Power and Light Company ("Louisiana"), 142 Delaronde Street, New Orleans, Lousiana 70174, a public-utility subsidiary company of Middle South Utilities, Inc. ("Middle South"), a registered holding company, has filed an application and an amendment thereto with this Commission pursuant to Sections 6(a) and 7 of the Public Utility Holding Company Act of 1935 ("Act") and Rules 23, 50(a) (2), and 50(a) (5) promulgated thereunder regarding the following proposed transactions. All interested persons are referred to the application, as amended, for a complete statement of the proposed transactions.

Louisiana presently has in effect a program covering its interim financing requirements (bank borrowings and sales of commercial paper) through December 31, 1978, as authorized by the Commission (HCAR No. 19825). To cover its interim financing requirements through June 30, 1980, Louisiana proposes, from time to time, to borrow from, pay, prepay and/or reborrow from one or more commercial banks and to issue and sell commercial paper to a dealer or broker in such securities in an aggregate principal amount not exceeding $120,000,000 outstanding at any one time. The proposed commercial bank loans would be evidenced by unsecured promissory notes of Louisiana, each to the order of the lending bank, maturing not later than June 30, 1980, and generally bearing interest at the prime rate in effect from time to time at certain New York banks. Such notes would be subject to prepayment in whole at any time or in part from time to time without penalty or premium. Set forth below are the respective maximum amounts which the banks participating in the bank loans have committed themselves to lend during the period through June 30, 1980:

Bank	Maximum amount
The Chase Manhattan Bank (National Association) New York, N.Y	$54,000,000
Irving Trust Co., New York, N.Y	12,000,000
Manufacturers Hanover Trust Co., New York, N.Y	9,000,000
Whitney National Bank of New Orleans, New Orleans, La	8,000,000
First National Bank of Louisville, Louisville, Ky	8,000,000
First National Bank of Commerce, New Orleans, La	6,000,000
Bank of Virginia, Richmond, Va	5,000,000
Hibernia National Bank, New Orleans, La	5,000,000
Securities Pacific National Bank, Los Angeles, Calif	5,000,000
National American Bank of New Orleans, New Orleans, La	2,800,000
The National Bank of Commerce in Jefferson Parish, New Orleans, La	750,000
First State Bank & Trust Co., Bogalusa, La	640,000
The Bank of New Orleans & Trust Co., New Orleans, La	500,000
Central Bank, Monroe, La	500,000
First National Bank of Jefferson Parish, Gretna, La	400,000
First National Bank of West Monroe, West Monroe, La	400,000
Assumption Bank & Trust Co., Napoleonville, La	240,000
Bastrop National Bank, Bastrop, La.	200,000
American Bank & Trust Co. in Monroe, Monroe, La	100,000
Bank of Louisiana in New Orleans, New Orleans, La	100,000
Guaranty Bank & Trust Co., Gretna, La	100,000
Metairie Bank & Trust Co., Metairie, La	100,000
Terrebonne Bank & Trust Co., Houma, La	100,000
Ouachita National Bank, Monroe, La	100,000
Bank of the South, Gretna, La	100,000
First Guaranty Bank, Hammond, La	75,000
Franklin State Bank & Trust Co., Winnsboro, La	50,000
Winnsboro State Bank & Trust Co., Winnsboro, La	50,000
Bank of Morehouse, Bastrop, La	25,000
Citizens Bank & Trust Co., Thibodaux, La	20,000
Total	119,350,000

Louisiana maintains accounts with the lending banks and, at September 30, 1978, balances in such accounts aggregated $2,543,432. Although the balances in some of these accounts may be deemed to be compensating balances, most of these bank accounts are working accounts and fluctuations in their balances do not reflect or depend upon fluctuations in the amount of bank loans outstanding. The minimum balances customarily maintained in such bank accounts aggregate $1,291,000. Louisiana believes that these balances are adequate as of this time. If minimum balances of 10% or 20% were required, the effective rate of interest would be, 12.22% and 13.75%, respectively using the present prime rate of 11%.

The commercial paper will be sold by Louisiana directly to Lehman Commercial Paper Incorporated ("Lehman") in denominations of not less than $50,000 or more than $1,000,000 at a discount which will not exceed the discount rate per annum prevailing at the respective dates of issuance for the particular maturities involved for sales of prime commercial paper of comparable quality by public utility issuers to commercial paper dealers. The maximum amount of commercial paper purchased and outstanding at any one time will not exceed $75,000,000. The proposed commercial paper of Louisiana would be in the form of unsecured bearer notes maturing not longer than nine months after their respective dates of issuance. No other costs, fees, commissions or additional charges will be payable by Louisiana to Lehman in connection with the issuance and sale of such commercial paper. The commercial paper will not be prepayable prior to maturity. As principal, Lehman will initially reoffer the commercial paper at a discount rate no greater than ⅛th of 1% per annum less than the discount rate to Louisiana, to corporations and institutional investors from a list of not more than 200 such proposed offerees.

Louisiana will not issue any of its commercial paper notes having a maturity of more than 90 days at an effective interest cost which exceeds the effective interest cost at which Louisiana could borrow from banks, and, in general, the nature of the borrowing or borrowings made at any particular time would be determined on the basis of market conditions with a view toward obtaining borrowed funds at the lowest possible cost.

The net proceeds of the borrowings herein proposed will be used, together with other funds available to Louisiana, for the construction of new facilities, for additions and improvements to present facilities, and for other corporate purposes. Louisiana's construction program contemplates expenditures of approximatey $257,500,000 in 1978, $269,000,000 in 1979, and $289,000,000 in 1980.

Louisiana expects to effect permanent financing also during the period through June 30, 1980, and may use part of all of the proceeds of such permanent financing to pay or prepay commercial bank loans or to pay commercial paper. Louisiana states that it is essential to its interim financing program & therefore proposes, that such use of the proceeds of permanent financing shall not reduce the aggregate principal amount of commercial paper and/or commercial bank loans which Louisiana herein seeks authorization to have outstanding at any one time during said period through June 30, 1980. Louisiana expects to retire all of the then outstanding borrowings covered by this application on or before June 30, 1980, from the proceeds of the sale of securities.

Louisiana requests exception from the competitive bidding requirements of Rule 50 for the proposed issue and sale of its commercial paper pursuant to paragraphs (a) (2) or (a) (5) thereof. It is stated that it is not necessary or appropriate in the public interest or for the protection of investors or consumers to invite competitive bids for the commercial paper because such paper will have a maturity not in excess of nine months, and because

current rates for commercial paper for such prime borrowers as Louisiana are published daily in financial publications.

Louisiana also requests authority to file certificates under Rule 24 with respect to the issue and sale of commercial paper on a quarterly basis.

No associate company or affiliate of Louisiana or affiliate of any such associate company has any material interest, direct or indirect in the transactions proposed.

No state commission and no federal commission, other than this Commission, has jurisdiction over the proposed transactions. The fees, commissions, and expenses to be incurred in connection with these transactions are estimated at $4,000 including legal fees not to exceed $2,000.

Notice is further given that any interested person may, not later than December 13, 1978, request in writing that a hearing be held on such matter, stating the nature of his interest, the reasons for such request, and the issues of fact or law raised by said application which he desires to controvert; or he may request that he be notified if the Commission should order a hearing thereon. Any such request should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request should be served personally or by mail upon the applicant at the above stated address, and proof of service (by affidavit or, in the case of an attorney at law, by certificate) should be filed with the request. At any time after said date, the application, as amended or as it may be further amended, may be granted and permitted to become effective as provided in Rule 23 of the General Rules and Regulations promulgated under the Act, or the Commission may grant exemption from such rules as provided in Rules 20(a) and 100 thereof or take such other action as it may deem appropriate. Persons who request a hearing or advice as to whether a hearing is ordered will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Corporate Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc. 78-33070 Filed 11-27-78; 8:45 am]

[8010-01-M]

[Release No. 10487; 811-1317]

MARATHON SECURITIES CORP.

NOVEMBER 17, 1978.

Notice is hereby given that Marathon Securities Corporation ("Applicant"), 635 Madison Avenue, New York, New York 10022, registered as a closed-end, non-diversified management investment company under the Investment Company Act of 1940 ("Act"), filed an application pursuant to Section 8(f) of the Act on September 20, 1978, for an order of the Commission declaring that Applicant has ceased to be an investment company as defined in the Act. All interested persons are referred to the application on file with the Commission for a statement of the representations set forth therein, which are summarized below.

Applicant was organized as a Delaware corporation and registered under the Act on or about May 14, 1965. At a meeting held on October 2, 1974, Applicant's stockholders considered and approved a plan for the liquidation and dissolution of Applicant and the termination of Applicant's status as a registered investment company. On December 6, 1974, Applicant filed a Certificate of Dissolution with the Secretary of State of Delaware and, under Delaware law, Applicant was thereby legally dissolved. On June 30, 1978, the Delaware Court of Chancery issued an order extending Applicant's time to complete winding up its affairs until December 31, 1978.

On December 9, 1974, Applicant made its first liquidating distribution to stockholders. Subsequently, Applicant has made four more liquidating distributions, and a final distribution of not more than $41,000, or about $0.10 per share, is expected to be made upon the granting of the requested order and the completion of the winding up of Applicant's affairs. The application states that such final distribution would represent the value of the assets of Applicant remaining after payment of all known expenses and other liabilities. Applicant further represents that it has no outstanding indebtedness, is not a party to any litigation or administrative proceeding and that it does not now nor does it propose to engage in any business activities other than those necessary for the winding up of its affairs.

Section 8(f) of the Act provides, in pertinent part, that when the Commission, upon application, finds that a registered investment company has ceased to be an investment company, it shall so declare by order and upon the effectiveness of such order, the registration of such company shall cease to be in effect.

Notice is further given that any interested person may, not later than December 12, 1978, at 5:30 p.m., submit to the Commission in writing a request for a hearing on the matter accompanied by a statement as to the nature of his interest, the reason for such request, and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission shall order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail upon Applicant at the address stated above. Proof of such service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed contemporaneously with the request. As provided by Rule 0-5 of the Rules and Regulations promulgated under the Act, an order disposing of the application will be issued as of course following said date unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons who request a hearing, or advice as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc. 78-33071 Filed 11-27-78; 8:45 am]

[8010-01-M]

[Rel. No. 10478; 812-4386]

MARYLAND TAX EXEMPT TRUST AND LEGG MASON WOOD WALKER INC.

Filing of Application

NOVEMBER 13, 1978.

Notice is hereby given that Maryland Tax Exempt Trust, Series 1 (and Subsequent Series) ("Trust"), a unit investment trust registered under the Investment Company Act of 1940 ("Act") and its Sponsor, Legg Mason Wood Walker Inc. ("Sponsor") (hereinafter the Sponsor and the Trust are referred to collectively as "Applicants"), 7 East Redwood Street, Baltimore, Maryland 21203, have filed an application on October 30, 1978, for an order of the Commission pursuant to Section 6(c) of the Act exempting the Applicants from the provisions of Section 14(a) of the Act, and Rule 19b-1 under the Act. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below.

Series 1 of the Trust is a unit investment trust, and is the first of a series of similar but separate trusts which the Sponsor intends to form (hereinafter all such subsequent Series are collectively referred to as the "Series"). The Series will be created under the laws of the state of New York pursuant to separate trust agreements, such agreements containing certain standard terms and conditions of trust common to all the Series. The Applicants represent that the investment objective of each Series will be to seek both the preservation of capital and income which is tax-exempt from both federal income taxes and Maryland personal income taxes through the investment in a portfolio of tax-free municipal bonds issued by issuers located in the state of Maryland ("Bonds") and, subject to certain limitations, Units of previously-issued Series of the Trust (the Bonds and previously issued Units are collectively called herein the "Trust Securities"). The Trust Securities which will constitute the portfolio of each Series will be selected in advance and will be identifiable in respect of each Series on the date of deposit with the Trustee.

The Sponsor has filed a Form S-6 Registration Statement under the Securities Act of 1933 ("1933 Act") covering fractional undivided interests in Series 1 to be offered to investors at a public offering price set forth in the prospectus included in the S-6 Registration Statement. The 1933 Act Registration Statement has not yet become effective. The Sponsor has also filed a Form N-8A Notification of Registration and a Form N-8B-2 Registration Statement under the Act relating to Series 1.

Each Series of the Trust will be governed by the provisions of a trust indenture and agreement ("Indenture") to be entered into by the Sponsor and a corporation organized and doing business under the laws of the United States or a state thereof, which is authorized under such laws to exercise corporate trust powers and having at all times an aggregate capital, surplus, and undivided profits of not less than $2,500,000 ("Trustee"). It is contemplated that the Bradford Trust Company will serve as Trustee for Series 1. The Sponsor will serve as Evaluator for Series 1. A separate Indenture will be entered into each time a Series is created and activated and the Trust Securities which comprise its portfolio (or delivery statements relating to contracts for the purchase of such Trust Securities together with funds represented by cash or an irrevocable letter of credit issued by a major commercial bank in the amount required for their purchase) are deposited with the Trustee. Each Series will be substantially identical except as to size, number of Units and the individual Trust Securities in the portfolio.

When a Series of the Trust is created, the Sponsor and the Trustee will enter into an Indenture and the Trust Securities to constitute such Series of the Trust (or delivery statements relating thereto and funds for the purchase thereof as set forth above) will be delivered to and deposited with the Trustee by the Sponsor. Substantially concurrently, the Trustee will issue in the name of the Sponsor, or such other name as the Sponsor may direct, one or more certificates evidencing the ownership of all of the undivided interests in such Series of the Trust. These Units will be separately offered for sale to the public at prices based upon their then respective current net asset values, after the registration statement filed in respect thereto under the 1933 Act has become effective.

Applicants state that Trust Securities will not be pledged or be in any other way subjected to any debt at any time after they are deposited with the Trustee. The Sponsor has been accumulating Trust Securities for the purpose of deposit in Series 1 and will follow a similar procedure of accumulating Trust Securities for each subsequent Series.

The assets of the Trust may consist of Bonds initially deposited, such Bonds as may continue to be held from time to time in exchange for or substitution of any of the Bonds, accrued and undistributed interest, undistributed cash and Units of previously issued Series of the Trust. On the date of deposit, the maximum number of Units in the Trust of a Series and the Bonds which will comprise the respective portfolios are determined. No additional Units can be issued, although the number of Units outstanding may be reduced by redemptions. No additional Trust Securities can be deposited in the Trust except that under certain circumstances, refunding bonds issued in exchange and substituted for outstanding Bonds may be deposited with the Trustee. The Trustee may dispose of Trust Securities when events occur which may affect their investment stability and distribute the proceeds thereof in partial liquidation to Unitholders; and the Trustee must sell Trust Securities if necessary for the payment of the redemption price of Units tendered for redemption. The proceeds from such dispositions will be distributed to the holders of Units of the Trust ("Unitholders"), and not reinvested.

Each Unit of the Trust will represent a fractional undivided interest, the numerator of the fractional interest represented will be 1 and the denominator will be the number of Units issued and outstanding in any particular Series. Units are redeemable, and in the event that any Units are redeemed, the fractional undivided interest represented by each Unit will be increased accordingly. Units will remain outstanding until redeemed or until the termination of the Indenture. The Indenture may be terminated by 100% agreement of the Unitholders or, in the event that the value of Trust Securities shall fall below an amount specified, either upon direction of the Sponsor to the Trustee or by the Trustee without such direction. There is no provision in the Indenture for the issuance of any Units after the initial issuance and such activity will not take place (except to the extent that the secondary trading by the Sponsor in the Units is deemed the issuance of Units under the Act).

SECTION 14(a)

Section 14(a) of the Act, in substance, provides that no registered investment company and no principal underwriter for such a company shall make a public offering of securities of which such company is the issuer unless (1) the company has a net worth of at least $100,000; (2) at the time of a previous public offering it had a net worth of $100,000; or (3) provision is made that a net worth of $100,000 will be obtained from not more than twenty-five responsible persons within ninety days, or the entire proceeds received, including sales charge, will be refunded.

Applicants seek an exemption from the provisions of Section 14(a) in order that a public offering of Units of the Trust as described above may be made. In connection with the requested exemption from Section 14(a) the Sponsor agrees (1) to refund, on demand and without deduction, all sales charges to purchasers of Units of a Series if, within ninety days from the time that a registration statement for a Series becomes effective under the Securities Act of 1933, the net worth of the Series shall be reduced to less than $100,000, or if such Series is terminated; (2) to instruct the Trustee on the date Trust Securities are deposited in each Series that in the event that redemption by the Sponsor of Units constituting a part of the unsold Units shall result in that Series having a net worth of less than 40% of the principal amount of Trust Securities originally deposited for such Series, the Trustee shall terminate the Series in the manner provided in the Indenture and distribute any Trust Securities or other assets deposited with the Trustee pursuant to the Indenture as provided therein; and (3) in the event of termination for the reasons described in (2) above, to refund any sales charges to any purchasers of Units

purchased from the Sponsor on demand and without any deduction.

The Sponsor has further represented that no Series of the Trust will be created which will contain in the portfolio on the date of deposit, Trust Securities (or delivery statements relating thereto and funds for the purchase thereof) having a face amount of less than $3,000,000. In the event the value of such Series should decrease to the greater of $1,000,000 or 20% of the amount of the Trust Securities initially deposited, for any reason, the Trustee may, and when so directed by the Sponsor shall, terminate and liquidate the Series. Thus, Applicants represent that it is highly unlikely that, except during the course of liquidation, the net worth of any Series would ever decline to $100,000 or less.

RULE 19b-1

Rule 19b-1 provides in substance that no registered investment company which is a "regulated investment company" as defined in Section 851 of the Internal Revenue Code shall distribute more than one capital gain dividend in any one taxable year. Paragraph (b) of the Rule contains a similar prohibition for a company not a "regulated investment company" but permits a unit investment trust to distribute capital gain dividends received from a "regulated investment company" within a reasonable time after receipt.

Distributions of interest and principal on each Series will be made to Unitholders semiannually unless a Unitholder elects to receive them monthly or quarterly. Applicants represent that distributions of principal constituting capital gains to Unitholders may arise in the following instances: (1) If an issuing authority calls or redeems an issue of Bonds held in the portfolio, the sums received by the Trust will be distributed on a pro rata basis to each Unitholder on the next distribution date; (2) if Units are redeemed by the Trustee and Trust Securities from the portfolio are sold to provide the funds necessary for such redemption, each Unitholder will receive his pro rata portion of the proceeds from the Trust Securities sold over the amount required to satisfy such redemption distribution; (3) if Bonds held in the portfolio are sold to maintain the investment stability of a Series of the Trust, the sums received by the Trust may be distributed on a pro rata basis to each Unitholder on the next distribution date; and (4) as Bonds mature by their terms, the sums received by the Trust will be distributed on a pro rata basis to each Unitholder on the next distribution date. In such instances, a Unitholder may receive in his distribution funds which constitute capital gains, since in some cases the value of the Trust Securities redeemed or sold may have increased since the date of their acquisition by the Trust.

As noted above, Paragraph (b) of Rule 19b-1 provides that a unit investment trust may distribute capital gain dividends received from a "regulated investment company" within a reasonable time after receipt. Applicants assert that the purpose behind such provision is to avoid forcing unit investment trusts to accumulate valid distributions received throughout the year and distribute them only at year end, and that the operations of Applicants in this regard are squarely within the purpose of such provision. However, in order to comply with the literal requirements of the Rule, each Series of the Trust would be forced to hold any monies which would constitute capital gains upon distribution until the end of its taxable year. The application contends that such practice would clearly be to the detriment of the Unitholders.

In support of the requested exemption, Appliants state that the dangers against which Rule 19b-1 is intended to guard do not exist in the situation at hand since neither the Sponsor nor the Trust has control over events which might trigger capital gains, e.g., the tendering of Trust Units for redemption and the prepayment of portfolio Bonds by the issuing authorities. In addition, it is alleged that any capital gains distribution will be clearly indicated as capital gains in the accompanying report by the Trustee to the Unitholder. Furthermore, Applicants assert that the sale of Bonds in an effort to maintain the investment stability of a Series of the Trust is an activity designed generally to prevent or to retard deterioration of values when certain adverse factors exist. These factors include a default in the payment of principal or interest on its Bonds, or an adverse change in the market, revenue or credit factors affecting the investment stability of the Bonds. Finally, Applicants contend that sale of Bonds in an effort to maintain investment stability of any Series is not expected to result in capital gain dividends to the Trust or its Unitholders because the above factors will normally have a depressing effect on the market value of the Bonds.

Section 6(c) of the Act provides, in pertinent part, that the Commission, by order upon application, may conditionally or unconditionally, exempt any person, security, or transaction, or any class or classes of persons, securities or transactions, from any provision of the Act or of any rule or regulation under the Act, if and to the extent such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Notice is further given that any interested person may, not later than December 4, 1978, at 5:30 P.M., submit to the Commission in writing a request for a hearing on the application accompanied by a statement as to the nature of his interest, the reasons for such request, and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission shall order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail upon Applicants at the address stated above. Proof of such service (by affidavit, or in the case of any attorney-at-law by certificate) shall be filed contemporaneously with the request. As provided by Rule 0-5 of the Rules and Regulations promulgated under the Act, an order disposing of the application herein will be issued as of course following said date unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons, who request a hearing or advice as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc. 78-33072 Filed 11-27-78; 8:45 am]

[8010-01-M]

[Rel. No. 10481; 812—4366]

MERRILL LYNCH, PIERCE, FENNER & SMITH INC. et al.

Notice of Filing of Application

In the matter of Merrill Lynch, Pierce, Fenner & Smith Incorporated; Bache Halsey Stuart Shields Incorporated; Dean Witter Reynolds, Inc.; Municipal Investment Trust Fund; The Corporate Income Fund; The Municipal Income Fund; and The Government Securities Income Fund, c/o Merrill Lynch, Pierce, Fenner & Smith Incorporated, 125 High Street, Boston, Massachusetts 02110.

Notice is hereby given that Merrill Lynch, Pierce, Fenner, & Smith Incorporated, Bache Halsey Stuart Shields Incorporated, Dean Witter Reynolds, Inc. (the "Sponsors"), and all presently outstanding or subsequently issued Series (exclusive of short term Series and any other Series where the appli-

cable sales charge is less than that applicable at the time to the public offering price of intermediate term series of Municipal Investment Trust Fund, The Corporate Income Fund, The Municipal Income Fund and The Government Securities Income Fund (the "Funds" or the individual Series thereof, a "Series") (collectively, the "Applicants"), filed an application on September 7, 1978, and an amendment thereto on November 2, 1978, pursuant to Sections 6(c) and 11 of the Investment Company Act of 1940 (the "Act"), for an order of the Commission to permit the exchange of units of any Series of any of the Funds for units of any other Series thereof on the basis of a reduced fixed sales charge per unit, subject to certain conditions specified in the application and as set forth below, and exempt such transactions of the Applicants from the provisions of Section 22(d) of the Act. All interested persons are referred to the application, which is on file with the Commission, for a statement of the representations made therein, which are summarized below.

Municipal Investment Trust Fund, the Corporate Income Fund, The Municipal Income Fund and The Government Securities Income Fund are investment companies registered under the Act, each of which is sponsored by one or more of the Sponsors and is made up of one or more Series of separate unit investment trusts registered under the Securities Act of 1933. While the structures of the Funds and the various Series are very similar in most respects, the investment objectives of the Funds are different. Thus, the primary objective of Municipal Investment Trust Fund and The Municipal Income Fund are tax-exempt income while the primary objective of The Corporate Income Fund and The Government Securities Income Fund is income which is subject to Federal income taxation. In addition, subgroupings of Series under the basic Fund structures are different. Thus, Series of Municipal Investment Trust Fund are variously invested in long-term municipal bonds, intermediate term municipal bonds and municipal bonds issued by particular states (such as Florida, New York, Pennsylvania, Michigan and Minnesota) and various Series of The Corporate Income Fund and The Government Securities Income Fund are variously invested in long-term corporate bonds, intermediate term corporate bonds, preferred stock and U.S. guaranteed "Ginnie Maes". In the future, it can be expected that additional Series of the Funds may be organized with investment objectives which, while they will be similarly structured and consistent with the basic objectives of the Funds of tax-exempt or taxable income, will have their particular investment objectives oriented towards specialized investments within these general categories.

The Applicants state that at the present time, more than 300 Series of the Funds have been issued, comprising portfolios of underlying securities aggregating some $8 billion, and additional Series are being created and offered to the public at a rate of more than one a week. The Applicants further state that the creation and public offering of all existing Series of the Funds has been undertaken with a view to full compliance with the requirements of the Act and the Securities Act of 1933 and it is anticipated that subsequent offerings of new Series will comply in all repects with these Acts.

The Applicants state that although the structure of particular Funds and particular Series differ in various respects depending on the nature of the underlying portfolios, the essential procedure followed in all cases is for the Sponsors to acquire a portfolio of securities, believed by them to satisfy the standards applicable to the investment objectives of the particular Series, which is then deposited in trust with a corporate fiduciary in exchange for certificates representing units of undivided interest in the deposited portfolio. These units are then offered to the public at a public offering price which is based upon the offering prices of the underlying securities plus a sales charge, which is currently 3¾% of the public offering price in the case of the Series investing in long-term debt securities and preferred stock and 3% in the case of offerings of Series investing in intermediate term bonds or "Ginnie Maes". The sales charge applicable to future Series may be varied by the Sponsors.

The Applicants state that although the Sponsors are not legally obligated to do so, the Sponsors maintain a secondary market for Units of outstanding Series and continually offer to purchase these Units at prices based upon the offering side evaluation of the underlying bonds, as determined by an independent evaluator. If the Sponsors discontinue maintaining such a market at any time, the Units of the Series can be liquidated by holders only by direct presentation to the trustee at redemption prices based upon the bid side evaluation of the underlying bonds.

The Applicants state that the Sponsors seek authority to offer, subject to the conditions and exceptions described below, an exchange option (the "Exchange Option") to certificateholders of the various Series of all of the Funds. The purpose of the Exchange Option would be to provide investors in any of the Series a convenient means of transferring interests as their investment requirements change into any other Series of any of the Funds. If the Sponsors implement the Exchange Option, they would intend to hold it open under most circumstances. However, they reserve the right to modify, suspend or terminate the Exchange Option at any time without further notice to certificateholders.

The Applicants state that it is intended the Exchange Option would operate as follows: The Exchange Option would be meant to operate only as to units of the various Series of the Funds as to which a secondary market may from time to time be maintained. A certificateholder wishing to dispose of those of his Units for which a market is maintained would have the option to exchange his Units into Units of any other Series of any Fund for which a market is also maintained. While it is not presently contemplated that certificateholders would be permitted to exchange their Units into Units of other Series which are available on original issue, the Sponsors might at some future date determine to permit such exchanges. When any certificateholder notifies the Sponsores of his desire to exercise his Exchange Option, the Sponsors would deliver to such certificateholder a current prospectus for those Series in which the certificateholder has indicated an interest and which the Sponsors have available to offer to the certificateholder as a result of acquisitions by them in the secondary market.

The Applicants state that the exchange transaction would operate in a manner essentially identical to any secondary transaction, except that the Sponsors seek authority to allow a reduced sales charge in a transaction pursuant to the Exchange Option. Heretofore, Units of any Series repurchased by the Sponsors have been resold at a public offering price based upon the offering side evaluation of the underlying securities plus a sales charge of either 3¾% or 3% depending on the nature of the portfolio making up the particular Series. The Applicants seek authority to sell Units pursuant to the Exchange Option at a price equal to the offering side evaluation of the underlying securities divided by the number of Units outstanding (the "Unit Offering Price"), plus a fixed charge of $15 per Unit, except as described in the next paragraph. Such $15 sales charge can be expected to approximate about 1½% of the offering price. The Sponsors reserve the right to change such fixed charge from time to time in the event of fluctuations in the cost of professional assistance and operational expenses in connection with these exchange transactions.

The Applicants state that certificateholders of a Series with a sales charge less than the sales charge of the Series for which such certificateholders desire to exchange who have held their Units for a period of at least eight months would be allowed to exercise the Exchange Option at the Unit Offering Price plus a fixed sales charge of $15 per Unit. However, such certificateholders of Series with a lower sales charge who wish to exchange their units for Units of a Series with a higher sales charge prior to the expiration of the eight month period would be allowed to exchange such Units at the Unit Offering Price plus a sales charge based on the greater of $15 per Unit or an amount which together with the initial sales charge paid in connection with the acquisition of the Units being exchanged equals the sales charge of the Series for which such certificateholders desire to exchange, determined as of the date of exchange.

The Applicants state that the certificateholder would not be permitted to make up any difference between the amount representing the Units being submitted for exchange and the Units being acquired. That is to say, the certificateholder would be permitted to acquire pursuant to the Exchange Option whole Units only and any excess amounts representing sales price of Units submitted for exchange would be remitted to the certificateholder.

Section 11(c) of the Act prohibits any type of offer of exchange of the securities of registered unit investment trusts for the securities of any other investment company unless the terms of the offer had been approved by the Commission or are in accordance with rules and regulations prescribed by the Commission with respect to such orders. None of the exemptions from the provisions of Section 11 appear to apply to the proposed Exchange Option. The Applicants state that they would therefore be unable to proceed with the Exchange Option unless the Commission grants the requested exemption from the provisions of Section 11(c) of the Act.

Section 22(b) of the Act prohibits a registered investment company from selling any redeemable security issued by it except either to or through a principal underwriter for distribution other than at the current public offering price described in its prospectus. None of the applicable exemptions from the provisions of that Section appears to apply to the Exchange Options. The Applicants state that they would therefore by unable to proceed with the Exchange Option unless, pursuant to Section 6(c) of the Act, the Commission exempts the Exchange Option from the provisions of Section 22(d).

The initially suggested reduced sales change of $15 rather than the customary 3¾% or 3% sales charges for regular primary and secondary market sales is proposed by the Applicants as a result of certain cost savings. In the judgment of the Applicants the proposed reduction would be beneficial to investors. The Applicants state that under the proposed Exchange Option, a person desiring to dispose of Units of one Series and acquire Units of another Series may wish to do so for a number of reasons—such as changes in his or her particular investment goals or requirements or in order to take advantage of possible tax benefits flowing from the exchange.

Taking these factors into account, it is asserted that it is likely that there will be a continuing need to assess an investors financial and tax position and in all probability the account executives of the Sponsors will actively participate in financially counseling the investor as to the proper course of action to follow taking into account all of the relevant investment factors involved. However, the fact that the investor is an existing customer whose essential investment needs have been identified should produce some transaction savings. Further, in view of the fact that all the Funds are very similar investment vehicles, an exchanging certificateholder may require somewhat less advice than if he were acquiring an interest in an entirely different kind of investment. It is the belief of the Applicants that a charge of $15 is a reasonable and justifiable expense to be allocated for the professional assistance and operational expenses which are contemplated in connection with these exchange transactions. This sales charge compares favorably to the regular 3¾% and 3% sales charges applicable to non-exchange transactions in connection with primary and secondary sales of Units of the Funds and, the Applicants contend, such a sales charge is warranted in that such charges should cover the reasonable costs related to the exercise of the Exchange Option and yet give exchanging certificateholders an opportunity to share in expected cost savings.

The Applicants state that the requirement that certificateholders of a Series with a lower sales charge pay an adjusted sales charge for exchanges made by them under the Exchanges Option during the first eight months in which they have held Units of a Series with a lower sales charge is appropriate since the sales charge relating to original purchases of Units of such Series is less than the sales charge of the Series to which they desire to convert. They state that it could be possible under certain circumstances for a person to acquire Units of Series with a lower sales charge and immediately convert such units into Units of other Series with a higher sales charge and pay a lower total sales charge than a person purchasing Units of such Series directly at the same time. Under normal circumstances this situation is unlikely, since the initial sales charge on direct purchases of units of Series with a lower sales charge (currently 3%) plus the conversion sales charge ($15 per Unit or approximately 1½% usually will exceed the sales charge related to direct purchases of Units of Series with a higher sales charge (currently 3¾%). However, if the price of the Units of Series with the higher sales charge were to increase sharply, the $15 sales charge on exhange could represent less than the difference between the lower sales charge and the higher sales charge, in which case the exchanging certificateholder could obtain an unfair price advantage when compared to investors making direct purchases of Units of the applicable Series. However, after a certificateholder of a Series with a lower sale charge has held his Units for an adequate period of time, the Applicants believe that the discriminatory nature of his effecting an exchange transaction is not as compelling, and thus the possible abuses outlined above are not material if the converting certificateholder of a Series with a lower sales charge has held his Units for at least an eight period of time.

Section 6(c) of the Act provides, in part, that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities or transactions from any provisions of the Act or of any rule or regulation under the Act, if and to the extent such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Notice is further given that any interested person may, not later than December 7, 1978, at 5:30 p.m., submit to the Commission in writing a request for a hearing on the application accompanied by a statement as to the nature of his interest, the reasons for such request, and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission shall order a hearing thereon. Any such communications should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C., 20549. A copy of such request shall be served personally or by mail upon the Applicants at the address stated above. Proof of such service (by affidavit, or

in case of an attorney-at-law, by certificate) shall be filed contemporaneously with the request. As provided by Rule 0-5 of the Rules and Regulations promulgated under the Act, an order disposing of the application will be issued as of course following said date, unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons who request a hearing, or advice as to whether a hearing is ordered, will receive any notice and orders issued in this matter, including the date of the hearing (if ordered and any postponements thereof).

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc. 78-33073 Filed 11-27-78; 8:45 am]

[4810-22-M]

DEPARTMENT OF THE TREASURY

Customs Service

AMPICILLIN TRIHYDRATE FROM SPAIN

Preliminary Countervailing Duty Determination

AGENCY: U.S. Customs Service, Treasury Department.

ACTION: Preliminary Countervailing Duty Determination.

SUMMARY: This notice is to advise the public that as a result of an investigation a preliminary determination has been made that benefits granted by the Government of Spain to manufacturers or exporters of ampicillin trihydrate constitute bounties or grants within the meaning of the countervailing duty law. A final determination will be made no later than March 23, 1979. Interested parties are invited to comment on this action.

EFFECTIVE DATE: November 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Michael E. Crawford, Operations Officer, Deputy Assessment Division, United States Customs Service, 1301 Constitution Avenue NW., Washington, D.C. 20229, telephone 202-566-5492.

SUPPLEMENTARY INFORMATION: On May 25, 1978, a "Notice of Receipt of Countervailing Duty Petition and Initiation of Investigation" was published in the FEDERAL REGISTER (43 FR 22479). The notice stated that a petition had been received alleging that payments or bestowals conferred by the Government of Spain upon the manufacture, production or exportation of ampicillin trihydrate constitute the payment or bestowal of a bounty or grant, directly or indirectly, within the meaning of section 303 of the Tariff Act of 1930, as amended (19 U.S.C. 1303). Imports covered by this investigation are classified under item 407.8525 of the Tariff Schedules of the United States Annotated.

On the basis of an investigation conducted pursuant to § 159.47(c) of the Customs Regulations (19 CFR 159.47(c)), it has been determined preliminarily that benefits have been paid or bestowed, directly or indirectly, on the exportation of ampicillin trihydrate by the Spanish Government which constitute "bounties or grants". The benefits are received in the form of an overrebate upon export of the Spanish indirect tax, the "Desgravacion Fiscal". The overrebate consists of two elements: (1) A number of "parafiscal taxes"which are included in the computation of the rebate and which are charges assessed for services rendered and are not directly related to the product and (2) a credit for a tax assessed on transactions between manufacturers and wholesalers which in fact is not assessed on export sales.

As dicussed in the notice published in the FEDERAL REGISTER of June 15, 1978 in the cases of *Zinc, Non-Rubber Footwear* and *Bottled Olives from Spain* (43 FR 25812), the Treasury does not regard the non-excessive rebate of the cascade tax in Spain as constituting the bestowal of a "bounty or grant". This policy was adopted after it was determined that the treatment under the countervailing duty law of rebates of a cascade type tax should be similar to the treatment accorded rebates of value-added taxes, as both are generally identical in their purpose and economic effects. However, for the reasons published in the Notice in the FEDERAL REGISTER on August 29, 1978 (43 FR 38658), this policy is under review. The Final Determination in this case will take into account the results of the general review now being undertaken.

Accordingly, it is determined preliminarily that bounties or grants, within the meaning of section 303 of the Tariff Act of 1930, as amended (19 U.S.C. 1303), are being paid or bestowed, directly or indirectly, upon the manufacture, production or exportation of ampicillin trihydrate from Spain. A final determination will be made not later than March 23, 1979.

Additionally, in making a final determination, consideration will be given to the volume of trade affected by any countervailing duty determined to be due. Preliminary indications suggest that although the *ad valorem* benefits determined to be bounties exceed *de minimis* levels, duties on all imports in 1977 would have been less than $100 in the aggregate. If such import levels are likely to continue, a *de minimis* determination may be appropriate.

Before a final determination is made, consideration will be given to any relevant data, views, or arguments submitted in writing with respect to this preliminary determination. Submissions should be addressed to the Commissioner of Customs, 1301 Constitution Avenue NW., Washington, D.C. 20229, in time to be received by his office not later than December 28, 1978.

This preliminary determination is published pursuant to section 303(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1303(a)).

Pursuant to Reorganization Plan No. 26 of 1950 and Treasury Department Order 190, Revision 15, March 16, 1978, the provisions of Treasury Department Order No. 165, Revised, November 2, 1954, and § 159.47 of the Customs Regulations (19 CFR 159.47), insofar as they pertain to the issuance of a preliminary countervailing duty determination by the Commissioner of Customs, are hereby waived.

HENRY C. STOCKELL, JR.,
Acting General Counsel of the Treasury.

NOVEMBER 20, 1978.

[FR Doc. 78-33218 Filed 11-27-78; 8:45 am]

[4810-22-M]

OLEORESINS FROM INDIA

Preliminary Countervailing Duty Determination

AGENCY: U.S. Customs Service, Treasury Department.

ACTION: Preliminary Countervailing Duty Determination.

SUMMARY: This notice is to advise the public that as a result of an investigation a preliminary determination has been made that certain benefits granted by the Government of India to manufacturers and/or exporters of oleoresins constitute bounties or grants. A final determination will be made no later than March 21, 1979.

EFFECTIVE DATE: November 28, 1978.

FOR FURTHER INFORMATION CONTACT:

William T. Trujillo, Deputy Assessment Division, U.S. Customs Service, 1301 Constitution Avenue NW., Washington, D.C. 20229, telephone 202-566-5492.

SUPPLEMENTARY INFORMATION: On May 16, 1978, a "Notice of Receipt of Countervailing Duty Petition and Initiation of Investigation" was published in the FEDERAL REGISTER (43 FR 21087). The notice stated that benfits conferred by the Government of India upon the manufacture, production or exportation of oleoresins may consti-

tute the payment or bestowal of a bounty or grant within the meaning of section 303, Tariff Act of 1930, as amended (19 U.S.C. 1303) (referred to as the "Act").

An investigation has been conducted pursuant to § 159.47(c) of the Customs Regulations (19 CFR 159.47(c)). On the basis of that investigation, it has been preliminarily determined that (1) the "Export Cash Assistance Program," under which exporters of oleoresins receive 20 percent of the f.o.b. value of their exported product, contains an element of overrebate which constitutes a bounty or grant; and (2) the program of import permits does not constitute a bounty or grant in the present case.

It is claimed that the purpose of the "Export Cash Assistance Program" is to refund various indirect taxes and to serve as compensation for extraordinary expenses incurred by locating in the State of Kerala, an industrially undeveloped area of India.

The non-excessive rebate of indirect taxes on inputs directly related to the final product upon exportation of the product, is not regarded a "bounty" or "grant" under the Act. The portion of the 20 percent payment which represents the rebate of such taxes is not countervailable; the remainder of the payment is preliminarily considered a bounty or grant and may be subject to a countervailing duty.

The dislocation costs claimed as a result of locating in Kerala are not preliminarily accepted as offsetting a share of the export rebate. More information will be required before a final determination is made to determine whether the producers would have been unlikely to located in Kerala but for the payment to offset such dislocation costs. The data provided is not conclusive since there also appear to be certain benefits derived from locating in Kerala.

The question of whether import permits, granted to exporters of the subject merchandise for imported goods valued at up to 2 percent of the f.o.b. value of the exports, constitute a bounty or grant, revolves around the marketability of the permit. Declarations by the exporters state that, notwithstanding the potential market value, the permits are not sold nor do they otherwise yield monetary gain. The import permits are fully utilized by the holder to obtain materials not available in India. Therefore, in the present case, the issuance and use of import permits are preliminarily determined not to constitute a bounty or grant.

A final determination in this case must be made on or before March 21, 1979.

For purposes of this notice, "oleoresins" means flavoring extracts, and fruit flavors, essences, esters, and oils, not containing alcohol, and not in ampoules, capsules, tablets, or similar forms, classifiable under item number 450.20 of the Tariff Schedules of the United States (TSUS). An oleoresin is a thick liquid extract of the flavor of a spice used primarily as a seasoning in the food industry.

Before a final determination is made, consideration will be given to any relevant data, views, or arguments submitted in writing with respect to this preliminary determination. Submissions should be addressed to the Commissioner of Customs, 1301 Constitution Avenue NW., Washington, D.C. 20229, in time to be received by his office no later than December 28, 1978.

This preliminary determination is published pursuant to section 303(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1303(a)).

Pursuant to Reorganization Plan No. 26 of 1950 and Treasury Department Order 190, Revision 15, March 16, 1978, the provisions of Treasury Department Order No. 165, Revised, November 2, 1954, and § 159.47 of the Customs Regulations (19 CFR 159.47) insofar as they pertain to the issuance of a preliminary countervailing duty determination by the Commissioner of Customs, are hereby waived.

HENRY C. STOCKELL, Jr.,
Acting General Counsel of the Treasury.

NOVEMBER 20, 1978.

[FR Doc. 78-33219 Filed 11-27-78; 8:45 am]

[4810-40-M]

Office of the Secretary

[Supplement to Dept. Circular—Public Debt Series—No. 28-78]

TREASURY NOTES SERIES V-1980

Interest Rate

NOVEMBER 22, 1978.

The Secretary of the Treasury announced on November 21, 1978, that the interest rate on the notes designated Series V-1980, described in Department Circular—Public Debt Series—No. 28-78, dated November 16, 1978, will be 9¼ percent. Interest on the notes will be payable at the rate of 9¼ percent per annum.

PAUL H. TAYLOR,
Fiscal Assistant Secretary.

SUPPLEMENTARY STATEMENT: The announcment set forth above does not meet the Department's criteria for significant regulations and, accordingly, may be published without compliance with the Departmental procedures applicable to such regulations.

[FR Doc. 78-33252 Filed 11-27-78; 8:45 am]

[7035-01-M]

INTERSTATE COMMERCE COMMISSION

Office of Proceedings

[Decisions Volume No. 47]

DECISION-NOTICE

Decided: November 6, 1978.

The following applications are governed by Special Rule 247 of the Commission's Rules of Practice (49 CFR § 1100.247). These rules provide, among other things, that a protest to the granting of an application must be filed with the Commission within 30 days after the date notice of the application is published in the FEDERAL REGISTER. Failure to file a protest, within 30 days, will be considered as a waiver of opposition to the application. A protest under these rules should comply with Rule 247(e)(3) of the Rules of Practice which requires that it set forth specifically the grounds upon which it is made, contain a detailed statement of protestant's interest in the proceeding, (as specifically noted below), and shall specify with particularity the facts, matters, and things relied upon, but shall not include issues or allegations phrased generally. A protestant should include a copy of the specific portions of its authority which protestant believes to be in conflict with that sought in the application, and describe in detail the method—whether by joinder, interline, or other means—by which protestant would use such authority to provide all or part of the service proposed. Protests not in reasonable compliance with the requirements of the rules may be rejected. The original and one copy of the protest shall be filed with the Commission, and a copy shall be served concurrently upon applicant's representative, or upon applicant if no representative is named. If the protest includes a request for oral hearing, such request shall meet the requirements of section 247(e)(4) of the special rules and shall include the certification required in that section.

Section 247(f) provides, in part, that an applicant which does not intend timely to prosecute its application shall promptly request that it be dismissed, and that failure to prosecute an application under the procedures of the Commission will result in its dismissal.

Further processing steps will be by Commission notice, decision, or letter which will be served on each party of

record. *Broadening amendments will not be accepted after the date of this publication.*

Any authority granted may reflect administratively acceptable restrictive amendments to the service proposed below. Some of the applications may have been modified to conform to the Commission's policy of simplifying grants of operating authority.

We find: With the exceptions of those applications involving duly noted problems (e.g., unresolved common control, unresolved fitness questions, and jurisdictional problems) we find, preliminarily, that each common carrier applicant has demonstrated that its proposed service is required by the public convenience and necessity, and that each contract carrier applicant qualifies as a contract carrier and its proposed contract carrier service will be consistent with the public interest and the national transportation policy. Each applicant is fit, willing, and able properly to perform the service proposed and to conform to the requirements of the Interstate Commerce Act and the Commission's regulations. 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 those proceeding containing a statement or note that dual operations are or may be involved we find, preliminarily and in the absence of the issue being raised by a protestant, that the proposed dual operations are consistent with the public interest and the national transportation policy subject to the right of the Commission which is hereby expressly reserved to impose such conditions as it finds necessary to insure that applicant's operations shall conform to the provisions of section 210 of the Interstate Commerce Act.

It is ordered: In the absence of legally sufficient protests, filed within 30 days of publication of this decision-notice (or, if the application later becomes unopposed), appropriate authority will be issued to each applicant (except those with duly noted problems) upon compliance with certain requirements which will be set forth in a notification of effectiveness of this decisions-notice. To the extent that the authority sought below may duplicate an applicant's existing authority, such duplication shall not be construed as conferring more than a single operating right.

Applicants must comply with all specific conditions set forth within 90 days after the service of the notification of the effectiveness of this decision-notice, or the application of a non-complying applicant shall stand denied. By the Commission, Review Board Number 2, Members Boyle, Eaton, and Liberman.

H. G. HOMME, Jr.,
Secretary.

MC 531 (Sub-361F), filed September, 5, 1978. Applicant: YOUNGER BROTHERS, INC., 4904 Griggs Road (P.O. Box 14048), Houston, TX 77021. Representative: Wray E. Hughes (same address as applicant). To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting: *chemicals,* in bulk, in tank vehicles, from the facilities of Union Carbide Corp., at or near Texas City, TX, to points in AL, AR, CA, CO, CT, FL, GA, IL, IN, IA, KS, KY, LA, MD, MA, MI, MN, MS, MO, MT, NE, NJ, NM, NY, NC, ND, OH, OK, OR, PA, SC, SD, TN, UT, VA, WV, WI, and WY. Restricted to the transportation of traffic originating at the above named origin. (Hearing site: Houston, TX.)

MC 2505 (Sub-3F), filed October 4, 1978. Applicant: LOTT MOTOR LINES, INC., a Pennsylvania corporation, West Cayuga Street, P.O. Box 751, Moravia, NY 13118. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 Eleventh Street NW., Washington, DC 20001. To operate as a *contract carrier,* by motor vehicle, over irregular routes, transporting *metal articles, and materials, equipment, and supplies* used in the manufacture and distribution of metal articles, between Buffalo, NY, Philadelphia, PA, and Edison, NJ, on the one hand, and, on the other, points in ME, VT, NH, MA, CT, RI, NY, NJ, PA, OH, WV, VA, MD, DE, and DC, under continuing contract(s) with Alcan Aluminum Corp. of Cleveland, OH. (Hearing site: Cleveland, OH, or Washington, DC.)

NOTE.—Dual operations are involved in this proceeding.

MC 2505 (Sub-4F), filed October 5, 1978. Applicant: LOTT MOTOR LINES, INC., a Pennsylvania corporation, West Cayuga Street, P.O. Box 751, Moravia, NY 13118. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 Eleventh Street NW., Washington, DC 20001. To operate as a *contract carrier,* by motor vehicle, over irregular routes, transporting *metal articles, and materials, equipment, and supplies* used in the manufacture and distribution of metal articles, between Marlborough, MA, Windsor, CT, and Baltimore, MD, on the one hand, and, on the other, points in ME, VT, NH, MA, CT, RI, NY, NJ, PA, OH, WV, VA, MD, DE, and DC, under continuing contract(s) with Alcan Aluminum Corp., of Cleveland, OH. (Hearing site: Cleveland, OH, or Washington, DC.)

NOTE.—Dual operations are involved in this proceeding.

MC 4405 (Sub-582F), filed October 5, 1978. Applicant: DEALERS TRANSIT, INC., 522 South Boston Avenue, Tulsa, OK 74103. Representative: Alan Foss, 502 First National Bank Bldg., Fargo, ND 58102. To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting *heating equipment and heating equipment parts,* between Tulsa, OK, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Tulsa, OK.)

MC 5623 (Sub-43F), filed September 18, 1978. Applicant: ARROW TRUCKING CO., a corporation, 4230 South Elwood, P.O. Box 7280, Tulsa, OK 74105. Representative: Wilburn L. Williamson, 280 National Foundation Life Building, Oklahoma City, OK 73112. To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting *(1)(a) commodities,* the transportation of, which by reason of size or weight, require the use of special equipment; *(b) general commodities* (except those of unusual value, classes A & B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment) when moving in the same shipment on the same bill of lading as commodities which by reason of size or weight require the use of special equipment; and *(c) self-propelled articles transported on trailers,* from the facilities of Riley Beird, Inc., at or near Shreveport, LA, to points in the United States (except AK and HI), and *(2) materials, equipment, and supplies* used in the manufacture and distribution of the commodities named in (1) (a), (b) and (c) above (except commodities in bulk), from points in the United States (except AK and HI), to the facilities of Riley Beird, Inc., at or near Shreveport, LA. (Hearing site: Dallas, TX.)

MC 18738 (Sub-46F), filed October 6, 1978. Applicant: SIMS MOTOR TRANSPORT LINES, INC., 610 West 138th Street, Riverdale, IL 60627. Representative: Walter F. Jones, Jr., 601 Chamber of Commerce Building, Indianapolis, IN 46204. To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting *iron and steel articles,* from the facilities of Northwestern Steel and Wire Co., at Sterling and Rock Falls, IL, to St. Louis, MO, points in IN, KY, OH, PA, NY, and points in the Lower Peninsula of MI. (Hearing site: Chicago, IL, or Washington, DC.)

MC 19311 (Sub-48F), filed September 5, 1978. Applicant: CENTRAL TRANSPORT, INC., 34200 Mound Road, Sterling Heights, MI 48077. Representative: Walter N. Bieneman, 100 West Long Lake Road, Bloomfield Hills, MI 48033. To operate as a *common carrier,* by motor vehicle,

er regular routes, transporting *general commodities* (except articles of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), (1) between Richville, MI and Bay City, MI, over MI Hwy 15, (2) between Bay City, MI, and Harbor Beach, MI, over MI Hwy 25, serving the off-route points of Pointe Aux Barques and Grindstone City, MI, (3) between junction MI Hwy 15 and MI Hwy 138, and junction MI Hwy 25 and MI Hwy 138, over MI Hwy 138, (4) between Unionville, MI, and Port Austin, MI, from Unionville over unnumbered Hwy (Bay City-Forestville Rd.) to junction MI Hwy 53 and then over MI Hwy 53 to Port Austin, and return over the same route, (5) between Sebewaing, MI, and junction unnumbered Hwy (Sebewaing Rd.) and MI Hwy 53, over unnumbered Hwy (Sebewaing Rd.), (6) between junction unnumbered Hwy (Bay City-Forestville Rd.) and unnumbered Hwy (Colwood Rd.), and junction unnumbered Hwy (Sebewaing Rd.) and unnumbered Hwy (Bay Port Rd.), from junction unnumbered Hwy (Bay City-Forestville Rd.) and unnumbered Hwy (Colwood Rd.), over unnumbered Hwy (Colwood Rd.) to junction unnumbered Hwy (Bay Port Rd.), then over unnumbered Hwy (Bay Port Rd.) to junction unnumbered Hwy (Sebewaing Rd.), and return over the same route, (7) between Owendale, MI, and junction unnumbered Hwy (McEldowney Rd.) and unnumbered Hwy (Bay City-Forestville Rd.), from Owendale over unnumbered Hwy (Owendale Rd.) to junction unnumbered Hwy (McEldowney Rd.), then over unnumbered Hwy (McEldowney Rd.) to junction unnumbered Hwy (Bay City-Forestville Rd.), and return over the same route, (8) between Bay Port, MI, and Harbor Beach, MI, from Bay Port over MI Hwy 25 to junction MI Hwy 142, and then over MI Hwy 142 to Harbor Beach, and return over the same route, (9) between Caseville, MI and Kinde, MI, over unnumbered Hwy (Kinde Rd.), (10) between Richville, MI, and Sandusky, MI, over MI Hwy 46, (11) between Elmer, MI, and junction MI Hwy 142 and MI Hwy 19, over MI Hwy 19, in (1) through (11) above, serving all intermediate points, (12) between Detroit, MI, and junction MI Hwy 53 and unnumbered Hwy (Bay City-Forestville Rd.), over MI Hwy 53, (13) between Davison, MI, and Richville, MI, over MI Hwy 15, (14) between Richville, MI, and Saginaw, MI, over MI Hwy 46, serving no intermediate points in (12), (13), and (14) above, serving all off-route points within 5 miles of the routes in (1) through (14) above, all of the service in (1) through (14) above restricted to the transportation of traffic at Harbor Beach, MI, for purposes of joinder only. (Hearing site: Lansing, MI.)

MC 22311 (Sub-7F), filed September 6, 1978. Applicant: WEST SHORE TRANSFER, INC., Z 215 Marble Street, Hammond, IN 46320. Representative: Anthony E. Young, 29 South LaSalle Street, Suite 350, Chicago, IL 60603. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *iron and steel articles*, and *materials, equipment, and supplies* used in the manufacture of iron and steel articles, (except commodities in bulk), between the facilities of Western Cold Drawn Steel, Division of Stanadyne Corp., at or near Gary, IN, on the one hand, and, on the other, points in IL, IA, KS, KY, MI, MO, MN, NE, OH, TN, and WI. (Hearing site: Chicago, IL.)

MC 35706 (Sub-14F), filed August 21, 1978. Applicant: ATSL, INC., Building A, 10 Oregon Avenue, Philadelphia, PA 19148. Representative: Steven M. Tannenbaum, 135 North Fourth Street, Philadelphia, PA 19106. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *ladies wearing apparel*, and (2) *equipment, materials and supplies* used in the distribution of ladies wearing apparel, (except commodities in bulk), from the facilities of Petrie Stores Corp., at Secaucus, NJ, to the facilities used by Petrie Stores Corp., at or near (a) Cleveland, OH, (b) Detroit, MI, (c) Chicago, IL, and (d) Dallas, TX. (Hearing site: Camden, NJ, or Philadelphia, PA.)

MC 51146 (Sub-629F), filed August 18, 1978. Applicant: SCHNEIDER TRANSPORT, INC., P.O. Box 2298, Green Bay, WI 54306. Representative: John R. Patterson, 2480 East Commercial Boulevard, Fort Lauderdale, FL 3308. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *general commodities* (except articles of unusual value, classes A & B explosives, commodities in bulk, household goods as defined by the commission, and commodities requiring special equipment), between points in the United States (except AK and HI). (Hearing site: Chicago, IL.)

MC 59367 (Sub-125F), filed September 6, 1978. Applicant: DECKER TRUCK LINE, INC., P.O. Box 915, Fort Dodge, IA 50501. Representative: William L. Fairbank, 1980 Financial Center, Des Moines, IA 50309. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *diagnostic equipment, electrical equipment and accessories, roll cabs, tools, tool storage units, and automotive supplies*, and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities named in (1) above, (except commodities in bulk), between Algona and Fort Dodge, IA, on the one hand, and, on the other, points in IL, IN, MI, MN, OH, and WI. (Hearing site: St. Paul, MN, or Milwaukee, WI.)

MC 59367 (Sub-126F), filed September 12, 1978. Applicant: DECKER TRUCK LINE, INC., P.O. Box 915, Fort Dodge, IA 50501. Representative: William L. Fairbank, 1980 Financial Center, Des Moines, IA 50309. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *lignin powder*, from points in Marathon and Oneida Counties, WI, to Fort Dodge, IA. (Hearing site: Chicago, IL, or St. Paul, MN.)

MC 59488 Sub-44F), filed October 19, 1978. Applicant: SOUTHWESTERN TRANSPORTATION CO., a Delaware Corporation, 7600 South Central Expressway, P.O. Box 226187, Dallas, TX 75266. Representative: Lloyd M. Roach (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *general commodities* (except articles of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between Memphis, TN, and New Orleans, LA, from Memphis over Interstate Hwy 55 to junction Interstate Hwy 12, then over Interstate Hwy 12 to junction U.S. Hwy 51, then over U.S. Hwy 51 to junction Interstate Hwy 10, then over Interstate Hwy 10 to New Orleans, and return over the same route, serving no intermediate points, and with service at New Orleans, LA, restricted to the transportation of traffic received from or delivered to connecting carriers. (Hearing site: Dallas, TX, or Washington, DC.)

NOTE.—Dual operations are involved in this proceeding.

MC 60190 (Sub-4F), filed August 25, 1978. Applicant: ACTIVE MOVING & STORAGE CO., INC., P.O. Box 9217, Seattle, WA 98109. Representative: George H. Hart, 1100 IBM Building, Seattle, WA 98101. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *used household goods* as defined by the Commission, between points in WA, restricted to the transportation of shipments having a prior or subsequent movement, in containers, beyond the points authorized, and further restricted to the performance of pickup and delivery service in connection with packing, crating, and containerization, or unpacking, uncrating, and decontainerization of such shipments. (Hearing site: Seattle or Spokane, WA.)

MC 61231 (Sub-129F), filed September 5, 1978. Applicant: EASTER ENTERPRISES, INC., d.b.a. Ace Lines, Inc., P.O. Box 1351, Des Moines, IA 50305. Representative: William L. Fairbank, 1980 Financial Center, Des Moines, IA 50309. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *Such commodities* as are dealt in by retail home improvement stores, home furnishing stores, and lumber stores, (except commodities in bulk), between points in AR, CO, IL, IN, IA, KS, KY, MI, MN, MO, NE, OK, OH, TX, and WI. (Hearing site: Chicago, IL.)

MC 67646 (Sub-77F), filed August 15, 1978. Applicant: HALL MOTOR TRANSIT CO., a corporation, 6060 Carlisle Pike, Mechanicsburg, PA 17055. Representative: John E. Fullerton, 407 North Front Street, Harrisburg, PA 17101. To operate as a *common carrier*, by motor vehicle, transporting *general commodities* (except articles of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment) (1) between Norfolk and Richmond, VA, over U. S. Hwy 60 or Interstate Hwy 64, (2) from Norfolk over U. S. Hwy 460 to Petersburg, VA, then over U. S. Hwy 1 or Interstate Hwy 95 to Richmond, VA, and return over the same routes, serving Richmond for the purpose of joinder only, and serving the intermediate or off-route points or Chesapeake, Franklin, Hampton, Newport News, Suffolk, Virginia Beach, Williamsburg, and Yorktown, VA, restricted to the transportation traffic originating at or destined to points in MD and DC. (Hearing site: Harrisburg, PA, or Washington, D.C.)

MC 99365 (Sub-5F), filed September 28, 1978. Applicant: SHORTY HALL RIG CO., INC., P.O. Box 2429, Odessa, TX 79760. Representative: Mike Cotton, P.O. Box 1148, Austin, TX 78767. To operate as a *common carrier*, by motor vehicle, over irregular routes transporting *materials, equipment, and supplies* used in the construction, operation, and servicing of (a) utility, electrical, uranium, and hydroelectric plants, (b) mines, and (c) disposal and industrial plants, (except commodities in bulk), between points in Ector and Midland Counties, TX, on the one hand, and, on the other points in NM, OK, and KS. (Hearing site: Dallas, TX.)

MC 99653 (Sub-7F), filed August 25, 1978. Applicant: VICTORY FREIGHT LINES, INC., P.O. Box 2254, Birmingham, AL 35201. Representative: George M. Boles, 727 Frank Nelson Building, Birmingham, AL 35203. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *(1) Water treatment equipment, pollution control equipment, and manufactured iron and steel articles*, from points in AL, to points in the United States (except AK and HI), and *(2)(a) water treatment equipment, (b) pollution control equipment, and (c) materials and supplies* used in the manufacture of the commodities above, from the destinations in (1) above, to points in Alabama. (Hearing site: Birmingham, AL, or Atlanta, GA.)

MC 102616 (Sub-960F), filed August 31, 1978. Applicant: COASTAL TANK LINES, INC., 250 North Cleveland-Massillon Road, Akron, OH 44313. Representative: David F. McAllister (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *liquefied petroleum gas*, in bulk, in tank vehicles, (1) from the facilities of the Cochin Pipeline, at or near (a) New Hampton, IA, (b) Mankato and Benson, MN, and (c) Carrington, ND, to points in IA, IL, MN, SD, and WI, and (2) from the facilities of Cochin Pipeline, at or near Milford, IN, to points in IL, KY, MI, and OH. (Hearing site: Chicago, IL, or Columbus, OH.)

NOTE.—The certificate to be issued here shall be limited in points of time to a period expiring 5 years from its effective date.

MC 107012 (Sub-279F), filed August 28, 1978. Applicant: NORTH AMERICAN VAN LINES, INC., 5001 U.S. Highway 30 West, P.O. Box 988, Fort Wayne, IN 46801. Representative: Gary M. Crist (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *new furniture*, from Florence, SC, to points in AL, FL, GA, IL, IN, IA, KY, LA, MI, MN, MS, NY, NC, LH, TN, and VA. (Hearing Site: Columbia, SC, or Atlanta, GA.)

MC 107515 (Sub-1175), filed September 13, 1978. Applicant: REFRIGERATED TRANSPORT CO., INC., P.O. Box 308, Forest Park, GA 30050. Representative: Alan E. Serby, 3390 Peachtree Road, fifth floor Atlanta, GA 30326. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *(1) foodstuffs, restaurant supplies, restaurant furniture, and restaurant fixtures, and (2) poultry, unprocessed agricultural commodities, and fish*, the transportation of which is otherwise exempt from regulation under Section (b)(6) of the Interstate Commerce Act, when moving in mixed loads with the commodities in (1) above, (except commodities in bulk), between Carpinteria, CA, and Florence, KY, restricted to the transportation of traffic originating at or destined to the facilities of Sambo's Restaurants, Inc. at the above named points. (Hearing site: Los Angeles, CA.)

NOTE.—Dual operations are involved in this proceeding.

MC 108053 (Sub-149F), filed September 25, 1978. Applicant: LITTLE AUDREY'S TRANSPORTATION CO., INC., P.O. Box 129, Fremont, NE 68025. Representative: Arnold L. Burke, 180 North LaSalle Street, Chicago, IL 60601. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *alcoholic liquors and wines*, (except commodities in bulk), from Lawrenceburg, IN, Frankfort, KY, Schenley, PA, and Tullahoma, TN, to points in AZ, CA, ID, MT, NV, NM, OR, UT, WA, and WY. (Hearing site: Cincinnati or Columbus, OH.)

MC 108207 (Sub-486F), filed September 8, 1978. Applicant: FROZEN FOOD EXPRESS, INC., P.O. Box 225888, Dallas, TX 75265. Representative: M. W. Smith (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *plastics and plastic products*, (except commodities in bulk), from Toledo, OH, to Chicago, IL, and to points in CA and TX, restricted to the transportation of traffic originating at the named origin and destined to the named destinations. (Hearing site: Toledo, OH.)

MC 109397 (Sub-427F), filed September 11, 1978. Applicant: TRI-STATE MOTOR TRANSIT CO., a corporation, P.O. Box 113, Joplin, MO 64801. Representative: Max G. Morgan, 223 Ciudad Building, Oklahoma City, OK 73112. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *foamed plastic carpet cushion*, from the facilities of North Carolina Foam Industries, at Mt. Airy, NC, to those points in the United States in and east of NM, IA, MO, AR, and LA. (Hearing site: Kansas City, MO, or Washington, DC.)

MC 109692 (Sub-71F), filed August 7, 1978. Applicant: GRAIN BELT TRANSPORTATION CO., a corporation, Route 13, Kansas City, MO 64161. Representative: Warren H. Sapp, P.O. Box 16047, Kansas City, MO 64112. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *roofing, roofing materials*, and *roofing supplies*, from the facilities of GAF Corporation, at or near Kansas City, MO, to Dallas, TX. (Hearing site: Kansas City, MO.)

MC 110525 (Sub-1265F), filed October 4, 1978. Applicant: CHEMICAL LEAMAN TANK LINES, INC., a Delaware corporation, 520 East Lancaster Avenue, Downingtown, TA 19335. Representative: Thomas J. O'Brien (same

address as applicant). To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting *chemicals,* (except petrochemicals), in bulk, in tank vehicles, from the facilities of E. J. DuPont, at or near Gregory, TX, to points in AL, AR, CO, FL, GA, IL, KS, KY, LA, MS, MO, NE, NM, OK, and TN. (Hearing site: Houston, TX.)

MC 111545 (Sub-257F), filed October 2, 1978. Applicant: HOME TRANSPORTATION CO., INC., P.O. Box 6426, Station A, Marietta, GA 30065. Representative: Robert E. Born (same address as applicant). To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting (1) *aluminum and aluminum products,* and (2) *materials, equipment, and supplies* used in the manufacture of the commodities in (1) above, (except commodities in bulk, in tank vehicles), between the facilities of Alumax, Inc., in Berkeley County, SC, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Washington, DC.)

MC 111545 (Sub-258F), filed October 4, 1978. Applicant: HOME TRANSPORTATION CO., INC., P.O. Box 6426, Station A, Marietta, GA 30065. Representative: Robert E. Born (same address as applicant). To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting *cast stone veneer,* from the facilities of Stucco Stone Products, Inc., at Napa, CA, to points in AL, AR, AZ, FL, GA, LA, MS, NM, NC, OK, SC, TN, and TX. (Hearing site: San Francisco or Los Angeles, CA.)

MC 111812 (Sub-588F), filed August 31, 1978. Applicant: MIDWEST COAST TRANSPORT, INC., P.O. Box 1233, Sioux Falls, SD 57101. Representative: David Peterson (same address as applicant). To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting (1) *ice making machines,* and metal finishing equipment; and (2) materials and supplies used in the manufacture, distribution, and operation of the commodities in (1) above, from Albert Lea, MN, to points in the United States (except AK, HI, and MN), restricted in (1) and (2) above to the transportation of traffic originating at the named origin. (Hearing site: St. Paul, MN.)

MC 113855 (Sub-449F), filed September 6, 1978. Applicant: INTERNATIONAL TRANSPORT, INC., a North Dakota corporation, 2450 Marion Road Southeast, Rochester, MN 55901. Representative: Kip B. H. Erickson, 502 First National Bank Building, Fargo, ND 58102. To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting (1) *tractors* (except truck tractors), and (2) *Attachments, parts, and equipment* designed for use with tractors, in mixed loads with tractors, from points in Harrison County, MS, to the ports of entry on the International Boundary line between the United States and Canada, at points in MN, ND, MT, ID, and WA, restricted to the transportation of traffic (a) originating at the facilities of International Harvester Company, in Harrison County, MS, and (b) destined to points in the Provinces of British Columbia, Alberta, Saskatchewan, Manitoba, and Ontario, Canada. CONDITION: Prior receipt from applicant of an affidavit setting forth its appropriate complementary Canadian authority or explaining why no such Canadian authority is necessary. This affidavit must be submitted within 90 days of the service of a notification of effectiveness of this decision-notice. (Hearing site: Chicago, IL.)

NOTE.—The restriction and conditions contained in the grant of authority in this proceeding are phrased in accordance with the policy statement entitled Notice to Interested Parties of New Requirements Concerning Applications for Operating Authority to Handle Traffic to and from Points in Canada published in the FEDERAL REGISTER on December 5, 1974, and supplemented on November 18, 1975. The Commission is presently considering whether the policy statement should be modified, and is in communication with appropriate Canadian officials, regarding this issue. If the policy statement is changed, appropriate notice will appear in the FEDERAL REGISTER and the Commission will consider all restrictions or conditions which were imposed pursuant to the prior policy statement, regardless of when the condition or restriction was imposed, as being null and void and having no force or effect.

MC 113855 (Sub-452F), filed September 29, 1978. Applicant: INTERNATIONAL TRANSPORT, INC., a North Dakota corporation, 2450 Marion Road Southeast. Rochester, MN 55901. Representative: Richard P. Anderson, 502 First National Bank Building, Fargo, ND 58102. To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting *building brick,* from the ports of entry on the International Boundary line between the United States and Canada in MT, to points in MT, WY, UT, NV, CA, OR, WA, and ID, restricted to the transportation of traffic originating at Medicine Hat, Alberta, Canada. CONDITION: Prior receipt from applicant of an affidavit setting forth its appropriate complementary Canadian authority or explaining why no such Canadian authority is necessary. This affidavit must be submitted within 90 days of the service of a notification of effectiveness of this decision-notice.(Hearing site: Billings, MT.)

NOTE.—The restriction and conditions contained in the grant of authority in this proceeding are phrased in accordance with the policy statement entitled Notice to Interested Parties of New Requirements Concerning Applications for Operating Authority to Handle Traffic to and from Points in Canada published in the FEDERAL REGISTER on December 5, 1974, and supplemented on November 18, 1975. The Commission is presently considering whether the policy statement should be modified, and is in communication with appropriate Canadian officials. If the policy statement is changed, appropriate notice will appear in the FEDERAL REGISTER and the Commission will consider all restrictions or conditions which were imposed pursuant to the prior policy statement, regardless of when the condition or restriction was imposed, as being null and void and having no force or effect.

MC 113855 (Sub-453F), filed September 29, 1978. Applicant: INTERNATIONAL TRANSPORT, INC., a North Dakota corporation, 2450 Marion Road Southeast, Rochester, MN 55901. Representative: Kip B. H. Erickson, 502 First National Bank Building, Fargo, ND 58102. To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting *aluminum articles,* and *materials, equipment, and supplies* used in the manufacture of aluminum articles (except commodities in bulk, in tank vehicles), between the facilities of Alumax, Inc., in Berkley County, SC, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Washington, DC.)

MC 114273 (Sub-419F), filed July 24, 1978 and previously published in the FEDERAL REGISTER of September 14, 1978. Applicant: CRST, INC., P.O. Box 68, Cedar Rapids, IA 52406. Representative: Kenneth L. Core (same address as applicant). To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting (1) *iron and steel shot,* (except in bulk, in tank vehicles), from Hamilton, OH, and Mt. Pleasant, PA, to points in WI, and those points in the Lower Peninsula of MI on and west of a line beginning at the OH/MI State Line and extending along U.S. Hwy 127 to junction U.S. Hwy 27, then along U.S. Hwy 27 to junction Interstate Hwy 75, then along Interstate Hwy 75 to Mackinaw City; (2) *ceramic foundry products and ceramic foundry supplies,* (except commodities in bulk, in tank vehicles), from Columbus, OH, to Milwaukee, WI, and (3) *silicon carbide* (except in bulk, in tank vehicles), from Niagara Falls, NY, to points in IL, IA, MN, and WI, restricted in (1), (2), and (3) above to the transportation of traffic originating at the named origins and destined to the indicated destination. CONDITION: In view of the findings in No. MC-114273 (Sub-Nos. 147 and 252), of which official notice is taken, the certificate to be issued here shall be limited in point of time to a period expiring 2 years from its date of issue, unless prior to its expiration (but not less than 6 months prior to its expira-

tion), applicant files a petition for permanent extension of the certificate showing that it has been in full compliance with applicable regulations. (Hearing site: Chicago, IL, or Washington, DC.)

NOTE.—This republication substitutes the word west for east in part (1).

MC 114273 (Sub-420F), filed July 24, 1978, and previously published in the FEDERAL REGISTER issue of September 14, 1978. Applicant: CRST, INC., P.O. Box 68, Cedar Rapids, IA 52406. Representative: Kenneth L. Core (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *iron and steel nails and staples, steel, plastic and nylon strapping and seals, and pneumatic hand tools*, and (2) *parts and accessories* used in the installation of the commodities named in (1) above, from Chicago, IL, Cincinnati, OH, Downingtown, PA, New York, NY, and Philadelphia, PA, to the facilities used by Carlson Stapler and Shippers Supply, Inc., at (a) Des Moines, IA, (b) Denver, CO, (c) Minneapolis, MN, (d) Omaha, NE, and (e) Wichita, KS, restricted to the transportation of traffic destined to the named destinations. CONDITION: In view of the finding in No. MC-114273 (Sub-Nos. 147 and 252), of which official notice is taken, the certificate to be issued here shall be limited in point of time to a period expiring 2 years from its date of issue, unless prior to its expiration (but not less than 6 months prior to its expiration), applicant files a petition for permanent extension of the certificate showing that it has been in full compliance with applicable regulations. (Hearing site: Chicago, IL or Washington, DC.)

NOTE.—this republication includes Des Moines, IA as a facility point.

MC 116077 (Sub-398F), filed September 11, 1978. Applicant: DSI TRANSPORTS, INC., 4550 Post Oak Place Drive, P.O. Box 1505, Houston, TX 77001. Representative: Pat H. Robertson, 500 West 16th Street, P.O. Box 1945, Austin, TX 78767. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *dry clay and clay slurry*, in bulk, in tank vehicles, from points in Warren County, GA, to points in MS, LA, OK, and TX. (Hearing site: Atlanta, GA, or Houston, TX.)

MC 116763 (Sub-438F), filed September 11, 1978. Applicant: CARL SUBLER TRUCKING, INC., North West Street, Versailles, OH 45380. Representative: H. M. Richters (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *chalk and tack boards, lockers, toilet compartments, building materials*, and *building supplies*, (except commodities in bulk, in tank vehicles) and (2) *doors, door sections and accessories and supplies* used in the manufacture and installation of doors and door sections, (except commodities in bulk in tank vehicles), from points in AR, CT, NJ, NY, OH, and PA, to points in IL, MI, MN, and WI. (Hearing site: Chicago, IL.)

MC 117068 (Sub-104F), filed October 16, 1978. Applicant: MIDWEST SPECIALIZED TRANSPORTATION, INC., P.O. Box 6418, Rochester, MN 55901. Representative: Paul F. Sullivan, 711 Washington Building, Washington, DC 20005. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *mining equipment and self-propelled vehicles*, (except automobiles, trucks, and buses), from the facilities of Wagner Mining Equipment, Inc., in Multnomah County, OR, to points in the United States (except AK and HI); and (2) *equipment, materials, and supplies* used in the manufacture of the commodities in (1) above, (except commodities in bulk), from points in the United States (except AK and HI), to the facilities of Wagner Mining Equipment, Inc., in Multnomah County, OR, restricted in (1) and (2) above to the transportation of traffic originating at or destined to the named facilities. (Hearing site: Chicago, IL, or Washington, DC.)

MC 117698 (Sub-16F), filed October 6, 1978. Applicant: LEO H. SEARLES, d.b.a. L. H. SEARLES, South Worcester, NY 12197. Representative: Neil D. Breslin, 600 Broadway, Albany, NY 12207. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *ice cream, ice cream products, ice confections, and ice mix confections*, (except commodities in bulk), in vehicles equipped with mechanical refrigeration, (1) from Lancaster, PA, Chicopee, MA, Richmond Hill, NY, and Suffield, CT, to Norfolk, VA, Baltimore and Gaithersburg, MD, New Haven, CT, Worcester, Brockton, Charlestown, Lowell, and Hyannis, MA, Toledo, OH, Romulus, MI, Lakewood and Mt. Holly, NJ, and Huntingdon Valley, PA, (2) from Philadelphia, PA, to New Haven, CT, and Charlestown and Brockton, MA, and (3) from Dunkirk, NY, Green Bay, WI, Ocala, FL, Baltimore, MD, and Huntingdon Valley, Allentown, and Lancaster, PA, to Boston, MA. (Hearing site: Albany, NY.)

MC 119493 (Sub-227F), filed August 14, 1978. Applicant: MONKEM CO., INC., P.O. Box 1196, Joplin, MO 64801. Representative: Lawrence F. Kloeppel (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *iron, steel and plastic articles*, and (2) *parts and accessories* used in the manufacture and installation of the commodities named in (1) above, between Holt, AL, and points in IA, KS, OK, MO, and NE. (Hearing site: Tuscaloosa, AL, or Little Rock, AR.)

MC 119702 (Sub-64F), filed August 30, 1978. Applicant: STAHLY CARTAGE CO., a corporation, 119 S. Main Street, P.O. Box 486, Edwardsville, IL 62025. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 11th Street NW., Washington, DC 20001. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *petroleum products*, in bulk, in tank vehicles, from Ashkum, IL, to points in IN. (Hearing site: Chicago, IL, or Washington, DC.)

MC 119988 (Sub-159F), filed September 1, 1978. Applicant: GREAT WESTERN TRUCKING CO., INC., P.O. Box 1384, Lufkin, TX 75901. Representative: Clayte Binion, 1108 Continental Life Building, Fort Worth, TX 76102. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *lumber, lumber mill products, forest products, wood products, and sawmill products*, (1) from points in CA, ID, MT, OR, and WA, to points in AZ, AR, CA, CO, IL, IN, IA, KS, LA, MI, MN, MO, MT, NE, NM, ND, NV, OK, SD, TX, UT, WY, and WI, and (2) from points in AZ, CO, and NM, to points in AR, IL, IN, IA, KS, LA, MI, MN, MO, NV, NE, ND, OK, SD, TX, UT, WY, and WI. (Hearing site: Portland, OR.)

NOTE: Dual operations are involved in this proceeding.

MC 119988 (Sub-164F), filed September 7, 1978. Applicant: GREAT WESTERN TRUCKING CO., INC., Highway 103, East, P.O. Box 1384, Lufkin, TX 75901. Representative: Kim G. Meyer, P.O. Box 872, Atlanta, GA 30301. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *foodstuffs*, from Denver, CO, to points in TX. (Hearing site: Denver, CO, or Houston, TX.)

NOTE: Dual operations are involved in this proceeding.

MC 119988 (Sub-165F), filed September 19, 1978. Applicant: GREAT WESTERN TRUCKING CO., INC., P.O. Box 1384, Lufkin, TX 75901. Representative: Clayte Binion, 1108 Continental Life Building, Fort Worth, TX 76102. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *such commodities* as are dealt in or used by nursery and horticultural stores (except commodities in bulk), from Pine Bluff, AR, and DeKalb, IL, to points in the United States (except AK and HI).

(Hearing site: Little Rock, AR, or Dallas, TX.)

NOTE: Dual operations involved in this proceeding.

MC 119988 (Sub-166F), filed September 27, 1978. Applicant: GREAT WESTERN TRUCKING CO., INC., P.O. Box 1384, Lufkin, TX 75901. Representative: Hugh T. Matthews, 2340 Fidelity Union Tower, Dallas, TX 75201. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *motor vehicle parts and motor vehicle accessories*, between Houston, TX, on the one hand, and, on the other, points in AZ and CA. (Hearing site: Dallas, TX.)

NOTE: Dual operations are involved in this proceeding.

MC 119988 (Sub-167F), filed September 29, 1978. Applicant: GREAT WESTERN TRUCKING CO., INC., P.O. Box 1384, Lufkin, TX 75901. Representative: Hugh T. Matthews, 2340 Fidelity Union Tower, Dallas, TX 75201. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *commercial refrigeration units and parts for commercial refrigeration units*, and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1) above, between Waxahachie, TX, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Dallas, TX.)

NOTE.—Dual operations are involved in this proceeding.

MC 119988 (Sub-168F), filed October 2, 1978. Applicant: GREAT WESTERN TRUCKING CO., INC., P.O. Box 1384, Lufkin, TX 75901. Representative: Clayte Binion, 1108 Continental Life Bldg., Fort Worth, TX 76102. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *foundry supplies and industrial mill supplies* (except commodities in bulk), from points in the United States (except AK and HI), to points in AR, LA, OK, and TX. (Hearing site: Dallas, TX or Washington, DC.)

NOTE.—Dual operations are involved in this proceeding.

MC 119988 (Sub-169F), filed October 4, 1978. Applicant: GREAT WESTERN TRUCKING CO., INC., P.O. Box 1384, Lufkin, TX 75901. Representative: Hugh T. Matthews, 2340 Fidelity Union Tower, Dallas, TX 75201. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *motor vehicle parts and motor vehicle accessories*, between San Antonio, TX, on the one hand, and, on the other, points in AZ and CA. (Hearing site: Dallas, TX.)

NOTE.—Dual operations are involved in this proceeding.

MC 119988 (Sub-170F), filed October 5, 1978. Applicant: GREAT WESTERN TRUCKING CO., INC., P.O. Box 1384, Lufkin, TX 75901. Representative: Hugh T. Matthews, 2340 Fidelity Union Tower, Dallas, TX 75201. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *plumbing fixtures and plumbing fittings*, and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1) above, between points in Brown County, TX, on the one hand, and, on the other, points in the United States (except AK, HI, and TX). (Hearing site: Dallas, TX.)

NOTE.—Dual operations are involved in this proceeding.

MC 119988 (Sub-171F), filed October 6, 1978. Applicant: GREAT WESTERN TRUCKING CO., INC., P.O. Box 1384, Lufkin, TX 75901. Representative: Hugh T. Matthews, 2340 Fidelity Union Tower, Dallas, TX 75201. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *air conditioning equipment, refrigeration equipment, and parts* for air conditioning and refrigeration equipment, and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1) above, between San Antonio, TX, on the one hand, and, on the other, those points in the United States in and west of MT, WY, CO, and NM (except AK and HI). (Hearing site: Dallas, TX.)

NOTE.—Dual operations are involved in this proceeding.

MC 119988 (Sub-172F), filed October 12, 1978. Applicant: GREAT WESTERN TRUCKING CO., INC., P.O. Box 1384, Lufkin, TX 75901. Representative: Hugh T. Matthews, 2340 Fidelity Union Tower, Dallas, TX 75201. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *playground apparatus, wheel goods, and motorized bicycles*, (2) *parts and accessories* for the commodities in (1) above, and (3) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1) and (2) above, (except commodities in bulk), between Olney, IL, and Little Rock, AR, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Dallas, TX.)

NOTE.—Dual operations are involved in this proceeding.

MC 119988 (Sub-173F), filed October 23, 1978. Applicant: GREAT WESTERN TRUCKING CO., INC., P.O. Box 1384, Lufkin, TX 75901. Representative: Clayte Binion, 1108 Continental Life Bldg., Fort Worth, TX 76102. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *plastic articles* (except commodities in bulk), and *equipment and supplies* used in the manufacture and distribution of plastic articles (except commodities in bulk), between points in the United States (except AK and HI). (Hearing site: Dallas, TX, or Washington, DC.)

NOTE.—Dual operations are involved in this proceeding.

MC 123408 (Sub-24F), filed September 25, 1978. Applicant: FOOD HAULERS, INC., 600 York Street, Elizabeth, N.J. 07207. Representative: Eugene M. Malkin, Suite 6193, 5 World Trade Center, New York, NY 10048. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting (1) *such commodities* as are dealt in or used by (a) drug stores and (b) grocery and food business houses (except commodities in bulk), from the facilities of Warner Lambert Company, at or near Lititz, PA, to points in GA, under continuing contract(s) with Warner Lambert Company, of Morris Plains, NJ; and (2) *such commodities* as are dealt in or used by grocery and food business houses (except commodities in bulk), from points in GA, NC, and SC, to Elizabeth and Edison, NJ, under continuing contract(s) with Wakefern Food Corporation, of Elizabeth, NJ. (Hearing site: New York, NY.)

MC 124212 (Sub-100F), filed August 22, 1978. Applicant: MITCHELL TRANSPORT, INC., an Indiana corporation, 6500 Pearl Road, P.O. Box 30248, Cleveland, OH 44130. Representative: J. A. Kundtz, 1100 National City Bank Building, Cleveland, OH 44114. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *cement mill waste and stack dust*, in bulk, from Mason City, IA, to points in IL and NE. (Hearing site: Washington, DC.)

NOTE.—Dual Operations are involved in this proceeding.

MC 124692 (Sub-231F), filed August 3, 1978. Applicant: SAMMONS TRUCKING, a corporation, P.O. Box 4347, Missoula, MT 59801. Representative: Donald W. Smith, P.O. Box 40659, Indianapolis, IN 46240. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *barium sulfate*, from Battle Mountain and Fallon, NV, and Salt Lake City, UT, to Orland, Lodi, and Bakersfield, CA, (2) *ferro chrome lignosulfonate*, from Rothschild, WI, to Lodi and Bakersfield, CA, and Laredo, TX, and (3) *lignite*, from Williston, ND, to Lodi and Bakersfield, CA. (Hearing site: Los Angeles, CA.)

MC 124692 (Sub-236F), filed August 24, 1978. Applicant: SAMMONS TRUCKING, a corporation, P.O. Box 4347, Missoula, MT 59801. Representative: J. David Douglas (same address

as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *iron and steel articles*, from the facilities of Church & Clark, Inc., at Dallas, TX, to points in the United States (except AK and HI), restricted to the transportation of traffic originating at the named orgins. (Hearing site: Dallas, TX.)

MC 124692 (Sub-237F), filed August 24, 1978. Applicant: SAMMONS TRUCKING, a corporation, P.O. Box 4347, Missoula, MT 59801. Representative: J. David Douglas (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *iron and steel articles*, from Oklahoma City, OK, to points in AZ, AR, IA, MN, MT, ND, SD, TX, WI, and WY. (Hearing site: Oklahoma City, OK.)

MC 124692 (Sub-238F), filed August 24, 1978. Applicant: SAMMONS TRUCKING, a corporation, P.O. Box 4347, Missoula, MT 59806. Representative: J. David Douglas (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *cleaning compounds*, from Dallas, TX, to points in AZ, CA, CO, ID, MN, MO, MT, NM, OR, TN, UT, and WA. (Hearing site: Dallas, TX.)

MC 124692 (Sub-239F), filed August 24, 1978. Applicant: SAMMONS TRUCKING, a corporation, P.O. Box 4347, Missoula, MT 59806. Representative: J. David Douglas (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *steel coils* and *steel decking* from the facilities of Merco Manufacturing, Inc., at (a) Dallas and Houston, TX, and (b) Little Rock, AR, to points in AZ, AR, CA, CO, KS, LA, MO, MT, NM, OK, and WY, restricted to the transportation of traffic originating at the named origins. (Hearing site: Dallas, TX.)

MC 125433 (Sub-166F), filed September 19, 1978. Applicant: F-B TRUCK LINE COMPANY, a corporation, 1945 South Redwood Road, Salt Lake City, UT 84101. Representative: David J. Lister (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *fabricated steel fireplaces and fireplace parts*, from Union City, TN, to points in the United States (except AK and HI), and (2) *materials and supplies* (except commodities in bulk), used in the manufacture of the commodities in (1) above (except commodities in bulk), from the destinations in (1) above, to Union City, TN. (Hearing site: Los Angeles, CA, or Salt Lake City, UT.)

MC 125433 (Sub-167F), filed September 25, 1978. Applicant: F-B TRUCK LINE COMPANY, a corporation, 1945 South Redwood Road, Salt Lake City, UT 84104. Representative: David J. Lister (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *coal and wood burning stoves*, and *coal and wood burning fireplaces*, from points in Salt Lake County, UT, to those points in the United States in and east of ND, SD, NE, KS, OK, and TX. (Hearing site: Salt Lake City, UT, or San Francisco, CA.)

MC 126422 (Sub-7F), filed August 30, 1978. Applicant: QUALITY TRANSPORT, INC., 1200 Simons Building, Dallas, TX 75201. Representative: Leroy Hallman, 4555 First National Bank Building, Dallas, TX 75202. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *cement*, from the facilities of Missouri Portland Cement Company, at or near Union, LA, to points in AL, AR, FL, GA, LA, MS, OK, and TX. (Hearing Site: New Orleans, LA, or Dallas, TX.)

MC 127042 (Sub-22F), filed August 21, 1978. Applicant: HAGEN, INC., P.O. Box 98—Leeds Station, Sioux City, IA 51108. Representative: Robert G. Tessar (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *such commodities* as are dealt in by (a) grocery and food business houses and (b) drug stores, (except frozen commodities and commodities in bulk), from the facilities of The Clorox Company, at Chicago, IL, to points in MN, ND, and SD. (Hearing site: Chicago, IL.)

MC 127625 (Sub-31F), filed September 26, 1978. Applicant: Santee Cement Carriers, Inc., P.O. Box 638, Holly Hill, SC 29059. Representative: Frank B. Hand, Jr., P.O. Drawer C, Berryville, VA 22611. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *aluminum, articles*, and *materials, equipment, and supplies* used in the manufacture of aluminum articles, (except commodities in bulk, in tank vehicles), between the facilities of Alumax, Inc., in Berkeley County, SC, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Columbia, SC, or Washington, DC.)

MC 128273 (Sub-320F), filed September 15, 1978. Applicant: MIDWESTERN DISTRIBUTION, INC., P.O. Box 189, Fort Scott, KS 66701. Representative: Elden Corban (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *cots, beds*, and *parts and accessories for cots and beds*, and (2) *materials and supplies* used in the manufacture of the commodities named in (1) above, (except commodities in bulk, in tank vehicles), (a) from Carthage, MO, to points in AZ, AR, CA, CO, FL, ID, KS, LA, MS, MT, NV, NM, ND, OK, OR, SD, UT, WA, and WY, (b) from Hominy, OK, to points in AZ, CA, CO, CT, DE, FL, ID, KS, ME, MA, MT, NE, NV, NH, NJ, NM, NY, ND, OR, RI, SD, TX, UT, VT, WA, and WY, and (c) from Ennis, Dallas, and Fort Worth, TX, to points in the United States on and west of a line beginning at the mouth of the Mississippi River, and extending along the Mississippi River to its junction with the western boundary of Itasca County, MN, thence northward along the western boundries of Itasca and Koochiching Counties, MN, to the United States-Canada international boundary line, (except points in AK, AR, HI, IA, KS, MO, NE, ND, OK, and SD). (Hearing site; Kansas City, MO.)

MC 128951 (Sub-20F), filed September 5, 1978. Applicant: ROBERT H. DITTRICH, d.b.a. BOB DITTRICH TRUCKING, 1000 North Front Street, New Ulm, MN 56073. Representative: James T. Flescher, 1745 Universtiy Avenue, St. Paul, MN 55104. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *Dry animal feed*, and *dry poultry feed*, from the facilities of Cargill, Nutrena Feed Division, at New Richland, MN, to points in IA, SD, WI, and the Upper Peninsula of MI. (Hearing Site: St. Paul, MN.)

NOTE.—Dual operations are involved in this proceeding.

MC 129032 (Sub-53F), filed August 17, 1978. Applicant: TOM INMAN TRUCKING, INC., 6015 So. 49th West Ave., Tulsa, OK 74107. Representative: David R. Worthington (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *such commodities* as are dealt in or used by manufacturers of rubber and rubber products, (except commodities in bulk), between the facilities of the Good- year Tire and Rubber Company, at or near Lawton, OK, on the one hand, and, on the other points in AL, AZ, AR, CA, CO, FL, GA, ID, IL, IN, IA, KS, KY, LA, MI, MN, MS, MO, MT, NE, NV, NM, NC, ND, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, WA, WV, WI, and WY. (Hearing site: Akron, OH, or Washington, DC.)

MC 129455 (Sub-35F), filed October 3, 1978. Applicant: CARRETTA TRUCKING, INC., South 160, Route 17 North, Paramus, NJ 07852. Representative: Charles J. Williams, 1815 Front Street, Scotch Plains, NJ 07076. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting (1) *such commodities* as are dealt in by a manufacturer of toilet preparations, (except commodities in bulk), from the facilities of The Mennen Company, at Morristown

and Newark, NJ, to points in AL, AR, FL, GA, IA, KS, KY, LA, MN, MS, NV, NM, NC, OR, SC, WA, and WI, and (2) *materials, equipment, and supplies* used in the manufacture and distribution of toilet preparations, (except commodities in bulk), from points in the United States in and east of MN, NE, KS, OK, and TX, to the facilities named in (1) above, under continuing contract(s) in (1) and (2) above, with The Mennen Company, of Morristown, NJ. (Hearing site: New York, NY.)

NOTE.—Dual operations are involved in this proceeding.

MC 129624 (Sub-17F), filed June 7, 1978, and previously noticed in the FEDERAL REGISTER issue of August 22, 1978. Applicant: ROUTE MESSENGERS OF PENNSYLVANIA, INC., 2425 Bainbridge Street, Philadelphia, PA 19146. Representative: Alan Kahn, 1920 Two Penn Center Plaza, Philadelphia, PA 19102. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *copying machine parts* and *copying machine supplies*, from Pennsauken, NJ, to points in Berks, Bucks, Lehigh, Luzerne, and Northampton Counties, PA. (Hearing site: Philadelphia, PA, or Washington, DC.)

NOTE.—Dual operations are involved in this proceeding. This republication amends the commodity description.

MC 133095 (Sub-202F), filed October 2, 1978. Applicant: TEXAS-CONTINENTAL EXPRESS, INC., P.O. Box 434, Euless, TX 76039. Representative: Hugh T. Matthews, 2340 Fidelity Union Tower, Dallas, TX 75201. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *alcoholic beverages* (except in bulk), and (2) *materials and supplies* used in the manufacture and distribution of alcoholic beverages, from Peoria, IL, to points in WY, NM, AZ, CA, NE, MN, IN, OH, KY, WV, VA, MD, DE, PA, NY, CT, RI, MA, VT, NH, ME, FL, GA, TN, and DC. (Hearing site: Dallas, TX.)

MC 133095 (Sub-204F), filed October 2, 1978. Applicant: TEXAS-CONTINENTAL EXPRESS, INC., P.O. Box 434, Euless, TX 76039. Representative: Kim G. Meyer, P.O. Box 872, Atlanta, GA 30301. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *materials, equipment, and supplies* used in the manufacture, distribution, and administration of drugs, nutritional and anti-coagulent solutions, and distilled water, from points in the United States on and east of U.S. Hwy 85, to the facilities of McGaw Laboratories, Inc., Division of American Hospital Supply, at Milledgeville and Atlanta, GA. (Hearing site: Atlanta, GA.)

MC 133221 (Sub-36F), filed September 5, 1978. Applicant: OVERLAND CO., INC., 1991 Buford Hwy., Lawrenceville, GA 30245. Representative: Alvin Button, 1644 Tullie Cir NE., Suite 102, Atlanta, GA 30329. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *aluminum stampings*, from Palestine, TX, to points in the United States (except AK and HI). (Hearing site: Atlanta, GA, or Washington, DC.)

MC 133655 (Sub-123F), filed September 15, 1978. Applicant: TRANS-NATIONAL TRUCK, INC., P.O. Box 31300, Amarillo, TX 79120. Representative: Warren L. Troupe, 2480 E. Commercial Blvd., Fort Lauderdale, FL 33308. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *general commodities* (except articles of unusual value, classes A & B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), from Chicago, IL, to Dallas, Houston, San Antonio, Amarillo, Lubbock, and Laredo, TX. (Hearing site: Chicago, IL.)

MC 134922 (Sub-275F), filed August 23, 1978. Applicant: B. J. MCADAMS, INC., Route 6, Box 15, North Little Rock, AR 72118. Representative: Bob McAdams (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *such commodities* as are dealt in by manufacturers and distributors of tile, (except commodities in bulk and those which because of size or weight require the use of special equipment), from Lansdale and Quakertown, PA, to points in TX.

Condition: Pursuant to the Decision in MC 134922 (Sub-95), et al., served September 7, 1978, this proceeding is being held open until such time as a determination of applicant's fitness has been made. (Hearing site: Philadelphia, PA, or Washington, DC.)

NOTE.—Applicant states the purpose of this filing is to substitute single-line service for existing joint-line service.

MC 135633 (Sub-14F), filed August 18, 1978. Applicant: NATIONWIDE TRANSPORTERS, INC., 2175 Lemoine Avenue, Fort Lee, NJ 07024. Representative: Harold G. Hernly, Jr., 118 North Saint Asaph Street, Alexandria, VA 22314. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *trucks, tractors, and chassis*, in secondary movements, in driveway service, between points in the United States (including AK, but excluding HI). (Hearing site: Washington, DC, or Chicago, IL.)

MC 136161 (Sub-16F), filed September 5, 1978. Applicant: ORBIT TRANSPORT INC., P.O. Box 163, Spring Valley, IL 61362. Representative: Elizabeth A. Purcell, 805 McLachlen Bank Building, 666 Eleventh Street, NW., Washington, DC 20001. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *containers*, and (2) *materials* and *supplies* used in the manufacture of containers, between Kankakee, IL, on the one hand, and, on the other, points in IN, MI, MO, OH, WI, MN, IA, AR, TN, KY, and WV. (Hearing site: Chicago, IL.)

MC 136818 (Sub-38F), filed September 8, 1978. Applicant: SWIFT TRANSPORTATION CO., INC., 335 West Elwood Road, P.O. Box 3902, Phoenix, AZ 85030. Representative: Donald E. Fernaays, Suite 320, 4040 East McDowell Road, Phoenix, AZ 85008. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *gypsum wallboard and gypsum plaster*, from points in Clark County, NV, to points in CA, ID, and UT. (Hearing site: Los Angeles, CA, or Las Vegas, NV.)

NOTE.—Dual operations are involved in this proceeding.

MC 138157 (Sub-85F), filed September 5, 1978. Applicant: SOUTHWEST EQUIPMENT RENTAL, INC., d.b.a. SOUTHWEST MOTOR FREIGHT, a California corporation, 2931 South Market Street, Chattanooga, TN 37410. Representative: Patrick E. Quinn, P.O. Box 9596, Chattanooga, TN 37412. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *fabricated and shaped metal articles*, (except commodities which by reason of size or weight require the use of special equipment), from the facilities of Norris Industries, Inc., in Los Angeles and Orange Counties, CA, to those points in the United States in and east of ND, SD, NE, KS, OK, and TX, restricted to the transportation of traffic originating at the noted facilities and destined to the indicated destinations. (Hearing site: Los Angeles, CA.)

NOTE: Dual operations are involved in this proceeding.

MC 138308 (Sub-57F), filed October 16, 1978. Applicant: KLM, INC., A Texas corporation, Old Hwy 49 South, P.O. Box 6098, Jackson, MS 39208. Representative: Donald B. Morrison, 1500 Deposit Guaranty Plaza, P.O. Box 22628, Jackson, MS 39205. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *television sets, radio sets, phonograph sets, recording sets, loudspeakers, and sound systems*, and (2) *stands and accessories* for the commodities in (1) above, (a) from the facilities of GTE Sylvania, Inc., at Smithfield, NC, to points in AZ, CA, CO, GA, IL, LA, MS, NV, NM, OK,

OR, NY, TN, and TX, (b) from the facilities of GTE Sylvania, Inc., at Atlanta, GA, to points in AL, OR, KY, LA, MS, TN, and TX, (c) from the facilities of GTE Sylvania, Inc., at Elk Grove Village, IL, to points in CO, (d) from the facilities of GTE Sylvania, Inc., at Los Angeles, CA, to points in GA, IL, NC, and NY, (e) from the facilities of GTE Sylvania, Inc., at Sparks, NV, to points in CA, OR, and WA, (f) between the facilities of GTE Sylvania, Inc., at Batavia, NY, and the facilities of GTE Sylvania, Inc., at Smithfield, NC, and (3) *supplies and accessories* used in the manufacture and distribution of the commodities in (1) and (2) above, (except commodities in bulk), between the facilities of GTE Sylvania, Inc., at (a) El Paso, TX, (b) Smithfield, NC, and (c) Elk Grove Village, IL, restricted in (1), (2), and (3) above to the transportation of traffic originating at the named origin facilities. (Hearing site: Jackson, MS, or Washington, DC.)

NOTE.—Dual operations are involved in this proceeding.

MC 138635 (Sub-63F), filed October 4, 1978. Applicant: CAROLINA WESTERN EXPRESS, INC., Box 3961, Gastonia, NC 28052. Representative: Eric Meierhoefer, Suite 423, 1511 K Street NW., Washington, DC 20005. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *foodstuffs*, from points in CA, to points in AL, FL, GA, NC, SC, TN, VA, and WV. (Hearing site: San Francisco, CA.)

NOTE. Dual operations are involved in this proceeding.

MC 138635 (Sub-64F), filed October 4, 1978. Applicant: CAROLINA WESTERN EXPRESS, INC., Box 3961, Gastonia, NC 28052. Representative: Eric Meierhoefer, Suite 423, 1511 K Street NW., Washington, DC 20005. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *such commodities* as are dealt in or used by manufacturers of rubber and rubber products, (except commodities in bulk), (1) from the facilities of The Good- year Tire and Rubber Co., at or near Lawton, OK, to points in CA, OR, WA, NC, AL, and MD, and (2) from the facilities of The Goodyear Tire and Rubber Co., at or near (a) Decatur and Scottsboro, AL, and (b) Rockmart, Cartersville, and Cedartown, GA, to the facilities of The Goodyear Tire and Rubber Co., at or near Lawton, OK. (Hearing site: Washington, DC.)

NOTE.—Dual operations are involved in this proceeding.

MC 138772 (Sub-6F), filed August 25, 1978. Applicant: ALL-WAYS FREIGHT LINES, INC., 215 North 18th Street, Leavenworth, KS 66048. Representative: John E. Jandera, 641 Harrison Street, Topeka, KS 66603. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *general commodities* (except articles of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between Hiawatha and Marysville, KS: from Hiawatha over U.S. Hwy 73 to junction U.S. Hwy 75, then over U.S. Hwy 75 to junction NE Hwy 4, then over NE Hwy 4 to junction NE Hwy 50, then over NE Hwy 50 to junction U.S. Hwy 136, then over U.S. Hwy 136 to junction U.S. Hwy 77, then over U.S. Hwy 77 to Marysville, and return over the same route, serving all intermediate points (except Falls City, NE), and all off-route points in Richardson (except Falls City), Pawnee, Gage, and Johnson Counties, NE. (Hearing site: Kansas City, MO.)

MC 138882 (Sub-137F), filed August 24, 1978. Applicant: WILEY SANDERS TRUCK LINES, INC., P.O. Drawer 707, Troy, AL 36081. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *wheel weights, lead, and steel holding and fastening devices*, from the facilities of Plumbiam Manufacturing Corp., at Bristol, TN, to points in the United States (except AK and HI). (Hearing site: Knoxville, TN, or Montgomery, AL.)

MC 138882 (Sub-144F), filed August 31, 1978. Applicant: WILEY SANDERS TRUCK LINES, INC., P.O. Box 707, Troy, AL 36081. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *malt beverages*, from the facilities of Pabst Brewing Co., at Pabst, GA, to points in NC, SC, and FL; and (2) *materials, equipment*, and *supplies* used in the manufacture and sale of malt beverages (except commodities in bulk), from points in NC, SC, and FL, to the facilities of Pabst Brewing Co., at Pabst, GA. (Hearing site: Atlanta, GA, or Birmingham, AL.)

MC 138882 (Sub-145F), filed August 24, 1978. Applicant: WILEY SANDERS TRUCK LINES, INC., P.O. Drawer 707, Troy, AL 36081. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *steel pipe, fittings and valves*, from the facilities of Piping and Equipment Company, Inc., at Jackson, MS, to points in TX, GA, KY, WI, IN, AR, NC, SC, OH, and MN, and (2) *steel pipe, and fittings*, from Lorain and Cleveland, OH, Fairless, PA, and Birmingham and Pelham, AL, to points in TX, GA, KY, WI, IN, AR, NC, SC, OH, MN, and MS. (Hearing site: Jackson, MS, or Montgomery, AL.)

MC 138882 (Sub-146F), filed August 31, 1978. Applicant: WILEY SANDERS, INC., P.O. Box 707, Troy, AL 36081. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *foodstuffs* (except frozen), in containers, from the facilities of Doxsee Foods, Inc., at or near Brundidge, AL, to points in GA, SC, NC, TN (except Memphis), VA and MD. (Hearing site: Birmingham or Montgomery, AL.)

MC 138882 (Sub-147F), filed August 31, 1978. Applicant: WILEY SANDERS, INC., P.O. Box 707, Troy, AL 36081. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *pipe, fittings, hydrants, valves*, and (2) *castings, parts*, and *accessories* for the commodities in (1) above, from Chattanooga, TN, to points in CO, WY, NM, TX, AR, and UT. (Hearing site: Montgomery or Birmingham, AL.)

MC 138882 (Sub-148F), filed August 31, 1978. Applicant: WILEY SANDERS, INC., P.O. Box 707, Troy, AL 36081. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *moulded pulp*, and *nested egg cartons*, from the facilities of the Packaging Corp. of America, at or near Macon, GA, to points in MI and IN; and (2) *scrap paper* and *waste paper* used for recycling, from points in MI, IN, AR, MO, KY, PA, and NJ, to the facilities of the Packaging Corp. of America, at or near Macon, GA. (Hearing site: Atlanta, GA, or Montgomery, AL.)

MC 139457 (Sub-8F), filed September 15, 1978. Applicant: G. L. SKIDMORE d.b.a. JELLY SKIDMORE TRUCKING CO., P.O. Box 38, Paris, TX 75460. Representative: Paul D. Angenend, P.O. Box 2207, Austin, TX 78768. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting *canned and preserved foodstuffs*, and *canned and packaged animal food*, from the facilities of Campbell Soup (Texas) Inc., at or near Paris, TX, to points in LA, under continuing contract(s) with Campbell Soup (Texas) Inc., of Paris, TX. (Hearing site: Dallas, TX, or Washington, DC.)

MC 139615 (Sub-21F), filed October 2, 1978. Applicant: D.R.S. TRANSPORT, INC., P.O. Box 29, Oskaloosa,

IA 52577. Representative: Larry D. Knox, 600 Hubbell Building, Des Moines, IA 50309. To operate as a *common carrier*, by motor vehicles, over irregular routes, transporting (1) *sewage treatment plants, aerators, and lift stations*, and (2) *materials, supplies, and accessories* used in the manufacture, distribution, and installation of the commodities in (1) above, from the facilities of Clow Corporation, at or near Richwood, KY, to points in the United States (except AK, KY, and HI). (Hearing site: Chicago, IL.)

MC 139723 (Sub-4F), filed July 25, 1978, previously noticed in the FEDERAL REGISTER issue of September 26, 1978 as MC 144711 Sub 2F. Applicant: FARISH R. THOMPSON d.b.a. THOMPSON TRUCKING, R. R. No. 1, Afton, WY 83110. Representative: Farish R. Thompson (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *lumber*, between Afton, WY, on the one hand, and, on the other, points in UT and ID. (Hearing site: Salt Lake City, UT, or Casper, Wy.)

NOTE.—This republication indicates that the applicant is seeking common carrier authority, and that the territorial description sought involves a radial movement.

MC 139858 (Sub-31F), filed October 16, 1978. Applicant: AMSTAN TRUCKING, INC., a Delaware corporation, 1255 Corwin Avenue, Hamilton, OH 45015. Representative: Chandler L. Van Orman, 1729 H Street, NW., Washington, DC 20006. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting (1) *stoves, fireplaces, and accessories* for stoves and fireplaces (except commodities which because of size or weight require the use of special equipment), and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1) above, (except commodities which because of size or weight require the use of special equipment), from Grand Rapids, MI, to Huntington and North Manchester, IN, under continuing contract(s) with American Standard, Inc., of New Brunswick, NJ. (Hearing site: Indianapolis, IN, or Washington, DC.)

MC 140123 (Sub-7F), filed September 25, 1978. Applicant: GRAHAM TRANSFER, INC., Route 2, Box 44, Linden TN 37906. Representative: Roland M. Lowell, 618 Imoted American Bank Building, Nashville, TN 37096. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *fiberglass articles, aluminum articles, and iron and steel articles*, between the facilities of IKG Industries, at (a) Nashville, TN (b) Gulfport, MS, and (c) New Orleans, LA. (Hearing site: Nashville, TN.)

MC 140168 (Sub-5F), filed October 6, 1978. Applicant: FANETTI REFRIGERATED TRANSPORT, Rt. 1, Box 29-A, Bloomer, WI 54724. Representative: Robert P. Sack, P.O. Box 6010, West St. Paul, MN 55118. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *building insulation* from Bloomer, WI, to points in MN and IA; and (2) *materials, equipment, and supplies* used in the manufacture and sale of building insulation, (except commodities in bulk), from Minneapolis, MN, and Columbus, OH, to Bloomer, WI. (Hearing site: St. Paul, MN.)

MC 140186 (Sub-28F), filed August 30, 1978. Applicant: TIGER TRANSPORTATION, INC., P.O. Box 2248, Missoula, MT 59801. Representative: David A. Sutherlund, 1150 Connecticut Avenue, NW., Suite 400, Washington, DC 20036. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *flour*, from Billings, MT, to points in CA. (Hearing site: Billings, MT.)

MC 140665 (Sub-39F), filed October 4, 1978. Applicant: PRIME, INC., Route 1, Box 115-B, Urbana, MO 65767. Representative: Clayton Geer, P.O. Box 786, Ravenna, OH 44266. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *automotive parts and accessories*, from the facilities of Ford Motor Company, at or near (a) Melvindale, MI, (b) Mansfield, OH, and (c) Nashville, TN, to Pico Rivera and Milpitas, CA. (Hearing site: Washington, DC, or Detroit, MI.)

NOTES.—(1) The person or persons engaged in common control of applicant and another regulated carrier must file an application under section 5(2) of the Interstate Commerce for common control or show why such application is not necessary. This must be done within 30 days after publication of the notice in the FEDERAL REGISTER.

(2) Dual operations may be involved in this proceeding.

MC 140665 (Sub-40F), filed October 4, 1978. Applicant: PRIME, INC., Route 1, Box 115-B, Urbana, MO 65767. Representative: Clayton Greer, P.O. Box 786, Ravenna, OH 44266. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *Paint, paint products, aerosol products, and adhesives*, and (2) *materials and supplies* used in the manufacture and distribution of the commodities in (1) above, (except commodities in bulk), between Hubbard, Deshler, Dayton, Brooklyn Heights, and Bedford Heights, OH, Fulton and Richmond, KY, and Elgin and Chicago, IL, on the one hand, and, on the other, points in CA and TX. (Hearing site: Cleveland, OH and Washington, DC.)

NOTES.—(1) The person or persons engaged in common control of application and another regulated carrier must file an application under section 5(2) of the Interstate Commerce Act for common control or show why such application is not necessary. This must be done within 30 days after publication of this notice in the FEDERAL REGISTER. (2) Dual operations may be involved in this proceeding.

MC 141046 (Sub-10F), filed August 30, 1978. Applicant: MASON O. MITCHELL, d.b.a., M. MITCHELL TRUCKING, 1911 I Street, LaPorte, IN 46350. Representative: Norman R. Garvin, 1301 Merchants Plaza, Indianapolis, IN 46204. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *corn products and soybean products*, and (2) *chemicals*, in containers, from Decatur, IL, to points in CT, MA, ME, NH, and RI, under continuing contract(s) with A. E. Staley Manufacturing Co., at Decatur, IL. (Hearing site: Indianapolis, IN, or Chicago, IL.)

MC 141232 (Sub-6F), filed August 29, 1978. Applicant: STATEWIDE TRUCKING CO., a corporation, 1801 W. Oxford, Englewood, CO 80110. Representative: A. B. Ballah Jr. (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *building materials*, and *fencing*, between points in WY, and on the one hand, on the other, points in NE on and west of U.S. Hwy 281. (Hearing Site: Denver, CO, or Cheyenne, WY.)

MC 141781 (Sub-10F), filed September 5, 1978. Applicant: LARSON TRANSFER & STORAGE CO., INC., 950 West 94th Street, Minneapolis, MN 55431. Representative: Samuel Rubenstein, 301 North Fifth Street, Minneapolis, MN 55403. To operate as a *Common Carrier*, by motor vehicle, over irregular routes, transporting (1) *such commodities* as are dealt in by retail stores (except foodstuffs and commodities in bulk) *and* (2) *foodstuffs*, in mixed shipments with the commodities in (1) above, from the facilites of Target Stores, at Minneapolis, MN, to points in SD. (Hearing site: Minneapolis or St. Paul, MN.)

NOTE.—Dual operations are involved in this proceeding.

MC 141781 (Sub-11F), filed September 5, 1978. Applicant: LARSON TRANSFER & STORAGE CO., INC., 950 West 94th Street, Minneapolis, MN 55431. Representative: Samuel Rubenstein, 301 North Fifth Street, Minneapolis, MN 55403. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *Wire steel springs*, from Logansport, IN, to Sioux Falls, SD. (Hearing site: Minneapolis or St. Paul, MN.)

NOTE.—Dual operations are involved in this proceeding.

MC 141921 (Sub-20F), filed September 6, 1978. Applicant: SAV-ON TRANSPORTATION, INC., 143 Frontage Road, Manchester, NH 03108. Representative: John A. Sykas (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *meats, meat products and meat byproducts, dairy products, and articles distributed by meat-packing houses* as described in sections A, B and C of Appexdix I to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 and 766 (except hides and commodities in bulk), from the facilities used by John Morrell and Company, at or near (a) Estherville, IA, and (b) Sioux Falls, SD, to points in CT, FL, GA, ME, MA, MD, NH, NJ, VT, RI, PA, NY, OH, DE, VA, WV, and DC, restricted to the transportation of traffic originating at the named origin facilities. (Hearing site: Concord, NH, or Boston, MA.)

NOTE.—Dual operations are involved in this proceeding.

MC 142672 (Sub-28F), filed August 28, 1978. Applicant: DAVID BENEUX PRODUCE & TRUCKING, INC., Post Office Drawer F, Mulberry, AR 72947. Representative: Don Garrison, 324 North Second Street, Rogers, AR 72756. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *meats, meat products and meat byproducts, and articles* distributed by meat-packing houses, as described in sections A and C of Appexdix I to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 and 766, (except hides and commodities in bulk), from Palestine, TX, to points in AL, AR, FL, GA, IL, IN, KY, LA, MS, MO, NY, OH, OK, PA, and TN. (Hearing site: Dallas, TX, or Tulsa, OK.)

NOTE.—Dual operations are involved in this proceeding.

MC 142941 (Sub-19F), filed September 6, 1978. Applicant: SCARBOROUGH TRUCK LINES, 1313 N. 25th Avenue, Phoenix, AZ 85009. Representative: Lewis P. Ames, 111 W. Monroe, 10th Floor, Phoenix, AZ 85003. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *foodstuffs* (except frozen) from the facilities of Ocean Spray Cranberries, Inc., at (a) Kenoska, WI, and (b) North Chicago, IL, to points in KS, OK, TX, NM, and to the facilities of Diamond Sunsweet, at (a) Yuba City, CA, and (b) Kansas City, MO. (Hearing site: Kinosha, WI.)

NOTE.—In view of the findings in MC 142941 (Sub-5) of which official notice is taken, the certificate to be issued in this proceeding will be limited to a period expiring 1 year from its effective date unless, prior to its expiration, applicant files a petition for the extension of said certificate and demonstrates that it has been conducting operations in full compliance with the terms and conditions of its certificate and with the requirements of the Interstate Commerce Act and applicable Commission regulations.

MC 143061 (Sub-2F), filed September 5, 1978. Applicant: ELECTRIC TRANSPORT, INC., Post Office Box 528, Eden, NC 27288. Representative: K. Edward Wolcott, Post Office Box 872, Atlanta, GA 30301. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting *such commodities* as are dealt in or used by a manufacturer of electrical products (except commodities which because of size or weight require special equipment, commodities in bulk, and aerospace craft and aerospace craft parts), between points in the U.S. (except AK and HI), under between continuing contract(s) with General Electric Company, of Schenectady, NY. (Hearing site: Washington, DC, or Atlanta, GA.)

MC 143085 (Sub-3F), filed September 26, 1978. Applicant: THE DANIEL CO. OF SPRINGFIELD, a corporation, 419 East Kearney, Springfield, MO 65803. Representative: Turner White, 910 Plaza Towers, Springfield, MO 65804. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *general commodities* (except articles of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), (a) between Springfield, MO, and Evansville, IN, (b) from Springfield, MO, and Evansville, IN, to points in TX, and (c) between Evansville, IN, and points in MI.

NOTE.—Dual operations are involved in this proceeding.

(Hearing site: Kansas City or St. Louis, MO.)

MC 143085 (Sub-4F), filed September 26, 1978. Applicant: THE DANIEL CO. OF SPRINGFIELD, a corporation, 419 East Kearney, Springfield, MO 65803. Representative: Turner White, 910 Plaza Towers, Springfield, MO 65804. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *general commodities* (except articles of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), from Springfield, MO, and Evansville, IN, to points in CA and OR.

NOTE.—Dual operations are involved in this proceeding.

(Hearing site: Kansas City or St. Louis, MO.)

MC 143117 (Sub-5F), filed September 11, 1978. Applicant: SAV-ON TRANSPORTATION, INC., 143 Frontage Road, Manchester, NH 03108. Representative: John A. Sykas (same address as applicant). To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting *cartons, knocked down, and macaroni, vermicelli, and noodles*, between the facilities of Prince Macaroni Manufacturing Company, Inc., at Lowell and Lawrence, MA, on the one hand, and, on the other, points in AL, FL, GA, IA, IL, IN, KY, LA, MD, MI, MN, NC, NE, NY, OH, OK, PA, SC, TX, VA, and WI, under continuing contract(s) with Prince Macaroni Manufacturing Company, Inc., of Lowell, MA.

NOTE.—Dual operations are involved in this proceeding.

(Hearing site: Concord, NH, or Boston, MA.)

MC 143127 (Sub-8F), filed July 26, 1978, previously noticed in the FEDERAL REGISTER issue of September 26, 1978. Applicant: K. J. TRANSPORTATION, INC., 1000 Jefferson Road, Rochester, NY 14623. Representative: S. Michael Richards, P.O. Box 225, Webster, NY 14580. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *canned goods*, from the facilities of (a) Curtice-Burns, Inc., at Alton, Egypt, Leicester, LeRoy, Phelps, Oakfield, Red Creek, Rushville, Shortsville, South Dayton, and Waterloo, NY, (b) Duffy-Mott Company, Inc., at Hamlin and Williamson, NY, and (c) Marion Foods Corp., Division of Seneca Foods Corp., at Dundee, Marion, Newark, Oaks Corners, Williamson, and East Williamson, NY, to points in AL, FL, GA, NC, and SC, restricted in (1), (2), and (3) above to the transportation of traffic originating at the named origins and destined to the indicated destinations. NOTE: This republication shows FL as a destination state in lieu of "GL." Dual operations are involved in this proceeding. (Hearing site: Buffalo or Syracuse, NY.)

MC 143775 (Sub-21F), filed October 4, 1978. Applicant: PAUL YATES, INC., 6601 West Orangewood, Glendale, AZ 85301. Representative: Edward N. Button, 1329 Pennsylvania Avenue, P.O. Box 1417, Hagerstown, MD 21740. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *swimming pools, and materials, equipment, and supplies* used in the manufacture, installation, and assembly of swimming pools, (except commodities in bulk), (a) from Holland, MI, to points in AZ, CO, NV, NM, UT, MT, OK, MO, KS, ND, TN, NE, KY, TX, WA, OR, CA, and GA, and (b) from points in CA, to Holland, MI. (Hearing site: Holland, MI.)

NOTE.—Dual operations are involved in the proceeding.

MC 143812 (Sub-3F), filed August 24, 1978. Applicant: MARTIN E. VAN DIEST, d.b.a., M. VAN DIEST CO., 8087 Victoria Avenue, Riverside, CA 92504. Representative: William J. Monheim, P.O. Box 1756, Whittier, CA 90609. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *liquid sugar*, in bulk, from Crockett, CA, to points in AZ, ID, NM, OR, TX, and WA; and (2) *liquid foodstuffs*, in bulk, from points in WA, to points in AZ and CA. (Hearing site: Los Angeles, CA.)

MC 144622 (Sub-5F), filed July 6, 1978, and previously published in the FEDERAL REGISTER issue of September 14, 1978. Applicant: GLENN BROS. MEAT CO., INC., P.O. Box 9343, Little Rock, AR 72209. Representative: Phillip Glenn (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *bicycles, and bicycle parts and accessories*, from Little Rock, AR, to points in MN, IA, MO, LA, KS, NE, OK, TX, WI, IL, MS, TN, KY, AL, GA, FL, IN, MI, OH, SC, NC, PA, WV, VA, MD, DE, MA, CT, NJ, and NY, restricted to the transportation of traffic originating at the facilities of AMF Incorporated at Little Rock, AR. (Hearing site: Little Rock, AR, or Washington, DC.)

NOTE. (1) Dual operations are involved in this proceeding. (2) This republication includes MO as a destination State.

MC 144672 (Sub 4F), filed August 22, 1978. Applicant: VICTORY EXPRESS, INC., Box 26189, Trotwood, OH 45426. Representative: Richard H. Schaefer (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *business and compu<ter forms*, and (2) *equipment, materials, and supplies* used in the manufacture of the commodities in (1) above, between Langhorne, PA, Dayton, OH, and Indianapolis, IN, on the one hand, and, on the other, those points in the United States on and east of Interstate Hwy 35. (Hearing site: Dayton or Columbus, OH.)

NOTE.—Dual operations are involved in this proceeding.

MC 144682 (Sub 5F), filed August 24, 1978. Applicant: R. R. STANLEY, Box 95, Mesquite, TX 75149. Representative: Richard T. Churchill, Suite 106, 5001 S. Hulen, Fort Worth, TX 76132. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *bakery goods, prepared dough, and icing paste*, from the plantside facilities of the Pillsbury Co., at Denison, TX, to points in NM and CO. (Hearing site: D-FW Airport or Dallas, TX.)

MC 144753 (Sub 1F), filed September 20, 1978. Applicant: RONALD D. OFFUTT, JR. d.b.a. RONALD OFFUTT & SON, Box 126, Glyndon, MN 56547. Representative: James B. Hovland, P.O. Box 1680, 414 Gate City Building, Fargo, ND 58102. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting *frozen potato products* (except in bulk), from the facilities of Potato Processing Co., at or near Atlanta, GA, to points in FL, AL, SC, VA, NC, TN, MD, LA, and MS, under continuing contract(s) with Potato Processing Co., of Atlanta, GA. (Hearing site: Minneapolis, MN, or Fargo, ND.)

MC 144853 (Sub-2F), filed September 21, 1978. Applicant: JAMES D. WATT, an individual, 729 Mansfield-Lucas Road, Mansfield, OH 44907. Representative: J. A. Kundtz, 1100 National City Bank Building, Cleveland, OH 44114. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting *air conditioning electric motor parts*, between the facilities of Ideal Electric Co., at Mansfield, OH, on the one hand, and, on the other, those points in the United States in and east of ND, SD, NE, KS, OK, and TX, under continuing contract(s) with Ideal Electric Co., of Mansfield, OH. (Hearing site: Columbus, OH.)

MC 144923 (Sub-1F), filed September 21, 1978. Applicant: KELTRAN, INC., 210 Industrial Parkway, Buffalo, NY 14224. Representative: William J. Hirsch, Suite 1125, 43 Court Street, Buffalo, NY 14202. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting *malt beverages*, in containers, between points in NJ, NY, OH, and PA, under continuing contract(s) with (1) Try-It Distributing Co., Inc., of Buffalo, NY, and (2) Spartan Beverage Corp., of Webster, NY. (Hearing site: Buffalo, NY.)

MC 145152 (Sub-2F), filed August 17, 1978. Applicant: BIG THREE TRANSPORTATION, INC., P.O. Box 706, Springdale, AR 72764. Representative: Don Garrison, 324 North Second Street, Rogers, AR 72756. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *chemicals, esters, fatty alcohol, coconut oil, softeners, textiles, liquid cleaning compounds, lubricating oils, wax*, and *fireproofing compounds*, (except commodities in bulk), from Mauldin, SC, Lock Haven, PA, Linden, NJ, and Santa Fe Springs, CA, to points in the United States (except AK and HI). (Hearing site: Mauldin, SC, or Tulsa, OK.)

MC 145152 (Sub-4F), filed August 31, 1978. Applicant: BIG THREE TRANSPORTATION, INC., P.O. Box 706, Springdale, AR 72764. Representative: Don Garrison, 324 North Second Street, Rogers, AR 72756. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *electrical applicances, equipment* and *parts* as described in Appendix VII to the report in Descriptions in Motor Carrier Certificates, 61 M.C.C. 209, 283, and *materials* used in the manufacture of electrical appliances (except commodities in bulk), from the facilities of Gibson-Metalux Corp., at or near Americus, GA, to points in the United States (except AK, AL, AR, AZ, CA, CO, GA, HI, ID, NM, NV, OR, UT, and WA). (Hearing site: Atlanta, Ga, or Little Rock, AR.)

MC 145236F, filed August 14, 1978. Applicant: MT. HOOD LIMOUSINE, INC., 8705 S. W. Barnes Road, Portland, OR 97225. Representative: Russell M. Allen, 1200 Jackson Tower, Portland, OR 97205. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *passengers and their baggage*, in the same vehicle with passengers, in charter operations, between Portland, OR, on the one hand, and, on the other, Timberline Lodge near Government Camp, OR, and Bowman's Resort near Weeme, OR, limited to the transportation of not more than fifteen (15) passengers in any one vehicle, not including the driver thereof. (Hearing site: Portland, OR.)

MC 145242F, filed August 21, 1978. Applicant: CASE HEAVY HAULING, INC., P.O. Box 1156, Huntington, WV 25714. Representative: Paul F. Beery, 275 East State Street, Columbus, OH 43215. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *iron and steel articles*, from Huntington, WV, to points in IN, IL, NC, NE, MD, DE, NJ, NY, GA (except Atlanta), DC those in MI on and south of MI Hwy 21, those in PA on and east of U.S. Hwy 15, and those in MS on and east of U.S. Hwy 78. (Hearing site: Columbus, OH.)

MC 144247 (Sub-3F), filed September 12, 1978. Applicant: DOWNEY ENTERPRISES INC., 31706 Coast Hwy, South Laguna, CA 92647. Representative: Gregory L. Parkin, 2500 West Orangethorpe, Suite U, Fullerton, CA 92633. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting *meats and meat products*, from Denver, CO, to New Haven, CT, Claremont, NH, Inglewood and Newark, NJ, and New York, NY, under continuing contract(s) with United Packing Co., of Denver, CO. (Hearing site: Denver, CO, or Washington, DC.)

MC 145205 (Sub-1F), filed October 4, 1978. Applicant: RECO TRANSPORTATION, INC., Route 1, Box 274, Black Mountain, NC 28711. Representative: George W. Clapp, P.O. Box 836, Taylors, SC 29687. To operate as a *contract carrier*, by motor vehicle,

over irregular routes, transporting *synthetic fibers and synthetic yarns*, from Enka and Highshoals, NC, Clemson, SC, and Chattanooga and Lowland, TN, to points in CA, under continuing contract(s) with American Enka Company, of Enka, NC. (Hearing site: Asheville, NC.)

MC 145252 (Sub-1F), filed August 30, 1978. Applicant: HENRY ANDERSEN, INC., P.O. Box 75, King George, VA 22485. Representative: Chester A. Zyblut, 366 Executive Building, 1030 Fifteenth Street NW, Washington, DC 20005. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *chimney assemblies, gas vents*, and *doors*, from Fredricksburg, VA, to points in the United States (except AK, HI, and VA). (Hearing site: Washington, DC.)

NOTE: Dual operations are involved in this proceeding.

MC 145268 (Sub-2F), filed September 26, 1978. Applicant: KENNETH B. HOLM AND GLEN STEED, a partnership, d.b.a. H&S ENTERPRISES, 3150 South 1200 West, P.O. Box 26302, Salt Lake City, UT 84126. Representative: Irene Warr, 430 Judge Building, Salt Lake City, UT 84111. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting *steel, and steel pipe*, from the facilities of Metra Steel, at Portland, OR, and Oakland, CA, to points in Salt Lake, Weber, Davis, and Utah Counties, UT, and (2) from the facilities of Metra Steel, at Portland, OR, to Oakland, CA, under continuing contract(s) with Metra Steel, of Portland, OR. (Hearing site: Washington, DC.)

MC 145272F, filed August 24, 1978. Applicant: LAWRENCE REIDLINGER, Box 109, Conception Junction, MO 64434. Representative: Tom B. Kretsinger, 20 East Franklin, Liberty, MO 64068. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *sand*, between Stanberry and Burlington Junction, MO, on the one hand, and, on the other, points in Page, Taylor, Ringgold, and Decatur Counties, IA; and (2) *crushed rock*, from points in Page and Taylor Counties, IA, to points in Nodaway and Atchison Counties, MO. (Hearing Site: Kansas City, MO.)

MC 145302F, filed August 29, 1978. Applicant: GULF STATES CORP., Box 7130, Tenton, NJ 08628. Representative: Theodore Polydoroff, Suite 301, 1307 Dolley Madison Boulevard, McLean, VA 22101. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting *materials* used in the manufacture of glass, between Fairfield, AL, Wilmington, DE, Shoals, IN, Bow, NH, Camden, NJ, Middletown, OH, Morrisville, PA, Memphis, TN, and Cresap, WV, on the one hand, and, on the other, points in the United States (except AK and HI), under continuing contract(s) with The Calumite Co., of Trenton, NJ. (Hearing Site: Washington, DC.)

MC 145403F, filed September 25, 1978. Applicant: ENSMINGER MOTOR LINES, INC., P.O. Box 166, Frankfort, IL 60425. Representative: Daniel C. Sullivan, 10 South LaSalle Street, Chicago, IL 60603. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting *plastic articles* (except commodities in bulk), from the facilities of Mobil Chemical Co., at Joliet, Frankfort, and Chicago, IL, to points in AR, CA, CO, GA, IN, IA, KS, KY, MA, MI, MN, MO, NE, NJ, NY, NC, ND, OH, OK, PA, SC, SD, TN, TX, WV, WI, and WY, under continuing contract(s) with Mobil Chemical Co., of Macedon, NY. (Hearing site: Chicago or Joliet, IL.)

NOTE: Dual operations are involved in this proceeding.

MC 145423F, filed September 21, 1978. Applicant: C. VAN BOXELL TRANSPORTATION, INC., 763 South Oakwood, Detroit, MI 48217. Representative: William B. Elmer, 21635 East Nine Mile Road, St. Clair Shores, MI 48080. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *coal tar and coal tar products*, in bulk, in tank vehicles, from Detroit, MI, to points in IL, IN, NJ, NY, OH, PA, and WI. (Hearing site: Detroit, MI, or Washington, DC.)

MC 145558F, filed October 16, 1978. Applicant: AL'S GARAGE, INC., 1805 Lennox Avenue, Lima, OH 45804. Representative: Andrew J. Burkholder, 275 East State Street, Columbus, OH 43215. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *wrecked, disabled, and repossessed motor vehicles* (except trailers designed to be drawn by passenger automobiles), and (2) *replacement vehicles* for wrecked and disabled motor vehicles, (except trailers designed to be drawn by passenger automobiles), by use of wrecker equipment only, between points in Allen, Hancock, Van Wert, Auglaize, and Hardin Counties, OH, on the one hand, and, on the other, those points in the United States on and east of U.S. Hwy 83. (Hearing site: Columbus, OH.)

MC 145453F, filed September 22, 1978. Applicant: L. CURTIS TRIPP, d.b.a. TAR HEEL STAGE LINES, 1603 Herrington Road, Elizabeth City, NC 27909. Representative: Frank B. Aycock, Jr., P.O. Box 427, Elizabeth City, NC 27909. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *passengers and their baggage*, in the same vehicle with passengers, in round-trip special and charter operations, beginning and ending at points in Martin, Bertie, Tyrrell, Chowan, Perquimans, Pasquotank, Camden, Currituck, Washington, Gates, and Hertford Counties, NC, and extending to points in the United States, including AK, but excluding HI. (Hearing site: Elizabeth City, NC, or Norfolk, VA.)

MC 145458F, filed September 28, 1978. Applicant: McLELLAN BUS LINES, P.O. Box 1095, Truro, Nova Scotia, Canada B2N 5G9. Representative: Jerry McLellan (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *passengers and their baggage*, in round-trip charter operations, beginning and ending at the ports of entry on the international boundary line between the United States and Canada located in ME, and extending to points in the United States (except AK and HI), restricted to the transportation of passengers beginning and ending in the Province of Nova Scotia, Canada. Condition: Prior receipt from applicant of an affidavit setting forth its complementary Canadian authority or explaining why no such Canadian authority is necessary. (Hearing site: Portland or Bangor, ME.)

NOTE: The restriction and condition contained in the grant of authority in this proceeding are phrased in accordance with the policy statement entitled Notice of Interested Parties of New Requirements Concerning Applications for Operating Authority to Handle Traffic to and from points in Canada published in the FEDERAL REGISTER on December 5, 1974, and supplemented on November 18, 1975. The Commission is presently considering whether the policy statement should be modified, and is in communication with appropriate officials of Canada regarding this issue. If the policy statement is changed, appropriate notice will appear in the FEDERAL REGISTER and the Commission will consider all restrictions or conditions which were imposed pursuant to the prior policy statement, regardless of when the conditions or restrictions was imposed, as being null and void and having no further force or effect.

[FR Doc. 78-33285 Filed 11-27-78; 8:45 am]

[7035-01-M]

[Decisions Volume No. 49]

DECISION-NOTICE

Decided: November 18, 1978.

The following applications are governed by Special Rule 247 of the Commission's *Rules of Practice* (49 CFR § 1100.247). These rules provide, among other things, that a protest to the granting of an application must be filed with the Commission within 30

days after the date notice of the application is published in the FEDERAL REGISTER. Failure to file a protest, within 30 days, will be considered as a waiver of opposition to the appplication. A protest under these rules should comply with Rule 247(e)(3) of the Rules of Practice which requires that it set forth specifically the grounds upon which it is made, contain a detailed statement of protestant's interest in the proceeding, (as specifically noted below), and shall specify with particularity the facts, matters, and things relied upon, but shall not include issues or allegations phrased generally. A protestant should include a copy of the specific portions of its authority which protestant believes to be in conflict with that sought in the application, and describe in detail the method—whether by joinder, interline, or other means—by which protestant would use such authority to provide all or part of the service proposed. Protests not in reasonable compliance with the requirements of the rules may be rejected. The original and one copy of the protest shall be filed with the Commission, and a copy shall be served concurrently upon applicant's representative, or upon applicant if no representative is named. If the protest includes a request for oral hearing, such request shall meet the requirements of section 247(e)(4) of the special rules and shall include the certification required in that section.

Section 247(f) provides, in part, that an applicant which does not intend timely to prosecute its application shall promptly request that it be dismissed, and that failure to prosecute an application under the procedures of the Commission will result in its dismissal.

Further processing steps will be by Commission notice, decision, or letter which will be served on each party of record. *Broadening amendments will not be accepted after the date of this publication.*

Any authority granted may reflect administratively acceptable restrictive amendments to the service proposed below. Some of the applications may have been modified to conform to the Commission's policy of simplifying grants of operating authority.

We Find:

With the exceptions of those applications involving duly noted problems (e.g., unresolved common control, unresolved fitness questions, and jurisdictional problems) we find, preliminarily, that each common carrier applicant has demonstrated that its proposed service is required by the public convenience and necessity, and that each contract carrier applicant qualifies as a contract carrier and its proposed contract carrier service will be consistent with the public interest and the national transportation policy. Each applicant is fit, willing, and able properly to perform the service proposed and to conform to the requirements of the Interstate Commerce Act and the Commission's regulations. 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 those proceeding containing a statement or note that dual operations are or may be involved we find, preliminarily and in the absence of the issue being raised by a protestant, that the proposed dual operations are consistent with the public interest and the national transportation policy subject to the rights of the Commission which is hereby expressly reserved to impose such conditions as it finds necessary to insure that applicant's operations shall conform to the provisions of section 210 of the Interstate Commerce Act.

It is ordered:

In the absence of legally sufficient protests, filed within 30 days of publication of this decision-notice (or, if the application later becomes unopposed), appropriate authority will be issued to each applicant (except those with duly noted problems) upon compliance with certain requirements which will be set forth in a notification of effectiveness of this decisions-notice. To the extent that the authority sought below may duplicate an applicant's existing authority, such duplication shall not be construed as conferring more than a single operating right.

Applicants must comply with all specific conditions set forth within 90 days after the service of the notification of the effectiveness of this decision-notice, or the application of a non-complying applicant shall stand denied.

By the Commission, Review Board Number 1, Members Carleton, Joyce, and Jones.

H. G. HOMME, Jr.,
Secretary.

MC 2202 (Sub-568F), filed September 12, 1978. Applicant: ROADWAY EXPRESS, INC., P.O. Box 471, 1077 Gorge Blvd., Akron, OH 44309. Representative: William O. Turney, Suite 1010, 7101 Wisconsin Ave., Washington, DC 20014. To operate as a *common carrier*, by motor vehicle, transporting *general commodities* (except articles of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), (1) between Beaumont, TX, and Las Cruces, NM, from Beaumont over U.S. Hwy 90 to Houston, TX, then over U.S. Hwy 290 to junction Interstate Hwy 10 near Junction, TX, then over Interstate Hwy 10 to Las Cruces, and return over the same route, (2) between McAllen, TX, and Kingman, AZ, from McAllen over U.S. Hwy 281 to San Antonio, TX, then over U.S. Hwy 87 to Amarillo, TX, then over U.S. Hwy 66 to Kingman, and return over the same route, (3) between Houston, TX, and junction U.S. Hwys 77 and 83, from Houston over U.S. Hwy 90 to San Antonio, TX, then over U.S. Hwy 81 to Laredo, TX, then over U.S. Hwy 83 to junction U.S. Hwy 77, and return over the same route, (4) between Houston and Brownsville, TX, from Houston over U.S. Hwy 59 to junction U.S. Hwy 77, then over U.S. Hwy 77 to Brownsville, and return over the same route, (5) between Victoria and Laredo, TX, over U.S. Hwy 59, (6) between junction TX Hwy 9 and U.S. Hwy 281 at or near Three Rivers, TX, and Corpus Christi, TX, from junction TX Hwy 9 and U.S. Hwy 281 over TX Hwy 9 to junction Interstate Hwy 37, then over Interstate Hwy 37 to Corpus Christi, and return over the same route, (7) between junction U.S. Hwys 60 and 87 and Las Cruces, NM, from junction U.S. Hwys 60 and 87 over U.S. Hwy 60 to Clovis, NM, then over U.S. Hwy 70 to Las Cruces, and return over the same route, (8) between junction U.S. Hwys 87 and 283 and Brady, TX, from junction U.S. Hwys 87 and 283 over U.S. Hwy 283 to junction U.S. Hwy 84, then over U.S. Hwy 84 to junction U.S. Hwy 80, then over U.S. Hwy 80 to junction U.S. Hwy 183, then over U.S. Hwy 183 to junction U.S. Hwy 377, then over U.S. Hwy 377 to Brady, and return over the same route, (9) between Victoria and San Antonio, TX, over U.S. Hwy 87, (10) between San Antonio and Del Rio, TX, over U.S. Hwy 90, (11) between Del Rio and Laredo, TX, from Del Rio over U.S. Hwy 277 to junction U.S. Hwy 81, then over U.S. Hwy 81 to Laredo, and return over the same route, (12) between Eagle Pass, TX, and junction TX Hwy 57 and U.S. Hwy 81 at or near Moore, TX, over TX Hwy 57, (13) between Lamesa and Midland, TX, over TX Hwy 349, (14) between Fort Worth and Lubbock, TX, from Fort Worth over U.S. Hwy 180 to junction U.S. Hwy 84, then over U.S. Hwy 84 to Lubbock, and return over the same route, (15) between junction U.S. Hwy 180 and Interstate Hwy 20 and Cisco, TX, over U.S. Hwy 80, (16) between Abilene, TX, and junction U.S. Hwys 84 and 180, over U.S. Hwy 84, (17) between Abilene and Anson, TX, over U.S. Hwy 83, (18) between Comfort, TX, and junction TX Hwy 27 and U.S. Hwy 290, over TX Hwy 27, and (19) between Shreveport, LA, and Beaumont, TX, from Shreveport over U.S. Hwy

171 to junction LA Hwy 5, then over LA Hwy 5 to junction U.S. Hwy 84, then over U.S. Hwy 84 to junction TX Hwy 7, then over TX Hwy 7 to junction U.S. Hwy 96, then over U.S. Hwy 96 to Beaumont, and return over the same route, serving in (19) no intermediate points and Shreveport for purposes of joinder only, and in (1) through (18), inclusive, serving all intermediate points and points in Aransas, Atascosa, Austin, Bee, Bexar, Brazoria, Brooks, Caldwell, Calhoun, Cameron, Chambers, Colorado, DeWitt, Duval, Fayette, Fort Bend, Frio, Galveston, Goliad, Gonzales, Guadalupe, Hardin, Harris, Hidalgo, Jackson, Jefferson, Jim Hogg, Jim Wells, Karnes, Kenedy, Kleberg, La Salle, Lavaca, Liberty, Live Oak, McMullen, Matagorda, Nueces, Orange, Refugio, San Patricio, Starr, Victoria, Waller, Webb, Wharton, Willacy, Wilson, and Zapata Counties, TX, as off-route points. (Hearing sites: San Antonio, Brownsville, Corpus Christi, and Lubbock, TX, and Albuquerque, NM.)

MC 2900 (Sub-342F), filed October 16, 1978. Applicant: RYDER TRUCK LINES, INC., 2050 Kings Rd., P.O. Box 2408, Jacksonville, FL 32203. Representative: S. E. Somers, Jr. (same address as applicant). To operate as a *common carrier*, by motor vehicle, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment) (1) between New Orleans, LA, and Albertville, AL, from New Orleans over U.S. Hwy 90 to Mobile, AL, then over U.S. Hwy 31 to Birmingham, AL, then over AL Hwy 75 to Albertville, and return over the same route, (2) between Meridian, MS, and Columbus, GA, over U.S. Hwy 80, (3) between Laurel, MS, and Bainbridge, GA, over U.S. Hwy 84, (4) between Meridian, MS, and Pensacola, FL, from Meridian over U.S. Hwy 45 to Mobile, AL, then over U.S. Hwy 90 to Pensacola, and return over the same route, (5) between Eutaw, AL, and Pensacola, FL, from Eutaw over U.S. Hwy 43 to Mobile, AL, then over U.S. Hwy 98 to Pensacola, and return over the same route, (6) between Huntsville, AL, and Marianna, FL, from Hunstville over U.S. Hwy 231 to junction U.S. Hwy 90, then over U.S. Hwy 90 to Marianna, and return over the same route, (7) between Huntsville and Dothan, AL, over U.S. Hwy 431, (8) between Stafford and Clanton, AL, over AL Hwy 22, (9) between Harpersville and Thomasville, AL, from Harpersville over AL Hwy 25 to junction AL Hwy 5, then over AL Hwy 5 to Thomasville, and return over the same route, (10) between Tallassee and Uniontown, AL, from Tallassee over AL Hwy 14 to Greensboro, AL, then over AL Hwy 61 to Uniontown, and return over the same route, (11) between Cuthbert, GA, and Tuscaloosa, AL, over U.S. Hwy 82, (12) between Seale and Troy, AL, from Seale over U.S. Hwy 26 to junction U.S. Hwy 82, then over U.S. Hwy 82 to junction U.S. Hwy 29, then over U.S. Hwy 29 to Troy, and return over the same route, (13) between Midway and Brundidge, AL, from Midway over AL Hwy 51 to Clio, AL, then over AL Hwy 10 to Brundidge, and return over the same route, (14) between Gadsden and Birmingham, AL, over U.S. Hwy 411, (15) between Anniston and Sylacauga, AL, from Anniston over AL Hwy 21 to junction Alternate U.S. Hwy 231, then over Alternate U.S. Hwy 231 to Sylacauga, and return over the same route, (16) between Selma and Atmore, AL, from Selma over AL Hwy 41 to junction AL Hwy 21, then over AL Hwy 21 to Atmore, and return over the same route, and (17) between Arab and Guntersville, AL, over AL Hwy 69, serving, in (1) (17), inclusive, all intermediate points. (Hearing site: Birmingham, AL, or Atlanta, GA.)

MC 2960 (Sub-23F), filed October 17, 1978. Applicant: ENGLAND TRANSPORTATION COMPANY OF TEXAS, a corporation, 2301 McKinney St., P.O. Box 18333, Houston, TX 77023. Representative: E. Larry Wells, Suite 1125 Exchange Park, P.O. Box 45538, Dallas, TX 75245. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *kitchen cabinets and vanities*, and (2) *such commodities as are used in the installation of the commodities named in (1) above*, from the facilities of Triangle Pacific Corp., at or near McKinney, TX, to points in AR, LA, and OK. (Hearing site: Dallas, TX.)

MC 5470 (Sub-161F), filed October 17, 1978. Applicant: TAJON, INC., a Delaware corporation, R.D. 5, Mercer, PA 16137. Representative: Brian L. Troiano, 918 16th St., NW., Washington, DC 20006. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *alloys and silicon metals*, in dump vehicles, between points in Montgomery County, AL, on the one hand, and, on the other, those points in the United States in and east of LA, AR, MO, IA, and MN. (Hearing site: Washington, DC, or Pittsburgh, PA.)

MC 7840 (Sub-5F), filed August 28, 1978. Applicant: ST. LAWRENCE FREIGHTWAYS, INC., 650 Cooper Street, Watertown, NY 13601. Representative: E. Stephen Heisley, 806 McLachlen Bank Building, 666 11th Street, NW., Washington, DC 20001. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *aluminum articles, aluminum ingot, aluminum sheet metal, aluminum plate, aluminum scrap, and aluminum foil*, between Oswego, NY, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Washington, DC.)

MC 11220 (Sub-160F), filed October 16, 1978. Applicant: GORDONS TRANSPORTS, INC., 185 W. McLemore Ave., Memphis, TN 38101. Representative: James J. Emigh (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between the facilities of International Paper Co., at or near Texarkana, TX, on the one hand, and, on the other, points in IL, IN, and OH, Shelby County, TN, and those in KY on and north of Interstate Hwy 64, restricted to the transportation of shipments originating at or destined to the facilities of International Paper Co., at or near Texarkana, TX. (Hearing site: Washington, DC.)

MC 21259 (Sub-4F), filed October 20, 1978. Applicant: GERTSEN CARTAGE CO., INC., 3000 Hirsch Street, Melrose Park, IL 60160. Representative: Anthony C. Vance, 1307 Dolley Madison Boulevard—Suite 301, McLean, VA 22101. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *refined copper*, in containers or in trailers, from the facilities used by ASARCO, Inc., at or near Chicago, IL, to points in IN, restricted to the transportation of traffic originating at the named origin and destined to the indicated destinations. (Hearing site: Chicago, IL.)

MC 25869 (Sub-145F), filed October 19, 1978. Applicant: NOLTE BROS. TRUCK LINE, INC., P.O. Box 7184, Omaha, NE 68107. Representative: James F. Crosby, P.O. Box 37205, Omaha, NE 68137. To operate as a *common carrier*, by motor vehicle, over irregular routes transporting (1) *Alcoholic beverages*, from points in MI and IL, to Denver, CO, and (2) *such commodities* as are dealt in or used by manufacturers and distributors of alcoholic beverages, from points in KY and TN, to Denver, CO. (Hearing site: Denver, CO, or Omaha, NE.)

MC 29910 (Sub-195F), filed October 17, 1978. Applicant: ARKANSAS-BEST FREIGHT SYSTEM, INC., 301 S. 11th Street, Fort Smith, AR 72901. Representative: Don A. Smith, P.O. Box 43, 510 N. Greenwood, Fort Smith, AR 72902. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Iron and steel articles* (except in bulk),

(1) from Staunton, IL, to points in AR, CO, KS, LA, MS, NM, OK, and TX, and (2) from St. Louis, MO, to points in the United States (except AK and HI). (Hearing site: Washington, DC, or St. Louis, MO.)

MC 29910 (Sub-196F), filed October 17, 1978. Applicant: ARKANSAS-BEST FREIGHT SYSTEM, INC., 301 S. 11th St., Fort Smith, AR 72901. Representative: Don A. Smith, P.O. Box 43, 510 N. Greenwood, Fort Smith, AR 72902. To operate as a *common carrier*, by motor vehicle, transporting: *General commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the Black Fox Nuclear Plant, at or near Inola, OK, as an off-route point in connection with carrier's otherwise authorized regular-route operations. (Hearing site: Tulsa, OK, or Washington, DC.)

MC 35320 (Sub-161F), filed October 10, 1978. Applicant: T.I.M.E.-DC, INC., a Delaware corporation, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). To operate as a *common carrier*, by motor vehicle, transporting: *General commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of General Electric Company, at or near Mount Vernon, IN, as a off-route point in connection with carrier's otherwise authorized regular-route operations. (Hearing site: Evansville, IN, or Louisville, KY.)

MC 51146 (Sub-633F), filed September 5, 1978. Applicant: SCHNEIDER TRANSPORT, INC., P.O. Box 2298, Green Bay, WI 54306. Representative: John R. Patterson, 2480 E. Commercial Blvd., Fort Lauderdale, FL 33308. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Such commodities* as are dealt in or used by manufacturers and distributors of educational and office supplies (except commodities in bulk), from the facilities of Mead Products, Division of The Mead Corporation, at Kalamazoo, MI, to points in the United States (except AK and HI), and (2) *equipment, materials, and supplies* used in the manufacture and distribution of the commodities named in (1) above (except commodities in bulk), in the reverse direction. (Hearing site: Chicago, IL.)

MC 51146 (Sub-634F), filed September 5, 1978. Applicant: SCHNEIDER TRANSPORT, INC., P.O. Box 2298, Green Bay, WI 54306. Representative: John R. Patterson, 2480 East Commercial Boulevard, Fort Lauderdale, FL 33308. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *salt and salt products* (except commodities in bulk), (a) from Manistee, MI, to those points in the United States in and east of ND, SD, NE, KS, OK, and TX, and (b) from Rittman, OH, to points in KY, NC, SC, TN, and VA, and (2) *equipment, materials and supplies* used in the manufacture and distribution of the commodities named in (1) above (except commodities in bulk), in the reverse direction. (Hearing site: Chicago, IL)

MC 51146 (Sub-635F), filed September 6, 1978. Applicant: SCHNEIDER TRANSPORT, INC., P.O. box 2298, Green Bay, WI 54306. Representative: John R. Patterson, 2480 East Commercial Boulevard, Fort Lauderdale, FL 33308. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *kitchen cabinets and vanities*, and (2) *materials, equipment, and supplies* used in the manufacture and distribution of kitchen cabinets and vanities (except commodities in bulk), between Adrian, MI, and Lakeville, MN, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Chicago, IL.)

MC 60014 (Sub-87F), filed August 31, 1978. Applicant: AERO TRUCKING, INC., a Ohio corporation, Box 308, Monroeville, PA 15146. Representative: A. Charles Tell, 100 East Broad Street, Columbus, OH 43215. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *building materials*, from the facilities of Johns Manville Sales Corporation at Waukegan, IL, to points in DE, MD, NJ, NY, OH, PA, VA, WV, and the Lower Peninsula of MI; and (2) *plastic pipe*, from the facilities of Johns Manville Sales Corporation at Jackson, TN, to the destinations named in (1) above. (Hearing site: Washington, DC.)

MC 61396 (Sub-358F), filed September 5, 1978. Applicant: HERMAN BROS., INC. 2565 St. Marys Avenue, P.O. Box 189, Omaha, NE 68101. Representative: John E. Smith II (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *liquefied petroleum gases*, in bulk, in tank vehicles, from the facilities of The Cochin Pipeline Company, (1) at or near Mankato and Benson, MN, to points in IA, ND, SD, and WI, (2) at or near Carrington, ND, to points in MN and SD, (3) at or near New Hampton, IA, to points in MN and WI, and (4) at or near Milford, IN, to points in IL, KY, MI, and OH. The certificate to be issued here shall be limited in points of time to a period expiring 5 years from the effective date thereof. (Hearing site: Minneapolis, MN, or Omaha, NE.)

NOTE.—The person or persons who appear to be engaged in common control between applicant and another regulated carrier must either file an application under Section 5(2) of the Interstate Commerce Act, or submit an affidavit indicating why such approval is unnecessary.

MC 75320 (Sub-198F), filed October 17, 1978. Applicant: CAMPBELL SIXTY-SIX EXPRESS, INC., P.O. Box 807, Springfield, MO 65801. Representative: John A. Crawford, 1700 Deposit Guaranty Plaza, P.O. Box 22567, Jackson, MS 39205. To operate as a *common carrier*, by motor vehicle, transporting *general commodities*, (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Kerr McGee Corporation, at or near Hamilton, MS, as an off-route point in connection with carrier's otherwise authorized regular-route operations. (Hearing site: Jackson, MS, or Oklahoma City, OK.)

MC 77061 (Sub-13F), filed August 29, 1978. Applicant: SHERMAN BROS., INC., 29534 Airport Road, P.O. Box 706, Eugene, OR 97402. Representative: Russell M. Allen, 1200 Jackson Tower, Portland, OR 97205. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *Sawmill machinery, logging equipment*, and *contractors' equipment*, (2) *parts* for the commodities named in (1) above, (3) *roadbuilding materials* and *roadbuilding supplies*, (except commodities in bulk), and (4) *iron and steel articles*, between points in Lane and Jackson Counties, OR, on the one hand, and, on the other, those points in CA in and north of Medocino, Glenn, Butte, Plumas and Lassen Counties. (Hearing site: Medford or Eugene, OR.)

NOTE.— Dual operations may be at issue in this proceeding.

MC 105733 (Sub-68F), filed October 3, 1978. Applicant: H.R. RITTER TRUCKING CO., INC., 928 East Hazelwood Avenue, Rahway, NJ 07065. Representative: Chester A. Zyblut, 366 Executive Building, 1030 Fifteenth Street NW., Washington, DC 20005. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *chemicals*, in bulk, from Gretna, LA, to points in TX, AR, MO, TN, AL, GA, FL, and LA. (Hearing site: Philadelphia, PA.)

MC 106009 (Sub-10F), filed October 24, 1978. Applicant: CAUSTIC SODA TRANSPORTATION CO., a corporation, P.O. Box 6035, Asheville, NC 28806. Representative: Henry E.

Seaton, 929 Pennsylvania Building, 425 13th Street NW., Washington, DC 20004. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *caustic soda*, in bulk, in tank vehicles, between Augusta, GA, those points in NC on and west of U.S. Hwy 1, those in SC on and west of U.S. Hwy 1, and those in TN on and east of U.S. Hwy 27. (Hearing site: Asheville, NC.)

MC 106603 (Sub-186F), filed October 4, 1978. Applicant: DIRECT TRANSIT LINES, INC., 200 Colrain Street, P.O. Box 8099, Grand Rapids, MI 49508. Representative: Martin J. Leavitt, 22375 Haggerty Road, P.O. Box 400, Northville, MI 48167. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *gypsum and gypsum products*, and (2) *materials and supplies* used in the distribution and installation of the commodities named in (1) above, from the facilities of Georgia-Pacific Corporation at or near (a) Wilmington, DE, to points in MI, and (b) Buchanan, NY, to points in MI and OH. (Hearing site: Washington, DC, or Chicago, IL.)

MC 106920 (Sub-78F), filed October 11, 1978. Applicant: RIGGS FOOD EXPRESS, INC., West Monroe Street, P.O. Box 26, New Bremen, OH 45869. Representative: David C. Venable, 805 McLachlen Bank Building, 666 11th Street NW., Washington, DC 20001. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *spaghetti noodles, and macaroni*, and (2) *products of the commodities named in (1) above*, from the facilities of C. F. Mueller Company, at or near Jersey City, NJ, to points in IL, IN, MI, OH, and WI. (Hearing site: New York, NY.)

MC 107403 (Sub-1117F), filed September 29, 1978. Applicant: MATLACK, INC., Ten West Baltimore Avenue, Lansdowne, PA 19050. Representative: Martin C. Hynes, Jr. (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *petroleum and petroleum products*, in bulk, in tank vehicles, from Marcus Hook, PA, to points in CT, RI, VA, NC, SC, GA, AL, MS, and FL.

Condition: Pursuant to the Decision in MC 107403 (Sub-1101F), served October 19, 1978, this proceeding is being held open until such time as a determination of applicant's fitness has been made in MC 107403 Sub-1101F. (Hearing site: Washington, DC.)

MC 107403 (Sub-1118F), filed October 2, 1978. Applicant: MATLACK, INC., Ten West Baltimore Avenue, Lansdowne, PA 19050. Representative: Martin C. Hynes, Jr. (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *petroleum lubricating oil*, in bulk, in tank vehicles, from New Orleans and Good Hope, LA, to points in AL, AR, FL, GA, IN, KY, MS, OH, and TN.

Condition: Pursuant to the Decision in MC 107403 (Sub-1101F), served October 19, 1978, this proceeding is being held open until such time as a determination of applicant's fitness has been made in MC 107403 (Sub-1101F). (Hearing site: Washington, DC.).

MC 107403 (Sub-1119F), filed October 3, 1978. Applicant: MATLACK, INC., 10 West Baltimore Avenue, Lansdowne, PA 19050. Representative: Martin C. Hynes, Jr., (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *calcium carbonate and ground limestone*, from points in Talladega County, AL, to points in AR, FL, GA, LA, MS, TN, and SC. CONDITION: Pursuant to the Decision in MC-107403 (Sub-No. 1101F), served October 19, 1978, this proceeding is being held open until such time as a determination of applicant's fitness has been made in MC-107403 (Sub-No. 1101F). (Hearing site: Washington, DC.)

MC 107403 (Sub-1120F), filed October 3, 1978. Applicant: MATLACK, INC., 10 West Baltimore Avenue, Lansdowne, PA 19050. Representative: Martin C. Hynes, Jr. (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *dry sugar*, in bulk, in tank vehicles, from Supreme, LA, to points in TX, OK, MO, AR, IL, IN, OH, TN, KY, NC, SC, GA, AL, and MS. CONDITION: Pursuant to the Decision in MC-107403 (Sub-No. 1101F), served October 19, 1978, this proceeding is being held open until such time as a determination of applicant's fitness has been made in MC-107403 Sub. 1101F. (Hearing site: Washington, DC.)

MC 107515 (Sub-1180F), filed October 6, 1978. Applicant: REFRIGERATED TRANSPORT CO., INC., P.O. Box 308, Forest Park, GA 30050. Representative: Alan E. Serby, 3390 Peachtree Road, fifth floor, Atlanta, GA 30326. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *malt beverages*, in vehicles equipped with mechanical refrigeration, (except in bulk), from Winston-Salem, NC, to points in GA. (Hearing site: Atlanta, GA.)

NOTE.—Dual operations may be involved in this proceeding.

MC 107515 (Sub-1181F), filed October 6, 1978. Applicant: REFRIGERATED TRANSPORT CO., INC., P.O. Box 308, Forest Park, GA 30050. Representative: Alan E. Serby, 3390 Peachtree Road, fifth floor, Atlanta, GA 30326. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *confectionery and confectionery products*, (except commodities in bulk), from the facilities of (1) Nabisco Confectioners Inc., and Merckens Chocolate, in Cambridge and Mansfield, MA, and (2) Deran Confectionery-Bordon, Inc. at Cambridge, MA, to points in CO, UT, CA, and OR. (Hearing site: Boston, MA.)

NOTE.—Dual operations may be involved in this proceeding.

MC 108461 (Sub-129F), filed May 25, 1978, previously noticed in the FEDERAL REGISTER on August 24, 1978 as MC 108461 Sub-128F. Applicant: SUNDANCE FREIGHT LINES, INC., d.b.a. SUNDANCE TRANSPORTATION, 821 East Pasadena, P.O. Box 7676, Phoenix, AZ 85011. Representative: James E. Snead, P.O. Box 2828, Santa Fe, NM 82501. To operate as a *common carrier*, by motor vehicle, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), (1) Between Amarillo, TX, and Carlsbad, NM: From Amarillo over U.S. Hwy 87 to Lubbock, TX, then over U.S. Hwy 62 to Carlsbad, and return over the same route, serving the intermediate points of Lubbock, TX, and Hobbs, NM, and serving the off-route points of Eunice, Humble City, Buckeye, Knowles, Lovington, Monument, and Oil City, NM, (2) Between Amarillo, TX, and Roswell, NM: From Amarillo over Interstate Hwy 27 to junction U.S. Hwy 60, then over U.S. Hwy 60 to junction U.S. Hwy 70, then over U.S. Hwy 70 to Roswell, and return over the same route, serving the intermediate points of Clovis and Portales, NM, (3) Between Lubbock, TX, and Clovis, NM, over U.S. Hwy 84, serving no intermediate points, and (4) serving Hobbs, NM, as an intermediate point in connection with carrier's presently authorized regular-route operations between Dallas, TX, and Carlsbad, NM. (Hearing sites: Albuquerque, Hobbs, and Roswell, NM, and Lubbock, TX.)

NOTE.—This republication indicates the correct sub number, and also includes several off-route points in the first territorial description.

MC 108676 (Sub-132F), filed August 28, 1978. Applicant: A. J. METLER HAULING & RIGGING, INC., 117 Chicamauga Avenue, Knoxville, TN 37917. Representative: Louis J. Amato, P.O. Box E, Bowling Green, KY 42101. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *sewage treatment plants, sewage lift stations*, and *parts and accessories* for sewage treatment plants and sewage lift stations, from the facilities of Clow Corporation, at or near

Richwood, KY, to points in the United States (except AK and HI). (Hearing site: Chicago, IL.)

MC 110325 (Sub-89F), filed October 10, 1978. Applicant: TRANSCON LINES, a corporation, P.O. Box 92220, Los Angeles, CA 90009. Representative: Wentworth E. Griffin, Widland Building, 1221 Baltimore Avenue, Kansas City, MO 64105. To operate as a *common carrier*, by motor vehicle, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving Stillwater, OK as an off-route point in connection with carrier's otherwise authorized regular-route operations. (Hearing site: Oklahoma City, OK.)

MC 111401 (Sub-531F), filed September 7, 1978. Applicant: GROENDYKE TRANSPORT, INC., 2510 Rock Island Boulevard, P.O. Box 632, Enid, OK 73701. Representative: Victor R. Comstock (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *petroleum naphtha*, in bulk, in tank vehicles, from Wynnewood, OK, to points in IN; and (2) *industrial waste material*, in bulk, in tank vehicles, from points in MS, to Tulsa, OK. (Hearing site: Dallas, TX, or Oklahoma City, OK.)

MC 112989 (Sub-78F), filed October 19, 1978. Applicant: WEST COAST TRUCK LINES, INC., 85647 Highway 99 South, Eugene, OR 97504. Representative: John G. McLaughlin, Suite 1440, 200 Market Building, Portland, OR 97201. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (A) *lumber, lumber mill products, millwork, and wood products*, from points in CA, ID, MT, OR, and WA, to points in AR, IL, IN, IA, KS, MI, MN, MO, NE, OH, OK, PA, TX, and WI; and (B)(1) *commodities* the transportation of which, because of size or weight, requires the use of special equipment or special handling, (2) *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, and commodities requiring special equipment), in mixed loads with commodities the transportation of which, because of size or weight, requires the use of special equipment or special handling when the mixed load moves on a single bill of lading from a single consignor, (3) *self-propelled articles*, (4) *farm equipment*, (5) *construction materials, construction equipment, and construction supplies*, (6) *metal articles and pipe*, (except iron and steel pipe), (a) from points in AR, IL, IN, IA, KS, MI, MN, MO, NE, OH, OK, PA, TX, and WI, to points in AZ, CA, ID, NV, OR, and WA, and (b) from points in CA, OR, and WA, to points in AR, IL, IN, IA, KS, MI, MN, MO, NE, OH, OK, PA, TX, and WI. (Hearing sites: Portland, OR, San Francisco, CA, Chicago, IL, and Dallas, TX.)

MC 113106 (Sub-60F), filed September 5, 1978. Applicant: THE BLUE DIAMOND CO., a corporation, 4401 East Fairmont Avenue, Baltimore, MD 21224. Representative: Chester A. Zyblut, 366 Executive Building, 1030 15th Street, NW., Washington, DC 20005. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *paper and paper products*, from Williamsport, PA, to points in DE, MD, NY (except New York, and Nassau and Suffolk Counties), and WV. (Hearing site: Washington, DC.)

MC 113267 (Sub-365F), filed August 30, 1978. Applicant: CENTRAL & SOUTHERN TRUCK LINES, INC., 3215 Tulane Road, P.O. Box 30130 AMF, Memphis, TN 38130. Representative: Lawrence A. Fischer (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *such commodities* as are dealt in by grocery houses, from the facilities of Southern States Distribution, Inc., at or near Memphis, TN, to points in AL, AR, FL, LA, MS, TN, those in KY on and west of U.S. Hwy 31E, and those in MO on and south Interstate Hwy 44. CONDITION: Pursuant to the Notice to the Parties in MC 113267 Sub-353, et al., served July 5, 1978, this proceeding is being held open until such time as a determination of applicant's fitness has been made in MC 113267 Sub-355. (Hearing site: Memphis, TN, or Washington, DC.)

MC 113459 (Sub-125F), filed October 18, 1978. Applicant: H. J. JEFFRIES TRUCK LINE, INC., P.O. Box 94850, Oklahoma City, OK 73109. Representative: James W. Hightower, 136 Wynnewood Professional Building, Dallas, TX 75224. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *dust collection systems*, and *parts* for dust collection systems, (2) *grain handling equipment*, and (3) *equipment, materials, and supplies* used in the manufacture of the commodities in (1) and (2) above, between Hutchinson, KS, on the one hand, and, on the other, those points in the United States in and east of ND, SD, NE, CO, OK, and TX. (Hearing site: Dallas, TX, or Kansas City, KS.)

MC 113459 (Sub-126F), filed October 24, 1978. Applicant: H. J. JEFFRIES TRUCK LINE, INC., P.O. Box 94850, Oklahoma City, OK 73109. Representative: J. Michael Alexander, 136 Wynnewood Professional Building, Dallas, TX 75224. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *Tractors* (except tractors used for pulling highway trailers), *lift trucks, excavators, motor graders, scrapers, engines, generators, generators and engines combined, road rollers, pipe layers, and dump trucks* designed for off-highway use, between ports of entry on the International Boundary Line between the United States and Canada in MT, on the one hand, and, on the other, points in the United States, (except AK and HI), restricted to the transportation of traffic originating at or destined to points in the Province of Alberta, Canada. CONDITION: Prior receipt from applicant of an affidavit setting forth its complementary Canadian authority or explaining why no such Canadian authority is necessary. (Hearing site: Dallas, TX, or Denver, CO.)

NOTE.—The restriction and conditions contained in the grant of authority in this proceeding are phrased in accordance with the policy statement entitled Notice to Interested Parties of New Requirements Concerning Applications for Operating Authority to Handle Traffic to and from points in Canada published in the FEDERAL REGISTER on December 5, 1974, and supplemented on November 18, 1975. The Commission is presently considering whether the policy statement should be modified, and is in communication with appropriate Canadian officials regarding this issue. If the policy statement is changed, appropriate notice will appear in the FEDERAL REGISTER and the Commission will consider all restrictions or conditions which were imposed pursuant to the prior policy statement, regardless of when the condition or restriction was imposed, as being null and void and having no force or effect.

MC 113974 (Sub-54F), filed August 29, 1978. Applicant: PITTSBURGH & NEW ENGLAND TRUCKING CO., a corporation, 211 Washington Avenue, Dravosburg, PA 15034. Representative: James D. Porterfield (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *rough iron* and *steel castings*, and *rough iron* and *steel forgings*, from Elyria, OH, to St. Louis, MO, Milwaukee, WI, and points in IN and IL. (Hearing site: Pittsburgh, PA, or Washington, DC.)

NOTE.—The person or persons who appear to be engaged in common control must either file an application under Section 5(2) of the Interstate Commerce Act, or submit an affidavit indicating why such approval is unnecessary.

MC 114045 (Sub-512F), filed October 10, 1978. Applicant: TRANS-COLD EXPRESS, INC., P.O. Box 61228, Dallas, TX 75261. Representative: J.B. Stuart (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *meats, meat products and*

meat byproducts, and articles distributed by meatpacking houses, as described in sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates,* 61 M.C.C. 209 and 766, (except hides and commodities in bulk), from the facilities of John Morrell & Co., at Shreveport, LA, and Memphis, TN, to points in CT, DE, ME, MD, MA, NH, NJ, NY, PA, RI, VT, VA, WV, and DC, restricted to the transportation of traffic originating at the named origins. (Hearing site: Chicago, IL, or Dallas, TX.)

MC 114569 (Sub-255F), filed October 23, 1978. Applicant: SHAFFER TRUCKING, INC., P.O. Box 418, New Kingstown, PA 17072. Representative: N.L. Cummins (same address as applicant). To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting *Printing paper and printed forms,* from Bedford and York, PA, to points in AZ, CA, MO, and TX. (Hearing site: Harrisburg, PA, or Washington, DC.)

NOTE.—Dual operations may be at issue in this proceeding.

MC 115162 (Sub-425F), filed August 25, 1978. Applicant: POOLE TRUCK LINE, INC., P.O. Drawer 500, Evergreen, AL 36401. Representative: Robert E. Tate (same address as applicant). To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting *such commodities* as are dealt in by retail home improvement, home furnishing, and lumber stores, (except commodities in bulk, in tank vehicles), between points in AL, AR, DE, FL, GA, IL, IN, KY, LA, MD, MS, NJ, NC, OH, OK, PA, SC, TN, TX, VA, WV, and DC, restricted to shipments originating at or destined to the facilities of the Wickes Corporation in the above-named States. (Hearing site: Detroit, MI, or Washington, DC.)

MC 115215 (Sub-33F), filed September 25, 1978. Applicant: NEW TRUCK LINES, INC., P.O. Box 639, Perry, FL 32347. Representative: Sol H. Proctor, 1101 Blackstone Building, Jacksonville, FL 32202. To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting *poles, pilings, crossties, crossarms, and lumber,* from the facilities of Koppers Company, Inc., at or near Gainesville, FL to points in AL, GA, MS, NC, KY, SC, TN, VA, and WV. (Hearing site: Jacksonville or Tallahassee, FL.)

MC 115311 (Sub-304F), filed September 11, 1978. Applicant: J & M TRANSPORTATION CO., INC., P.O. Box 488, Milledgeville, GA 31061. Representative: Paul M. Daniell, P.O. Box 872, Atlanta, GA 30301. To operate as a *common carrier,* by motor vehicle, over irregular routes transporting *Lumber, particleboard, wallboard, poles, piling, pallets, timbers, crossties, composition board,* and *hardboard,* from points in FL, GA, NC, SC, TN, and VA, to those points in the United States in and east of WI, IA, NE, KS, OK, and TX. (Hearing site: Atlanta, GA.)

MC 115557 (Sub-17F), filed September 13, 1978. Applicant: CHARLES A. McCAULEY, 308 Leasure Way, New Bethlehem, PA 16242. Representative: Henry M. Wick, Jr., 2310 Grant Building, Pittsburgh, PA 15219. To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting (1) *prefabricated log buildings, knocked-down or in sections,* and (2) *materials and supplies* used in construction, and erection of prefabricated log buildings, from Houlton, ME to points in PA. (Hearing site: Pittsburgh, PA, or Washington, DC.)

MC 115654 (Sub-107F), filed August 29, 1978. Applicant: TENNESSEE CARTAGE CO., INC., P.O. Box 23193, Nashville,. TN 37202. Representative: Henry E. Seaton, 915 Pennsylvania Building, 13th and Pennsylvania Avenue NW., Washington, DC 20004. To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting *fresh meats and packinghouse products,* from the facilities of the Rath Packing Co., at or near Indianapolis, IN, to points in AL, MS, and TN. (Hearing site: Indianapolis, IN, or Nashville, TN.)

NOTE.—In view of the findings in No. MC-115654 (Sub-No. 43) of which official notice is take the certificate to be issued in this proceeding will be limited to a period expiring 3 years from its effective date unless, prior to its expiration (but not less than 6 months prior to its expiration), applicant files a petition for the extension of said certificate and demonstrates that it has been conducting operations in full compliance with the terms and conditions of its certificate and and with the requirements of the Interstate Commerce Act and applicable Commission regulations.

MC 115841 (Sub-645F), filed September 8, 1978. Applicant: COLONIAL REFRIGERATED TRANSPORTATION, INC., 9041 Executive Park Drive, Suite 110, Building 100, Knoxville, TN 37919. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 11th Street NW., Washington, DC 20001. To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting *general commodities* (except commodities in bulk, classes A and B explosives, and household goods as defined by the Commission), from the facilities of Wheelabrator-Frye, Inc., at or near Mishawaka, IN, and Bedford, VA, to points in AL, AR, AZ, CA, FL, GA, LA, MS, NC, NM, NV, OK, OR, SC, TN, TX, UT, and WA, restricted to the transportation of traffic originating at the named origins and destined to the indicated destinations. (Hearing site: Chicago, IL, or Washington, DC.)

MC 115904 (Sub-122F), filed August 29, 1978. Applicant: GROVER TRUCKING CO., a corporation, 1710 West Broadway, Idaho Falls, ID 83401. Representative: Irene Warr, 430 Judge Building, Salt Lake City, UT 84111. To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting *iron and steel articles,* (except commodities bulk), between the facilities of (a) Commercial Shearing, Inc., at Youngstown, OH, (b) Gregory Galvanizing Co., at Canton, OH, (c) Dura Bond, Inc., at Export, PA, (d) Young Galvanizing Co., at Pulaski, PA, (e) Hanlon Gregory Co., at Pittsburgh, PA, and (f) Commercial Stamping and Forging at Bedford Park, IL, on the one hand, and, on the other, points in the United States, (except AK and HI), restricted to the transportation of traffic originating at or destined to the above indicated points. (Hearing site: Washington, DC.

MC 116325 (Sub-78F), filed October 6, 1978. Applicant: JENNINGS BOND, d.b.a. Bond Enterprises, P.O. Box 8, Lutesville, MO 63762. Representative: Ernest A. Brooks II, 1301 Ambassador Bldg. St. Louis, MO 63101. To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting *clay and clay products,* (except commodities in bulk), from points in Pulaski County, IL, to points in the United States in and east of ND, SD, NE, CO, and NM. (Hearing site: Indianapolis, IN.)

MC 116459 (Sub-74F), filed October 20, 1978. Applicant: RUSS TRANSPORT, INC., P.O. Box 4022, Chattanooga, TN 37405. Representative: Charles T. Williams (same address as applicant). To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting *ground limstone and ground limestone products,* in bulk, in hopper-type vehicles, from the facilities of Franklin Limestone Co., at or near Crab Orchard, TN, to points in AL, GA, KY, NC, and SC. (Hearing site: Chattanooga or Nashville, TN.)

MC 116459 (Sub-75F), filed October 20, 1978. Applicant: RUSS TRANSPORT, INC., P.O. Box 4022, Chattanooga, TN 37405. Representative: Charles T. Williams (same address as applicant.) To operate as a *common carrier,* by motor vehicle, over irregular routes, transporting *asphalt and asphalt products,* in bulk, in tank vehicles, from Knoxville, TN, to points in KY. (Hearing site: Chattanooga, TN, or Houston, TX.)

MC 116519 (Sub-55F), filed October 24, 1978. Applicant: FREDERICK TRANSPORT, LTD., Rural Route 6, Chatham, ON, Canada M7M 5J6. Rep-

resentative: Jeremy Kahn, Suite 733 Investment Building, 1511 K street NW., Washington, DC 20005. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *Iron and steel articles*, from the facilities of Allegheny Ludlum Steel Corporation in Allegheny, Armstrong, Chester, and Westmoreland Counties, PA, Henry County, IN, and New Haven County, CT, to ports of entry on the International Boundary line between the United States and Canada in MI and NY, restricted to the transportation of traffic moving in foreign commerce and destined to points in the Providence of Ontario, Canada. CONDITION: Prior receipt from applicant of an affidavit setting forth its complementary Canadian authority or explaining why no such Canadian authority is necessary. (Hearing site: Washington, DC.)

NOTE.—The restriction and conditions contained in the grant of authority in this proceeding are phrased in accordance with the policy statement entitled Notice to Interested Parties of New Requirements Concerning Applications for Operating Authority to Handle Traffic to and from points in Canada published in the FEDERAL REGISTER on December 5, 1974, and supplemented on November 18, 1975. The Commission is presently considering whether the policy statement should be modified, and is in communication with appropriate Canadian officials regarding this issue. If the policy statement is changed, appropriate notice will appear in the FEDERAL REGISTER and the Commission will consider all restrictions or conditions which were imposed pursuant to the prior policy statement, regardless of when the condition or restriction was imposed, as being null and void and having no force or effect.

MC 116519 (Sub-56F), filed October 24, 1978. Applicant: FREDERICK TRANSPORT, LTD., Rural Route 6, Chatham, ON, Canada M7M 5J6. Representative: Jeremy Kahn, Suite 733 Investment Building, 1511 K Street NW., Washington, DC 20005. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Scrap metals* for recycling, between ports of entry on the International Boundary line between the United States and Canada in MI, NY, VT, and NH, on the one hand, and, on the other, points in CT, IL, IN, MI, NJ, NY, OH, PA, WV, and WI, restricted to the transportation of traffic moving in foreign commerce and originating at or destined to points in the Provisions of Ontario and Quebec, Canada. CONDITION: Prior receipt from applicant of an affidavit setting forth its complementary Canadian authority or explaining why no such Canadian authority is necessary. (Hearing site: Washington, DC.)

NOTE.—The restriction and conditions contained in the grant of authority in this proceeding are phrased in accordance with the policy statement entitled Notice to Interested Parties of New Requirements Concerning Applications for Operating Authority to Handle Traffic to and from points in Canada published in the FEDERAL REGISTER on December 5, 1974, and supplemented on November 18, 1975. The Commission is presently considering whether the policy statement should be modified, and is in communication with appropriate Canadian officials regarding this issue. If the policy statement is changed, appropriate notice will appear in the FEDERAL REGISTER and the Commission will consider all restrictions or conditions which were imposed pursuant to the prior policy statement, regardless of when the condition or restriction was imposed, as being null and void and having no force or effect.

MC 116915 (Sub-62F), filed May 30, 1978, and previously noticed in the FEDERAL REGISTER issue of August 24, 1978. Applicant: ECK MILLER TRANSPORTATION CORP., 1830 South Plate Street, P.O. Box 1365, Kokomo, IN 46901. Representative: Fred F. Bradley, P.O. Box 773, Frankfort, KY 40602. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *cranes, draglines, backhoes, shovels, and loaders*, and (2) *machinery, attachments, accessories, and parts* used in connection with the commodities in (1) above, between points in the United States (except AK and HI). (Hearing Site: Chicago, IL.)

NOTE.—This republication shows that traffic will not necessarily be moving between specified facilities or be restricted with respect to origin and destination.

MC 117730 (Sub-27F), filed October 4, 1978. Applicant: KOUBENEC MOTOR SERVICE, INC., Route 47, Huntley, IL 60142. Representative: Stephen H. Loeb, Suite 200, 205 West Touhy Avenue, Park Ridge, IL 60068. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *chemicals* (except commodities in bulk, in tank vehicles), in vehicles equipped with mechanical refrigeration, from the facilities of Rohm & Haas Company, Inc., at or near Bristol, Croydon, and Philadelphia, PA, to points in IL, IN, WI, MO, IA, KS, MI, TN, and MN, restricted to the transportation of traffic originating at the named origins and destined to the indicated destinations. (Hearing site: Washington, DC.)

MC 117730 (Sub-29F), filed October 18, 1978. Applicant: KOUBENEC MOTOR SERVICE, INC., Route 47, Huntley, IL 60142. Representative: Stephen H. Loeb, Suite 200, 205 West Touhy Avenue, Park Ridge, IL 60068. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *hospital supplies and drugs*, in vehicles equipped with mechanical refrigeration, from the facilities of Abbott Laboratories, at North Chicago, IL, to those points in the United States in and east of MT, WY, CO, and NM, restricted to the transportation of traffic originating at the named origin and destined to the indicated destinations. (Hearing site: Chicago, IL.)

MC 117765 (Sub-246F), filed October 10, 1978. Applicant: HAHN TRUCK LINE, INC., 1100 South MacArthur, P.O. Box 75218, Oklahoma City, OK 73147. Representative: R. E. Hagan (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *roofing materials*, in containers, from Wynnewood, OK, to points in TX. (Hearing site: Oklahoma City, OK.)

MC 118130 (Sub-91F), filed October 11, 1978. Applicant: SOUTH EASTERN XPRESS, INC., P.O. Box 6985, Fort Worth, TX 76115. Representative: Billy R. Reid, P.O. Box 9093, Forth Worth, TX 76107. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *foodstuffs*, Jacksonville, Orlando, and Madison, FL, to points in LA, OK, and TX. (Hearing site: Dallas, TX, or Jacksonville, FL.)

MC 118159 (Sub-294F), filed October 23, 1978. Applicant: NATIONAL REFRIGERATED TRANSPORT, INC., P.O. Box 51366, Dawson Station, Tulsa, OK 74151. Representative: Warren L. Troupe, 2480 East Commercial Boulevard, Fort Lauderdale, FL 33308. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *Such commodities* as are dealt in by home improvement stores, between points in the United States (except AK and HI). (Hearing site: Atlanta, GA.)

MC 118831 (Sub-165F), filed September 8, 1978. Applicant: CENTRAL TRANSPORT, INC., P.O. Box 7007, High Point, NC 27264. Representative: Ben H. Keller, III (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *liquid commodities*, in bulk, from points in GA, to points in the United States (except AK and HI). (Hearing site: Washington, DC)

MC 119349 (Sub-9F), filed October 24, 1978. Applicant: STARLING TRANSPORT LINES, INC., P.O. Box 1733, Fort Pierce, FL 33450. Representative: Harry C. Ames, Jr., 805 McLachlen Bank Building, 666 11th Street NW., Washington, DC 20001. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *petroleum and petroleum products*, in containers, from Edison, NJ, to points in FL. (Hearing site: New York, NY.)

MC 119399 (Sub-82F), filed September 26, 1978. Applicant: CONTRACT FREIGHTERS, INC., P.O. Box 1375,

Joplin, MO 64801. Representative: Wilburn L. Williamson, 280 National Foundation Life Building, Oklahoma City, OK 73112. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *canned goods*, from the facilities of Oconomowoc Canning Co., in Columbia, Dane, Dodge, and Lincoln Counties, WI, to points in AR, KS, LA, MO, NM, OK, and TX. (Hearing site: Kansas City, MO.)

MC 119399 (Sub-83F), filed October 20, 1978. Applicant: CONTRACT FREIGHTERS, INC., P.O. Box 1375, Joplin, MO 64801. Representative: Wilburn L. Williamson, 280 National Foundation Life Bldg., 3535 NW., 58th Street, Oklahoma City, OK 73112. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *uncrated flat glass*, and (2) *crated flat glass* moving in mixed loads with uncrated flat glass, from Tulsa, OK, to points in AL, AZ, CA, CT, DE, FL, GA, ID, ME, MD, MA, MT, NV, NJ, NH, NY, NC, OH, OR, PA, RI, SC, UT, VT, VA, WA, WV, and DC. (Hearing site: Tulsa, OK, or Kansas City, MO.)

MC 119654 (Sub-60F), filed August 29, 1978. Applicant: HI-WAY DISPATCH, INC., 1401 West 26th Street, Marion, IN 46952. Representative: Norman R. Garvin, 1301 Merchants Plaza, Indianapolis, IN 46204. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *Such commodities* as are dealt in or used by manufacturers and distributors of paper products and plastic products (except commodities in bulk, and those which because of size or weight require the use of special equipment), (1) between Chicago, IL, on the one hand, and, on the other, points in IN, KY, MI, MO, OH and WI, and (2) between Louisville, KY, on the one hand, and, on the other, points in IL, IN, MI, MO, OH and WI, restricted to the transportation of traffic originating at or destined to the facilities of Continental Plastics Industries. (Hearing site: Indianapolis, IN, or Chicago, IL.)

MC 119741 (Sub-110F), filed September 7, 1978. Applicant: GREEN FIELD TRANSPORT COMPANY, INC., 1515 Third Avenue NW., P.O. Box 1235, Fort Dodge, IA 50501. Representative: D. L. Robson, P.O. Box 1235, Fort Dodge, IA 50501. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *frozen foods*, from the facilities of Mid-Continent Underground Storage, at or near Bonner Springs, KS, to points in TX and OK. Restricted to the transportation of traffic originating at the named origin and destined to the indicated destinations. (Hearing site: Kansas City, MO.)

MC 119765 (Sub-60F), filed October 10, 1978. Applicant: EIGHT WAY XPRESS, INC., 5402 South 27th Street, Omaha, NE 68107. Representative: Arlyn L. Westergren, Suite 106, 7101 Mercy Road, Omaha, NE 68106. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *meats, meat products and meat byproducts, and articles distributed by meat-packing houses*, as described in sections A and C of Appendix I to the report in "Descriptions in Motor Carrier Certificates," 61 MCC 209 and 766, (except hides and commodities in bulk), from Omaha, NE, to the facilities of Royal Packing Company, at St. Louis, MO. (Hearing site: Omaha, NE, or Chicago, IL.)

MC 119765 (Sub-61F), filed October 10, 1978. Applicant: EIGHT WAY XPRESS, INC., 5402 South 27th Street, Omaha, NE 68107. Representative: Arlyn L. Westergren, Suite 106, 7101 Mercy Road, Omaha, NE 68106. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *cheese*, from the facilities of Newman Grove Creamery, at Newman Grove, NE, to points in the United States (except AK and HI). (Hearing site: Omaha, NE.)

MC 119765 (Sub-62F), filed October 10, 1978. Applicant: EIGHT WAY XPRESS, INC., 5402 South 27th Street, Omaha, NE 68107. Representative: Arlyn L. Westergren, Suite 106, 7101 Mercy Road, Omaha, NE 68106. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *meats, meat products and meat byproducts, and articles distributed by meat-packing houses*, as defined in Sections A and C of Appendix I to the report in "Descriptions in Motor Carrier Certificates," 61 MCC 209 and 766 (except hides and commodities in bulk), from Omaha, NE, to points in WI. (Hearing site: Omaha, NE.)

MC 119789 (Sub-525F), filed October 19, 1978. Applicant: CARAVAN REFRIGERATED CARGO, INC., P.O. Box 226188, Dallas, TX 75266. Representative: Lewis Coffey (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *meats, meat products and meat byproducts, and articles distributed by meat-packing houses*, as described in Sections A and C of Appendix I to the report in "Descriptions in Motor Carrier Certificates," 61 MCC 209 and 766 (except hides and commodities in bulk), from Guymon, OK and Clovis, NM, to points in AL, CT, DE, FL, GA, KY, ME, MA, MD, MS, NH, NJ, NY, NC, PA, RI, SC, TN, VT, VA, and WV. (Hearing site: Chicago, IL.)

MC 119789 (Sub-526F), filed October 19, 1978. Applicant: CARAVAN REFRIGERATED CARGO, INC., P.O. Box 226188, Dallas, TX 75266. Representative: Lewis Coffey (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *carbonated mineral water*, in containers, from New York, NY, Baltimore, MD, Charleston, SC, Savannah, GA, Jacksonville, Miami, and Tampa, FL, Mobile, AL, New Orleans, LA, Dallas, Houston, and Galveston, TX, and Los Angeles and San Francisco, CA, to points in the United States (except AK and HI). (Hearing site: New York, NY.)

MC 119789 (Sub-527F), filed October 23, 1978. Applicant: CARAVAN REFRIGERATED CARGO, INC., P.O. Box 226188, Dallas, TX 75266. Representative: Lewis Coffey (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *meats, meat products and meat byproducts, and articles distributed by meat-packing houses*, as described in Sections A and C of Appendix I to the report in "Descriptions in Motor Carrier Certificates," 61 MCC 209 and 766 (except hides and commodities in bulk), from Kansas City, MO, Grand Island, NE, and Rochelle, Bradley, and St. Charles, IL, to points in CT, DE, ME, MD, MA, NH, NJ, NY, PA, RI, VT, VA, and WV. (Hearing site: Chicago, IL.)

MC 121496 (Sub-13F), filed September 6, 1978. Applicant: CANGO CORP., Suite 2900, 1100 Milam Building, Houston, TX 77002. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 Eleventh Street, NW., Washington, DC 20001. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *Chemicals*, in bulk, in tank vehicles, from the facilities of Union Carbide Corp., at or near Texas City, TX, to points in AL, AR, CA, CO, CT, FL, GA, IL, IN, IA, KS, KY, LA, MD, MA, MI, MN, MS, MO, MT, NE, NJ, NM, NY, NC, ND, OH, OK, OR, PA, SC, SD, TN, UT, VA, WV, WI, and WY, restricted to the transportation of traffic originating at the named origin. (Hearing site: Houston, TX.)

MC 121777 (Sub-2F), filed September 13, 1978. Applicant: PACKARD TRUCK LINES, INC., P.O. Box Drawer H, Buras, LA 70041. Representative: Harry C. Ames, Jr., 805 McLachlen Bank Building, 666 Eleventh Street, NW., Washington, DC 20001. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *oil field machinery, equipment, materials, and supplies*, (except commodities in bulk), between Cameron, LA, on the one hand, and, on the other, points in TX. (Hearing site: New Orleans or Baton Rouge, LA.)

MC 124025 (Sub-12F), filed October 10, 1978. Applicant: GLASS TRUCKING CO., a corporation, 200 Chestnut Street, P.O. Box 276, Newkirk, OK 74647. Representative: C. L. Phillips, Room 248, Classen Terrace Building, 1411 North Classen, Oklahoma City, OK 73106. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting (1) *fencing and fencing materials, and wire and wire products*, from the facilities of Bekaert Steel Wire Corp., at Van Buren, AR, to points in the United States (except AR, AL, GA, IL, IN, IA, KS, KY, LA, MS, MO, NM, OH, OK, NE, TN, TX, AK, and HI), (2) *coiled steel wire rods*, from points in the United States (except AK and HI), to the facilities of Bekaert Steel Wire Corp., at Van Buren, AR, and (3) *steel wire carriers*, from the facilities of Georgetown Steel Corp., at or near Beaumont, TX, to the facilities of Bekaert Steel Wire Corp., at Van Buren, AR, under a continuing contract in (1), (2), and (3) above, with Bekaert Steel Wire Corp., of Van Buren, AR. (Hearing site: Fort Smith, AR.)

MC 124151 (Sub-8F), filed September 6, 1978. Applicant: VANGUARD TRANSPORTATION, INC., Lafayette Street, Carteret, NJ 07008. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 11th Street, NW., Washington, DC 20001. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *liquid chemicals* and *petroleum products*, in bulk, in tank vehicles, from points in Bergen, Essex, Hudson, Middlesex, and Union Counties, NJ, to points in MA, CT, RI, NY, NJ, PA, DE, and MD; (2) *chemicals*, from Philadelphia, PA, to New York, NY; and (3) *silver slurry*, in bulk, in tank vehicles, from Binghamton, NY, to Linden, NJ. (Hearing site: Washington, DC or New York, NY.)

MC 124692 (Sub-241F), filed September 11, 1978. Applicant: SAMMONS TRUCKING, a corporation, P.O. Box 4347, Missoula, MT 59806. Representative: J. David Douglas (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *iron* and *steel articles*, (1) from Chicago, IL, Wilmington, DE, Canonsburg, PA, Jersey City and Camden, NJ, New Orleans, LA, Savannah, GA, and Houston, TX, to those points in the United States in and east of ND, SD, NE, CO, and AZ, and (2) from Los Angeles, CA, to points in AZ, CA, CO, and NM. (Hearing site: Portland, OR.)

MC 124692 (Sub-242F), filed September 11, 1978. Applicant: SAMMONS TRUCKING, a corporation, P.O. Box 4347, Missoula, MT 59806. Representative: J. David Douglas (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *bolts, nuts*, and *washers*, from Lakeville, MN, to points in AZ, CA, ID, MT, NV, OR, UT, WA, and WY, restricted to the transportation of traffic originating at the named origin. (Hearing site: Minneapolis, MN.)

MC 124692 (Sub-244F), filed September 11, 1978. Applicant: SAMMONS TRUCKING, a corporation, P.O. Box 4347, Missoula, MT 59806. Representative: J. David Douglas (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *steel bars, wire products* on tubular carriers, and *fabricated steel articles*, from Maryville, MO, to points in AZ, CA, CO, ID, IA, KS, MN, MT, NE, NM, ND, OK, OR, SD, TX, UT, WA, and WY. (Hearing site: St. Louis, MO.)

MC 126514 (Sub-45F), filed August 28, 1978. Applicant: SCHAEFFER TRUCKING, INC., 5200 West Bethany Home Road, Glendale, AZ 85301. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *photographic and reproductive equipment, parts and accessories* for photographic and reproductive equipment, *chemicals, paper, paper products, and plastic articles*, (except commodities in bulk), in vehicles equipped with mechanical refrigeration, and (2) *equipment, materials, and supplies* used in the manufacture and sale of the commodities in (1) above, (except commodities in bulk), in vehicles equipped with mechanical refrigeration, between the facilities of Scott Graphics, Inc., at Holyoke, MA, on the one hand, and, on the other, points in AZ and CA, restricted to the transportation of traffic originating at or destined to the above indicated points. (Hearing site: New York, NY, or Boston, MA.)

MC 127042 (Sub-226F), filed September 11, 1978. Applicant: HAGEN, INC., P.O. Box 98, Leeds Station, Sioux City, IA 51108. Representative: Robert G. Tessar (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *cleaning compounds, polishing compounds, sodium hypochlorite solution, soap based compounds, rust preventive lube oils, rust preventive lube oils and greases, deodorants, disinfectants, facric softeners, textile softeners, plastic bags*, and *coffee filters* (except commodities in bulk), from the facilities of Economics Laboratory, Inc., at Joliet, IL, to points in AZ, CA, CO, IA, MN, NE, NV, OR, SD, UT, and WA, restricted to the transportation of traffic originating at the named origin. (Hearing site: Chicago, IL.)

MC 127625 (Sub-32F), filed September 26, 1978. Applicant: SANTEE CEMENT CARRIERS, INC., P.O. Box 638, Holly Hill, SC 29059. Representative: Frank B. Hand, Jr., P.O. Drawer C, Berryville, VA 22611. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *cement mixes and mortar mixes, coal mix asphalt, sand, vinyl concrete patcher, lime, masonry coating, tile grout, hydraulic cement*, and *adhesives*, in containers, from the facilities of W. R. Bonsal Company, at or near Lilesville, NC, to points in SC. (Hearing site: Charlotte, NC, or Washington, DC.)

MC 128652 (Sub-14F), filed September 11, 1978. Applicant: LARSON TRANSFER & STORAGE CO., INC. 950 West 94th Street, Minneapolis, MN 55431. Representative: Samuel Rubenstein, 301 North Fifth Street, Minneapolis, MN 55403. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting *meats, meat products* and *meat byproducts*, and *articles* distributed by meat-packing houses, as described in sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 and 766, (except hides and commodities in bulk), from Minneapolis, MN, to points in the United States (except AK, HI, and MN), under a continuing contract with International Multifoods, King Food Division, of South St. Paul, MN. (Hearing Site: Minneapolis or St. Paul, MN.)

NOTE.—Dual operations are at issue in this proceeding.

MC 129537 (Sub-28F), filed September 11, 1978. Applicant: REEVES TRANSPORTATION CO., a Florida corporation, Rt. 5, Dews Pond Road, Calhoun, GA 30701. Representative: John C. Vogt, Jr., 406 N. Morgan Street, Tampa, FL 33602. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *plastic articles*, and (2) *materials and supplies* used in the manufacture and distribution of plastic articles, from points in LA and TX, to points in AL, FL, GA, KY, NC, SC, and TN. (Hearing site: Atlanta, GA.)

MC 133314 (Sub-4F), filed August 31, 1978. Applicant: SILVAN TRUCKING CO., INC., R.R. 2, Box 137, Pendleton, IN 46064. Represetative: Walter F. Jones, Jr., 601 Chamber of Commerce Building, Indianapolis, IN 46204. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *animal feed, feed ingredients, additives, and materials and supplies* used in the manufacture and distribution of animal feeds, (except commodities in bulk), between the facilities of Kal Kan Foods, Inc., at or near Mattoon, IL, Columbus, OH, Terre Haute,

IN, Indianapolis, IN, Sherburne, NY, Hutchinson, KS, Ogden, UT, and Vernon, CA, on the one hand, and, on the other, points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the named facilities. (Hearing site: Indianapolis, IN, or Louisville, KY.)

MC 133591 (Sub-41F), filed May 10, 1978, and previously noticed in the FEDERAL REGISTER issue of July 18, 1978. Applicant: WAYNE DANIEL TRUCK, INC., P.O. Box 303, Mount Vernon, MO 65712. Representative: Harry Ross, 58 South Main Street, Winchester, KY 40391. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *Heating and cooling systems, steel, insulation, insulation materials, electric motors, blowers*, and *paint*, (2) *materials, supplies*, and *equipment* used in production and installation of heating and cooling systems; and (3) *parts* and *accessories* of heating and cooling systems, (except commodities in bulk and commodities which, require use of special equipment), from Mount Vernon, MO, to points in MN, WI, MI, IA, TN, KY, IL, AR, LA, MS, TX, OK, KS, NE, ND, SD, MT, WY, CO, NM, AZ, UT, ID, WA, OR, CA, and NV. (Hearing site: Kansas City or St. Louis, MO.)

NOTES.—(1) This republication modifies the commodity description. (2) The carrier must satisfy the Commission that its operations will not result in objectionable dual operations because of its authority under MC 134494.

MC 135070 (Sub-13F), filed October 3, 1978. Applicant: JAY LINES, INC., P.O. Box 30180, Amarillo, TX 79120. Representative: Gailyn L. Larsen, P.O. Box 81849, Lincoln, NE 68501. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *cleaning compounds* (except in bulk), from the facilities, of The Proctor & Gamble Distributing Company, at or near Alexandria, LA, to Houston, TX. (Hearing site: Cincinnati, OH, or Amarillo, TX.)

MC 135183 (Sub-9F), filed August 16, 1978. Applicant: KERR CONTRACT CARRIAGE, INC., Route 4, Salem, MO 65560. Representative: B. W. LaTourette, Jr., 11 S. Meramec, Suite 1400, St. Louis, Mo 63105. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *charcoal* and *charcoal briquettes*, from Seymour, MO, to points in IA, NE, AR, WV, AL, MN, SC, NC, FL, GA, IL, IN, KS, KY, MI, MS, OH, OK, WI, PA, TX, VA, LA, and TN (except Memphis), under a continuing contract with Floyd Charcoal Co., of Salem, MO. (Hearing site: St. Louis or Jefferson City, MO.)

MC 136511 (Sub-26F), filed September 11, 1978. Applicant: VIRGINIA APPALACHIAN LUMBER CORP., 9640 Timberlake Road, Lynchburg, VA 24502. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 Eleventh Street NW., Washington, DC 20001. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *new furniture, furniture parts*, and *clocks*, (1) from points in Henry County, VA, and Moore and Davidson Counties, NC, to points in ID, MT, WY, CO, and NM, and (2) from points in VA (except Henry County and points in NC (except Moore and Davidson Counties, to points in CA, OR, WA, ID, NV, AZ, MT, WY, UT, CO, and NM. (Hearing site: Greensboro, or Charlotte, NC.)

NOTE.—Taking official notice pursuant to the Decision in MC 136511 Sub 7, et al., served July 13, 1978, applicant must submit written evidence in the form of a verified statement demonstrating that it is fit, willing, and able to perform the service granted in this proceeding.

MC 136605 (Sub-76F), filed October 6, 1978. Applicant: DAVIS BROS. DIST., INC., P.O. Box 8058, Missoula, MT 59807. Representative: Allen P. Felton (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *prefabricated metal buildings*, knocked down, and (2) *parts, components, and accessories* used in the manufacture of the commodities in (1) above, from the facilities of Kirby Building Systems, at or near Spanish Fork, UT, to those points in the United States in and west of ND, SD, NE, CO, and NM (Except UT, AK, and HI). (Hearing site: Salt Lake City, UT.)

MC 138157 (Sub-84F), filed September 1, 1978. Applicant: SOUTHWEST EQUIPMENT RENTAL, INC., d.b.a. SOUTHWEST MOTOR FREIGHT, a California corporation, 2931 South Market Street, Chattanooga, TN 37410. Representative: Patrick E. Quinn, P.O. Box 9596, Chattanooga, TN 37412. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *plastic carpeting, adhesives, sealants, solvents, stains, preservatives, weather stripping, wood trim, wood fillers, paint, and supplies for paint and wall covering*, (except commodities in bulk, in tank vehicles), from the facilities of Roberts Consolidated Industries, Inc., at (a) Kalamazoo, MI and (b) Dayton, OH, to those points in the United States east of MT, WY, CO, and NM, restricted to the transportation of traffic originating at the named origins and destined to the indicated destinations. (Hearing site: Lost Angeles, CA.)

NOTE.—Dual operations are at issue in this proceeding.

MC 138510 (Sub-10F), filed September 29, 1978. Applicant: RICCI TRANSPORTATION CO., INC., Odessa Avenue, Pomona, NJ 18240. Representative: J. Raymond Clark, Suite 1150, 600 New Hampshire Avenue NW., Washington, DC 20037. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting *malt beverages*, in containers, from Rochester, NY, to Pleasantville, NJ, under a continuing contract with Harrison Beverage Co., of Pleasantville, NJ. (Hearing site: Atlantic City or Trenton, NJ.)

NOTE.—Dual operations may be involved.

MC 138762 (Sub-26F), filed September 7, 1978. Applicant: MUNICIPAL TANK LINES LTD., a corporation, P.O. Box 3500, Calgary, Alberta, Canada T2P 2P9. Representative: Richard H. Streeter, 1729 H Street NW., Washington, DC 20006. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *liquid asphalt products*, in bulk, in tank vehicles, from the port of entry on the International Boundary line between the United States and Canada, at or near Buffalo, NY, to points in NY, restricted to the transportation of traffic originating at points in the Province of Ontario, Canada. (Hearing site: Washington, DC, or Buffalo, NY.)

NOTE.—The restriction and conditions contained in the grant of authority in this proceeding are phrased in accordance with the policy statement entitled Notice to Interested Parties of New Requirements Concerning Applications for Operating Authority to Handle Traffic to and from Points in Canada published in the FEDERAL REGISTER on December 5, 1974, and supplemented on November 18, 1975. The Commission is presently considering whether the policy statement should be modified, and is in communication with appropriate Canadian officials, regarding this issue. If the policy statement is changed, appropriate notice will appear in the FEDERAL REGISTER and the Commission will consider all restrictions or conditions which were imposed pursuant to the prior policy statement, regardless of when the condition or restriction was imposed, as being null and void and having no force or effect.

NOTE.—(1) The person or persons who appear to be engaged in common control must either file an application under Section 5(2) of the Interstate Commerce Act, or submit an affidavit indicating why such approval is unnecessary. (2) Dual operations may be at issue in this proceeding.

MC 138875 (Sub-113F), filed October 10, 1978. Applicant: SHOEMAKER TRUCKING CO., a corporation, 11900 Franklin Road, Boise, ID 83705. Representative: F. L. Sigloh (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *recyclable scrap materials* (except in bulk, in tank vehicles), from points in CO, NM, and NV, to points in CA, NV, OR, UT,

and WA. (Hearing site: Denver, CO, or Boise, ID.)

MC 138882 (Sub-138F), filed August 24, 1978. Applicant: WILEY SANDERS TRUCK LINES, INC., P.O. Drawer 707, Troy, AL 36081. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *non-ferrous scrap metal*, in containers, from points in GA, MS, IL, OH, PA, MO, MI, IN, NJ, TN, KY, AL, and NC, to the facilities of Metal Processors, Inc., at Jackson, MS. (Hearing site: Jackson, MS, or Montgomery, AL.)

MC 138882 (Sub-154F), filed September 11, 1978. Applicant: WILEY SANDERS TRUCK LINES, INC., P.O. Drawer 707, Troy, AL 36081. Representative: James W. Segrest (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *perlite board*, from the facilities of the Johns-Manville Corp., at Natchez, MS, to the facilities of the Celotex Corp., at Elizabethtown, KY. (Hearing site: Tampa, FL, or Montgomery, AL.)

MC 138956 (Sub-9F), filed September 4, 1978. Applicant: ERGON TRUCKING, INC., 202 East Pearl Street, Jackson, MS 39201. Representative: Donald B. Morrison, 1500 Deposit Guaranty Plaza, P.O. Box 22628, Jackson, MS 39205. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *petroleum crude oil and petroleum crude oil condensates*, in bulk, in tank vehicles, from those points in MS on and south of U.S. Hwy 80, to Chalmette and Meraux, LA. (Hearing site: Jackson, MS.)

MC 139247 (Sub-3F), filed September 21, 1978. Applicant: COOPER BROTHERS, INC., P.O. Box 167, Braselton, GA 30517. Representative: Frank D. Hall, Suite 713, 3384 Peachtree Road NE, Atlanta, GA 30326. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting *such commodities* as are dealt in or used by grocery and food business houses, (except commodities in bulk), from points in AL, AR, CT, DE, FL, GA, IA, IL, IN, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NH, NJ, NY, OH, PA, RI, SC, TN, VA, VT, WI, WV, and DC, to the facilities of Colonial Stores, Inc., at Cordele, GA, under continuing contract with Colonial Stores, Inc., of Atlanta, GA. (Hearing site: Atlanta, GA.)

MC 139897 (Sub-6F), filed September 21, 1978. Applicant: ORRAN HOFSTETTER, INC., P.O. Box 237, Route 2, Orrville, OH 44667. Representative: James Duvall, P.O. Box 97, 220 West Bridge Street, Dublin, OH 43017. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *coal*, in bulk, in dump vehicles, from points in Monogalia County, WV, to points in Sandusky and Seneca Counties, OH. (Hearing site: Columbus, OH.)

MC 140024 (Sub-127F), filed August 28, 1978. Applicant: J. B. Montgomery, Inc., a Delaware corporation, 5565 East 53d Avenue, Commerce City, CO 80022. Representative: Jeffrey A. Knoll (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes transporting (1) *iron castings and steel castings*, from La Porte and New Castle, IN, Ludington, MI, and Tiffin, OH, to Colorado Springs, CO; (2) *iron castings, steel castings, iron stampings, steel stampings, and internal combustion engine parts*, from Auburn IN, to Colorado Springs, CO, restricted in (1) and (2) above to the transportation of traffic originating at the named origins and destined to the indicated destinations. (Hearing site: Colorado Springs or Denver, CO.)

MC 141795 (Sub-2F), filed September 7, 1978. Applicant: A & B EXPRESS CO., INC., P.O. Box 567, Fair Lawn, NJ 07410. Representative: A. David Millner, P.O. Box 1409, 167 Fairfield Road, Fairfield, NJ 07006. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *citrus products* (except in bulk), *and canned non-acoholic beverages and beverage concentrates*, between the facilities of Tropicana Products, Inc., at Kearny, NJ, on the one hand, and, on the other, points in CT, DE, ME, MD, MA, NH, NJ, NY, PA, RI, VT, and DC, under a continuing contract with Tropicana Products, Inc., of Kearny, NJ. (Hearing site: New York, NY.)

MC 143456 (Sub-3F), filed September 11, 1978. Applicant: THEODORE ROSSI TRUCKING CO., INC., P.O. Box 332, Barre, VT 05641. Representative: William L. Rossi (same address as applicant). To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting (1) *stone, stone working materials, stone working machinery, and stone working supplies*, (a) between the facilities of Rock of Ages Corporation in VT, and the facilities of Rock of Ages Building Granite Corporation, at Concord, NH, (b) between the facilities of Rock of Ages Building Granite Corporation, at or near Concord, NH, on the one hand, and, on the other, points in TX and those in the United States in and east of WI, IL, KY, TN, MS, and LA; (c) from points in Texas and those in the United States in and east of WI, IL, KY, TN, MS, and LA, to the facilities of Rock of Ages Corporation in VT, and (2) *building stone*, from the facilities of Rock of Ages Corporation in VT, to points in PA, OH, MD, VA, and DC, under continuing contract in (1) and (2) above, with Rock of Ages Corporation of Barre, VT, and Rock of Ages Building Granite Corporation, of Concord, NH.

Condition: The carrier must satisfy the Commission that its common control possibilities are either approved by the Commission or do not require Commission approval. (Hearing site: Barre, VT, or Concord, NH.)

NOTE.—Dual operations may be at issue in this proceeding.

MC 143873 (Sub-3F), filed October 2, 1978. Applicant: TITAN TRANSFER, INC., 4302 South 30th Street, Omaha, NE 68107. Representative: Donald L. Stern, Suite 610, 7171 Mercy Road, Omaha, NE 68106. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *meat, meat products and meat byproducts, and articles distributed by meatpacking houses*, as described in sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 and 766, (except hides and commodities in bulk), (1) from the facilities of Swift & Co., at Des Moines, IA, to Omaha, NE, and (2) from Fremont, NE, to those points in IA on south and west of a line beginning at the Missouri River and IA Hwy 175, then east on IA Hwy 175 to junction U.S. Hwy 65, then south along U.S. Hwy 65 junction to U.S. Hwy 34, then east along U.S. Hwy 34 to junction U.S. Hwy 63, and south along U.S. Hwy 63 to the IA-MO State line. (Hearing site: Omaha, NE.)

MC 144282 (Sub-2F), filed August 28, 1978. Applicant: JAMES RECK, d.b.a. JAMES RECK TRUCKING, 4029 West McDowell, No. 4, Phoenix, AZ 85009. Representative: A. Michael Bernstein, 1441 East Thomas Road, Phoenix, AZ 85014. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting *cement roofing tile, and accessories* used in the installation of cement roofing tile, from the facilities of Staco Roof Tile, In Phoenix, AZ, to points in CA, CO, NV, NM, TX, and UT, under a continuing contract with Staco Roof Tile, Division of Kinsman Industries, of Phoenix, AZ. (Hearing site: Phoenix, AZ.)

MC 144330 (Sub-45F), filed October 3, 1978. Applicant: UTAH CARRIERS, INC., P.O. Box 1218, Clearfield, UT 84016. Representative: Rick J. Hall, P.O. Box 2465, Salt Lake City, UT 84110. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting (1) *asbestos cement pipe, couplings*, and *fittings*, and (2) *accessories* used in the installation of the commodities named in (1) above, (except commodities in bulk), from the facilities of CertainTeed Cor-

poration, at or near Hillsboro, TX, to points in the United States (except AK and HI). (Hearing site: Salt Lake City, UT, or Philadelphia, PA.)

MC 144330 (Sub-47F), filed October 16, 1978. Applicant: UTAH CARRIERS, INC., P.O. Box 1218, Freeport Center, Clearfield, UT 84016. Representative: Rick J. Hall, P.O. Box 2465, Salt Lake, UT 84110. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *wooden pallets*, from Fayetteville and Van Buren, AR, and Morris, OK, to points in KS, TX, and UT. (Hearing site: Salt Lake City, UT, or Little Rock, AR.)

MC 144440 (Sub-3F), filed October 11, 1978. Applicant: RICHARD D. DOMBACH, 58 South Duke Street, Millersville, PA 17551. Representative: John W. Metzger, 49 North Duke Street, Lancaster, PA 17602. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting *agricultural chemicals* (1) from the facilities of Lebanon Chemical Corporation, at or near Baltimore, MD, to Millersville, PA, and points in Chester, Columbia, Cumberland, Dauphin, Lebanon, Snyder, and York Counties, PA, and (2) from the facilities of Lebanon Chemical Corporation, at or near Allentown, PA, to Baltimore, MD, under a continuing contract with Lebanon Chemical Corporation, of Lebanon, PA. (Hearing site: Lancaster or Harrisburg, PA.)

MC 144622 (Sub-14F), filed August 28, 1978. Applicant: GLENN BROS. TRUCKING, INC., P.O. Box 9343, Little Rock, AR, 72219. Representative: Ted Polydoroff, 1307 Dolley Madison Boulevard, McLean, VA 22101. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *mattresses, boxsprings, batting* and *wadding*, from Memphis, TN, to points in OK, TX, LA, FL, AL, NC, SC, IL, and OH. (Hearing site: Memphis, TN, or Washington, DC.)

NOTE.—Dual operations may be involved in this proceeding.

MC 144622 (Sub-15F), filed August 28, 1978. Applicant: GLENN BROS. TRUCKING INC., P.O. Box 9343, Little Rock, AR 72219. Representative: Ted Polydoroff, 1307 Dolley Madison Boulevard, McLean, VA 22101. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *protective coating paint, insulation, ice-making and refrigerating kits, cork*, and *insulation tape*, from Wynne and Colt, AR, to points in NJ, NY, MD, OH, and MI. (Hearing site: Memphis, TN, or Washington, DC.)

NOTE.—Dual operations may be involved in this proceeding.

MC 144622 (Sub-17F), filed September 15, 1978. Applicant: GLENN BROS. TRUCKING INC., P.O. Box 9343, Little Rock, AR 72219. Representative: Phillip Glenn (same address as applicant). To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *straw florist forms*, from Gastonia, NC, to points in AL, AR, CT, CO, DE, FL, GA, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, NE, NJ, NY, NC, ND, OH, NH, OK, PA, RI, SC, SD, TX, TN, VT, VA, WV, and WI. (Hearing site: Washington, DC.)

NOTE.—Dual operations are at issue in this proceeding.

MC 144692 (Sub-1F), filed September 11, 1978. Applicant: G. L. MAN TRUCKING, 551 East 18th Street, Hastings, MN 55033. Representative: Samuel Rubenstein, 301 North Fifth Street, Minneapolis, MN 55403. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *dry fertilizer*, in bulk, (1) from Pine Bend, MN, to points in IA, the Upper Peninsula of MI, NE, ND, SD, MN, and WI, and (2) from Minneapolis and Winona, MN, to points in ND and WI. (Hearing site: Minneapolis or St. Paul, MN.)

MC 144926 (Sub-2F), filed September 5, 1978. Applicant: E. W. WYLIE CORP., P.O. Box 1188, Fargo, ND 58102. Representative: Gene P. Johnson, P.O. Box 2471, Fargo, ND 58108. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting (1) *sugar beet pulp pellets*, in bulk, from the facilities of Minn-Dak Farmers Cooperative, Inc., at or near Wahpeton, ND, to Minneapolis, MN, (2) *sugar beet pulp pellets*, from the facilities of Minn-Dak Farmers Cooperative, Inc., at or near Wahpeton, ND, to Duluth, MN, and (3) *limerock*, from Duluth, MN, to the facilities of Minn-Dak Farmers Cooperative, Inc., at or near Wahpeton, ND, under a contract with Minn-Dak Farmers Cooperative, Inc., of Minneapolis, MN. (Hearing site: Fargo, ND, or Minneapolis, MN.)

MC 145150 (Sub-3F), filed October 5, 1978. Applicant: HAYNES TRANSPORT CO., INC., P.O. Box 9, R.R. 32, Salina, KS 67401. Representative: Clyde N. Christey, Kansas Credit Union Building, 1010 Tyler, Suite 110L, Topeka, KS 66612. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *anhydrous ammonia*, in bulk, from the facilities of the Mapco Pipeline Terminal, at or near Mocane, OK, to points in KS and TX. (Hearing site: Kansas City, MO.)

MC 145214 (Sub-1F), filed August 31, 1978. Applicant: DONALD M. CAMPBELL, d.b.a. CAMPBELL TRUCKING CO., 3017 Falls Church Lane, Mesquite, TX 75149. Representative: Harry F. Horak, Room 109, 5001 Brentwood Stair Road, Fort Worth, TX 76112. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting *soil inoculant* (except in bulk, in tank vehicles), from Dallas, TX, to points in the United States (except AK and HI) under continuing contract with SnCorp, Inc., of Dallas, TX. (Hearing site: Dallas, TX.)

MC 145267 (Sub-1F), filed August 31, 1978. Applicant: CAMPBELL TRANSPORT, INC., P.O. Box 386, Vineland, NJ 08360. Representative: L. Agnew Myers, Jr., 407 Walker Building, 734 15th Street NW., Washington, DC 20005. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting *metal alloys, aluminum articles, containers, cement brick, mortar brick, castings, forgings, chemicals, polishing compounds, graphite crucibles, furnace electrodes, fluorspar, fly ash, powdered iron, scrap iron, metals, ores, pallets, and slag pots*, (1) from the facilities of Shieldalloy Corporation, at or near Newfield, NJ, to points in AL, IA, IL, IN, KY, LA, MD, MI, MO, NC, NY, OH, PA, TN, TX, and WV, and (2) from Birmingham, AL, Chicago, IL, St. Louis, MO, Atlanta, GA, and Freeport and Texas City, TX, to the facilities of Shieldalloy Corporation, at or near Newfield, NJ, under continuing contract, with Shieldalloy Corporation, of Newfield, NJ. (Hearing site: Philadelphia, PA, or Washington, DC.)

MC 145317 (Sub-1F), filed September 21, 1978. Applicant: QUALITY SERVICE TANK LINES, INC., 9022 Perrin Beitel, San Antonio, TX 78218. Representative: Pat H. Robertson, 500 West 16th Street, P.O. Box 1945, Austin, TX 78767. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *cement*, in bulk, from points in Hays County, TX, to points in AR, LA, NM, and OK. (Hearing site: San Antonio or Austin, TX.)

MC 145317 (Sub-2F), filed September 21, 1978. Applicant: QUALITY SERVICE TANK LINES, INC., 9022 Perrin Beitel, San Antonio, TX 78218. Representative: Pat H. Robertson, 500 West 16th Street, P.O. Box 1945, Austin, TX 78767. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *cement*, in bulk, from points in Bexar County, TX, to points in AR, LA (except Bossier City), NM, and OK. (Hearing site: San Antonio or Austin, TX.)

MC 145336 (Sub-1F), filed September 5, 1978. Applicant: R. G. H. TRANSPORTATION, INC., 6000 Gum Springs Road, P.O. Box 7072, Longview, TX 75602. Representative:

Paul D. Angenend, P.O. Box 2207, Austin, TX 78768. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting *paneling*, from Jacksonville, FL, to points in AR, IA, KS, MO, NE, OK, and TX, under continuing contract with D. G. Shelter Products, Inc., of Newton, KS. (Hearing site: Dallas, TX, or Washington, DC.)

MC 145351F, filed September 11, 1978. Applicant: CHARLES SORRELS, d.b.a. SORREL's TRUCKING CO., 66 East Farrow, Memphis, TN 38106. Representative: Dale Woodall, 900 Memphis Bank Bldg., Memphis, TN 38103. To operate as a *common carrier*, by motor vehicle, over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment) (1) between Memphis, TN, and Burnsville, MS, over U.S. Hwy 72, serving the intermediate point of Corinth, MS, and serving all points in Tishomingo County, MS, as off-route points, (2) between Corinth, MS, and Savannah, TN, from Corinth over U.S. Hwy 45 to junction MS Hwy 2, then over MS Hwy 2 to the MS-TN State line, then over TN Hwy 22 to junction U.S. Hwy 64, then over U.S. Hwy 64 to Savannah, TN, and return over the same route, serving no intermediate points but serving the off-route point of Counce, TN, (3) between Corinth, MS, and Bethel Springs, TN, over U.S. Hwy 45, serving the intermediate point of Selmer, TN, and the off-route point of Ramer, TN, and (4) between Savannah, TN, and Selmer, TN, over U.S. Hwy 64, serving no intermediate points, as an alternate route for operating convenience only, restricted in (1) above against the transportation of traffic in that portion of the Memphis, TN commercial zone within AR. (Hearing site: Memphis, TN, and Corinth, MS.)

MC 145589F, filed October 22, 1978. Applicant: HALL SYSTEMS, INC., 212 South 10th Street, Birmingham, AL 35233. Representative: Ronald L. Stichweh, 727 Frank Nelson Building, Birmingham, AL 35203. To operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting (1) *pipe, valves, couplings, gaskets, fittings, hydrants, and castings*, from the facilities of United States Pipe & Foundry Co., Birmingham Division, at or near Birmingham and Bessemer, AL, to points in the United States (except AK and HI), and (2) *machinery, materials* and *supplies* used in the manufacture of the commodities in (1) above (except commodities in bulk, in tank vehicles), in the reverse direction, under a continuing contract in (1) and (2) above, with United States Pipe & Foundry Company, of Birmingham, AL. (Hearing site: Birmingham, AL, or Washington, DC.)

MC 145591F, filed September 11, 1978. Applicant: ACE MOVING & STORAGE CO., INC., 2400 34th Street, Gulfport, MS 39501. Representative: B. W. LaTourette, Jr., 11 South Meramec, Suite 1400, St. Louis, MO 63105. To operate as a *common carrier*, by motor vehicle, over irregular routes, transporting *used household goods*, between points in Baldwin, Clarke, Conecuh, Escambia, Mobile, and Washington Counties, AL, Jefferson, Orleans, St. Bernard, St. Tammany, Tangipahoa, and Washington Parishes, LA, and Covington, Forrest, George, Greene, Hancock, Harrison, Jackson, Jefferson Davis, Jones, Lamar, Lawrence, Marion, Pearl River, Perry, Pike, Stone, Walthall, and Wayne Counties, MS. Restricted to the transportation of shipments having a prior or subsequent movement, in containers, beyond the points authorized, and further restricted to the performance of pickup and delivery service in connection with the packing, crating, and containerization or unpacking, uncrating, and decontainerization of such shipments. (Hearing site: Gulfport or Biloxi, MS.)

[FR Doc. 78-33286 Filed 11-27-78; 8:45 am]

[7035-01-M]

[No. MC-129068 (Sub-No. 38)]

GRIFFIN TRANSPORTATION, INC., EXTENSION—UNITED STATES (OKLAHOMA CITY, OK)

Decision

Decided: November 1, 1978.

We have considered the application and the record in this proceeding, including the initial decision of the Administrative Law Judge, the exceptions filed by Chandler Trailer Convoy, Inc., protestant, and the reply filed by applicant.

The Administrative Law Judge recommended the granting to applicant of the certificate authorizing the operations described in the appendix to this decision.

The pleadings raise no new or meterial matters of fact or law not adequately considered and properly disposed of by the Administrative Law Judge in his initial decision, and are not of such nature as to require the issuance of a decision discussing the evidence in the light of the pleadings.

We find:

The evidence considered in the light of the pleadings does not warrant a result different from that reached by the Administrative Law Judge. The statement of facts, the conclusions, and the findings of the Administrative Law Judge in his initial decision are proper and correct in all material respects, and are affirmed and adopted as our own. This decision does not significantly affect the quality of the human environment. An appropriate certificate should be granted.

It is ordered:

The application is granted to the extent set forth below. A certificate will be issued if applicant complies with the appropriate requirements set forth in the Code of Federal Regulations (49 CFR 1043, 1044 and 1307). Applicant must comply within 90 days after the date of service of this decision (or such additional time as may be authorized by the Commission). If it fails to comply, the grant of authority will be void.

This decison will become effective 30 days from the date of service.

By the Commission, Division 2, Commissioners Stafford, Gresham, and Christian. Commissioner Stafford dissenting.

H. G. Homme, Jr.,
Acting Secretary.

SERVICE AUTHORIZED: Operation by applicant, in interstate or foreign commerce, as a common carrier by motor vehicle, over irregular routes, transporting trailers designed to be drawn by passenger automobiles, in secondary movements (except recreational vehicles), from points in Alabama, California, Florida, Georgia, Indiana, Mississippi, North Carolina, and South Carolina to points in the United States (except Alaska and Hawaii).

CONDITION: The above service authorization is subject to prior publication in the Federal Register of a notice of the authority actually granted by this decision and any interested party will have 30 days from the publication of the notice to petition for intervention or other appropriate relief, showing precisely how it has been prejudiced by the grant of authority.

NOTICE: By this decision, this proceeding is rendered administratively final within the meaning of 49 CFR 1101.2(f) of the Commission's regulations; and, in accordance with the provisions of Section 558(c) of the Administrative Procedure Act, any corresponding temporary authority expires and operations thereunder must cease upon the effective date of this decision, except that to the extent permanent authority is granted in this proceeding (and if partial, only to that extent) the corresponding temporary authority or portion thereof will continue in effect until a certificate or permit is issued and becomes effective. The filing of any further pleadings in this matter will not stay the expiration of the temporary authority related to the denied portion of the sought permanent authority.

[FR Doc. 78-33288 Filed 11-27-78; 8:45 am]

[7035-01-M]

[Volume No. 125]

MOTOR CARRIER, BROKER, WATER CARRIER AND FREIGHT FORWARDER OPERATING RIGHTS

Applications

NOVEMBER 22, 1978.

The following applications are governed by Special Rule 247 of the Commission's General Rules of Practice (49 CFR 1100.247). These rules provide, among other things, that a protest to the granting of an application must be filed with the Commission within 30 days after the date of notice of filing of the application is published in the FEDERAL REGISTER. Failure to seasonably file a protest will be construed as a waiver of opposition and participation in the proceeding. a protest under these rules should comply with Section 247(e)(3) of the rules of practice which requires that it set forth specifically the grounds upon which it is made, contain a detailed statement of protestant's interest in the proceeding (including a copy of the specific portions of its authority which protestant believes to be in conflict with that sought in the application, and describing in detail the method—whether by joinder, interline, or other means—by which protestant would use a such authority to provide all or part of the service proposed), and shall specify with particularity the facts, matters, and things relied upon, but shall not include issues or allegations phrased generally. Protests not in reasonable compliance with the requirements of the rules may be rejected. The original and one copy of the protest shall be filed with the Commission, and a copy shall be served concurrently upon applicant's representative, or applicant if no representative is named. All pleadings and documents must clearly specify the "F" suffix where the docket is so identified in this notice. If the protest includes a request for oral hearing, such request shall meet the requirements of Section 147(e)(4) of the special rules, and shall include the certification required therein.

Section 247(f) further provides, in part, that an applicant who does not intend timely to prosecute its application shall promptly request dismissal thereof, and that failure to prosecute an application under procedures ordered by the Commission will result in dismissal of the application.

Further processing steps will be by Commission decision which will be served on each party of record. *Broadening amendments will not be accepted after the date of this publication except for good cause shown, and restrictive amendments will not be entertained following publication in the* FEDERAL REGISTER *of a notice that the proceeding has been assigned for oral hearing.*

Each applicant states that approval of its application will not significantly affect the quality of the human environment nor involve a major regulatory action under the Energy Policy and Conservation Act of 1975.

MC 119774 (Sub-96F), filed October 30, 1978. Applicant: EAGLE TRUCKING COMPANY, a Corporation, P.O. Box 471, Kilgore, TX 75662. Representative: Bernard H. English, 6270 Firth Road, Fort Worth, TX 76116. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) Machinery, equipment, materials and supplies used in, or in connection with, the discovery, development, production, refining, manufacture, processing, storage, transmission, and distribution of natural gas and petroleum and their products and by-products, and machinery, materials, equipment and supplies used in, or in connection with the construction, operation, repair, servicing, maintenance and dismantling of pipe lines, including the stringing and picking up thereof, (2) earth drilling machinery and equipment, and machinery, equipment, materials, supplies and pipe incidental to, used in, or in connection with (a) the transportation, installation, removal, operation, repair, servicing, maintenance, and dismantling of drilling machinery and equipment, (b) the completion of holes or wells drilled, (c) the production, storage, and transmission of commodities resulting from drilling operations at well or hole sites; and (d) the injection or removal of commodities into or from holes or wells, (a) between points in AZ, CO, MT, NV, ND, SD, UT and WY; and (b) between points in AZ, CO, MT, NV, ND, SD, UT and WY, on the one hand, and, on the other, points in TX, OK, KS, LA, and NM. (Hearing Site, Denver, CO, November 28, 1978, 9:30 a.m. local time.)

By the Commission.

H. G. HOMME, Jr.,
Secretary.

[FR Doc. 78-33289 Filed 11-27-78; 8:45 am]

[7035-01-M]

[Notice No. 135]

MOTOR CARRIER TRANSFER PROCEEDINGS

Dated: November 28, 1978

Application filed for temporary authority under section 210a(b) in connection with transfer application under section 212(b) and transfer rules, 49 CFR part 1132:

MC-FC 77716. By application filed November 13, 1978, GRAHAM H. BELL, an individual, d.b.a. B & W TRUCKING, P.O. Box 281, Gloucester, MA 01930, seeks temporary authority to transfer a portion of the operating rights of ROGER D. PETERSON, an individual, d.b.a. PETERSON MOTOR TRANSPORTATION, 107 Portland Street, Rochester, NH 03867, under section 210a(b). The transfer to GRAHAM H. BELL, an individual, d.b.a. B & W TRUCKING, of a portion of the operating rights of ROGER D. PETERSON, an individual, d.b.a. PETERSON MOTOR TRANSPORTATION, is presently pending.

MC-FC 77930. By application filed November 14, 1978, T & E TRUCKING INC., Box 342, Clarksville, VA 23927, seeks temporary authority to transfer the operating rights of CLARENCE OVERTON THOMAS, and individual, d.b.a. C. O. THOMAS TRUCKING, Route 1, Box 153, New Canton, VA 23123, under section 210a(b). The transfer to T & E TRUCKING INC., of the operating rights of CLARENCE OVERTON THOMAS, an individual, d.b.a. C. O. THOMAS TRUCKING, is presently pending.

By the Commission.

H. G. HOMME, Jr.,
Secretary.

[FR Doc. 78-33287 Filed 11-27-78; 8:45 am]

[7035-01-M]

[Notice No. 221]

MOTOR CARRIER TEMPORARY AUTHORITY APPLICATIONS

NOVEMBER 17, 1978.

The following are notices of filing of applications for temporary authority under Section 210a(a) of the Interstate Commerce Act provided for under the provisions of 49 CFR 1131.3. These rules provide that an original and six (6) copies of protests to an application may be filed with the field official named in the FEDERAL REGISTER publication no later than the 15th calendar day after the date the notice of the filing of the application is published in the Federal Register. One copy of the protest must be served on the applicant, or its authorized representative, if any, and the protestant must certify that such service has been made. The protest must identify the operating authority upon which it is predicated, specifying the "MC" docket and "Sub" number and quoting the particular portion of authority upon which it relies. Also, the protes-

tant shall specify the service it can and will provide and the amount and type of equipment it will make available for use in connection with the service contemplated by the TA application. The weight accorded a protest shall be governed by the completeness and pertinence of the protestant's information.

Except as otherwise specifically noted, each applicant states that there will be no significant effect on the quality of the human environment resulting from approval of its application.

A copy of the application is on file, and can be examined at the office of the Secretary, Interstate Commerce Commission, Washington, D.C., and also in the ICC Field Office to which protests are to be transmitted.

MOTOR CARRIERS OF PROPERTY

MC 6461 (Sub-18TA), filed October 16, 1978. Applicant: B-LINE TRANSPORT CO., INC., East 7100 Broadway, Spokane, WA 99206. Representative: Max Gray (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Concrete products* from the facilities of Central Pre Mix Concrete Co., located in Spokane County, WA to points in Morrow, Umatilla, Wallowa, Union and Baker Counties, OR, for 180 days. Supporting shipper: central Pre Mix Concrete-prestress, N. 922 Carahan Road, Spokane, WA 99206. Send protests to: Hugh H. Chaffee, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 858 Federal Building, Seattle, WA 98174.

MC 7205 (Sub-6TA), filed October 16, 1978. Applicant: POZZI BROTHERS TRANSPORTATION, INC., 21441 76th South, Kent, WA 98031. Representative: Tom Pozzi, 21250 North Tapps Highway, Sumner, WA 98390. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Paints, stains, wall and floor coverings and materials and supplies* used in the installation of such commodities, from Kent, WA to Portland, OR and its commercial zone, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Standard Brands Paint Co. Northwest, Inc., 19021 80th South, Kent, WA 98031. Send protests to: Hugh H. Chaffee, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 858 Federal Building, 915 Second Avenue, Seattle, WA 98174.

MC 13569 (Sub-42TA), filed September 7, 1978, and published in the FR issue of October 19, 1978, and republished as corrected this issue. Applicant: THE LAKE SHORE MOTOR FREIGHT CO., INC., 1200 South State Street, Girard, OH 44420. Representative: John P. Tynan, 167 Fairfield Road, P.O. Box 1409, Fairfield, NJ 07006. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Iron and steel articles*, from the plantsites of the Jones & Laughlin Steel Corporation, an LTV Company, located at Cleveland, Louisville, Warren and Youngstown, OH, to points in the State of IN, for 180 days. Applicant has also filed an underlying seeking up to 90 days of operating authority. Supporting shipper: Jones & Laughlin Steel, an LTV Co., 3341 Jennings Road, Cleveland, OH 44109. Send protests to: Interstate Commerce Commission, 731 Federal Building, 1240 East Ninth St., Cleveland, OH 44199. The purpose of this republication is to show IN, in lieu of IL, as previously published.

MC 19311 (Sub-50TA), filed September 15, 1978. Applicant: CENTRAL TRANSPORT, INC., 4200 Mound Road, Sterling Heights, MI 48077. Representative: Walter N. Bieneman, 100 West Long Lake Road, Suite 102, Bloomfield Hills, MI 48033. Authority sought to operate as a *common carrier*, by motor vehicle, over regular routes, transporting: *General commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment), (1) between Bay City, Mich., and Sault Ste. Marie, Mich., from Bay City, over Interstate Highway 75 to Sault Ste. Marie, and return over the same route, serving all intermediate points (except Linwood, Pinconning and Standish); (2) between Saginaw, Mich., and Farwell, Mich., from Saginaw, over Michigan Highway 47 to junction U.S. Highway 10, thence over U.S. Highway 10 to Farwell, and return over the same route, serving all intermediate points; (3) between St. Johns, Mich., and junction Interstate Highway 75, from St. Johns over U.S. Highway 27 to junction Interstate Highway 75, and return over the same route, serving all intermediate points; (4) between Midland, Mich., and junction U.S. Highway 27 at Mt. Pleasant, Mich., from Midland over Michigan Highway 20 to junction with U.S. Highway 27 at Mt. Pleasant, and return over the same route, serving all intermediate points; (5) between St. Louis, Mich., and junction Michigan Highway 20 west of Midland, Mich., from St. Louis over unnumbered county road (River Road) thence northeast to junction Michigan Highway 20 west of Midland, and return over the same route, serving all intermediate points; (6) between Meredith, Mich., and Roscommon, Mich., and Interstate Highway 75, from Meredith over Michigan Highway 18 to Roscommon, thence over Business Route Interstate Highway 75 to junction Interstate Highway 75, and return over the same route, serving all intermediate points; (7) between junction U.S. Highway 27 and Michigan Highway 55 and junction Interstate Highway 75, from junction U.S. Highway 27 and Michigan Highway 55 over Michigan Highway 55 to junction Interstate Highway 75 and Michigan Highway 55, and return over the same route, serving all intermediate points; (8) between Mackinaw City, Mich., and junction Interstate Highway 75, from Mackinaw City over U.S. Highway 23 to Cheboygan, Mich., thence over Michigan Highway 27 to junction Interstate Highway 75, and return over the same route, serving all intermediate points; (9) between junction U.S. Highway 31 and Interstate Highway 75 and Frankfort, Mich., from junction U.S. Highway 31 and Interstate Highway 75 near Mackinaw City, Mich., over U.S. Highway 31 to junction Michigan Highway 115 at Benzonia, thence over Michigan Highway 115 to Frankfort, and return over the same route, serving all intermediate points; (10) between Indian River, Mich., and junction U.S. Highway 31, from Indian River over Michigan Highway 68 to junction U.S. Highway 31, and return over the same route, serving all intermediate points; (11) between junction County Road C-48 and Interstate Highway 75 and junction U.S. Highway 131, from junction County Road C-48 and Interstate Highway 75 near Vanderbilt, Mich., over County Road C-48 to Boyne Falls, Mich., thence over Michigan Highway 75 over Boyne City, Mich., to junction with U.S. Highway 131, and return over the same route, serving all intermediate points; (12) between Gaylord, Mich., and Alba, Mich., from Gaylord over Michigan Highway 32 to East Jordan, Mich., thence over County Road C-48 to Atwood; also from junction Michigan Highway 32 and County Road C-42 to Alba, Mich., and return over the same route, serving all intermediate points; (13) between junction County Road C-38 and Interstate Highway 75 at Eastport, Mich., from junction County Road C-38 and Interstate Highway 75 near Otsego Lake, Mich., over County Road C-38 to Mancelona, Mich., thence over Michigan Highway 88 to Eastport, Mich., and return over the same route, serving all intermediate points; (14) between junction Michigan Highway 88 and County Road C-65 and Charlevoix, Mich., from junction Michigan Highway 88 and County Road C-65 near Central Lake, Mich., over County Road C-65 to Charlevoix, and return over the same route, serving all intermediate points; (15) between Grayling,

Mich., and Acme, Mich., from Grayling over Michigan Highway 72 to Acme, and return over the same route, serving all intermediate points; (16) between Petoskey, Mich., and Kalkaska, Mich., from Petoskey over U.S. Highway 131 to Kalkaska, and return over the same route, serving all intermediate points; (17) between Charlevoix, Mich., and Mancelona, Mich., from Charlevoix over Michigan Highway 66 to Mancelona, and return over the same route, serving all intermediate points; (18) between Grand Rapids, Mich., and junction Michigan Highway 46 and Elmore, Mich., from Grand Rapids over U.S. Highway 131 to junction Michigan Highway 46, thence over Michigan Highway 46 to Elmore, and return over the same route, as an alternate route serving no intermediate points; and (19) serving all off<route points within five miles of routes 1 through 17 above described except Linwood, Pinconning and Standish, also serving all off-route points in the Counties of Antrim, Charlevoix and Emmet, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: There are approximately 56 statements of support attached to this application which may be examined at the Interstate Commerce Commission in Washington, DC, or copies thereof which may be examined at the field office named below. Send protests to: T. S. Quinn, District Supervisor, Interstate Commerce Commission, 604 Federal Building and U.S. Courthouse, 231 West Lafayette Boulevard, Detroit, Mich. 48226.

MC 26396 (Sub-206TA), filed October 12, 1978. Applicant: POPELKA TRUCKING CO., d.b.a. THE WAGGONERS, P.O. Box 990, Livingston, MT 59047. Representative: Bradford E. Kistler, P.O. Box 82028, Lincoln, NE 68501. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Roofing materials*, from the facilities of Certain Teed Corporation, located in Shakopee, MN to points in the State of WY, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shippers: CertainTeed Corp., P.O. Box 860, Valley Forge, PA 19482, Dresco, Inc., 140 Chamberlain Rd., Box 175, Mills, WY 82644, Casper Lumber Co., Inc., 601 E. Street, Casper, WY 82601. Send protests to: District Supervisor Paul J. Labane, ICC, 2602 First Ave. North, Billings, MT 59101.

MC 30844 (Sub-628TA), filed October 12, 1978. Applicant: KROBLIN REFRIGERATED XPRESS, INC., 2125 Commercial Street, P.O. Box 5000, Waterloo, IA 50702. Representative: John P. Rhodes (same as applicant). Authority sought to operate as a *commom carrier*, by motor vehicle, over irregular routes, transporting: *Canned and preserved foodstuffs* from the facilities of Heinz U.S.A., Division of H.J. Heinz Co., at or near Pittsburgh, PA to points in MN and WI, for 180 days. Supporting shipper: Heinz U.S.A., Division of H.J. Heinz Co., P.O. Box 57, Pittsburgh, PA 15230. Send protests to: Herbert W. Allen, District Supervisior, Bureau of Operations, Interstate Commerce Commission, 518 Federal Building, Des Moines, IA 50309.

MC 52574 (Sub-55TA), filed October 12, 1978. Applicant: ELIZABETH FREIGHT FORWARDING CORP., 120 South 20th Street, Irvington, NJ 07111. Representative: Edward F. Bowes, Esq., 167 Fairfield Road, Fairfield, NJ 07006. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Bakery products* from Frederick, MD to Charlottesville, VA, under a continuing contract or contracts with S.B. Thomas Inc., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: S.B. Thomas Inc., 930 North Riverview Drive, Totowa, NJ 0711. Send protests to: District Supervisor Joel Morrows, Interstate Commerce Commission, 9 Clinton St., Newark, NJ 07102.

MC 71536 (Sub-14 TA), filed October 13, 1978. Applicant: ARROW CARRIER CORP., 2600 Penhorn Avenue and State Hwy 3, North Bergen, NJ 07047. Representative: A. David Millner, Esq. and Michael R. Werner, Esq., P.O. Box 1409, 167 Fairfield Road, Fairfield, NJ 07006. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *General commodities* (except those of unusal value, classes A & B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment) serving Merrimack, NH, as an off-route point in connection with carrier's authorized regular route operations to and from Lowell, MA restricted to the transportation of traffic originating at or destined to the facilities of Nashua Corporation, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Nashua Corporation, 44 Franklin Street, Nashua, NH 03060. Send protests to: Robert E. Johnston, District Supervisor, Interstate Commerce Commission, 9 Clinton Street, Newark, NJ 07102.

MC 100449 (Sub-98TA), filed October 12, 1978. Applicant: MALLINGER TRUCK LINE, INC., R.R. No. 4, Fort Dodge, IA 50501. Representative: Thomas E. Leahy, Jr., 1980 Financial Center, Des Moines, IA 50309. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Frozen foods*, except in bulk, (1) from the facilities of Rich Products Corp. at or near Appleton, WI to the facilities of Rich Products Corp. at or near Murfreesboro, TN and (2) from the facilities of Rich Products Corp. at or near Murfreesboro, TN to points in Tx. Restricted to shipments originating at the named origins and destined to the named destinations, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Rich Products Corp., 1145 Niagara St., Buffalo, NY 14213. Send protests to: Herbert W. Allen, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 518 Federal Building, Des Moines, IA 50309.

MC 107012 (Sub-285TA), filed October 12, 1978. Applicant: NORTH AMERICAN VAN LINES, INC., 5001 U.S. Highway 30 West, P.O. Box 988, Fort Wayne, IN 46801. Representative: Gerald A. Burns, P.O. Box 988, Fort Wayne, IN 56801. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Snow Throwers, and parts and accessories*, from Plymouth, WI, to points in IN, MI, MD, MO, NH, NY, OH, PA and VT. Restricted to traffic originating to the facilities of Cilson Brothers, Inc. and destined to the facilities of Montgomery Ward and Company, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Montgomery Ward and Co., Number 1 Montgomery Ward Plaza, Chicago, IL 60671. Send protests to: J. H. Gray, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 343 West Wayne St., Suite 113, Fort Wayne, IN 46802.

MC 107496 (Sub-1169TA), filed October 16, 1978. Applicant: RUAN TRANSPORT CORP., 666 Grand Avenue, Des Moines, IA 50309. Representative: E. Check, (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Fertilizer*, in bulk, in tank vehicles from Brunswick, MO to points in IA, NE, KS, OK, AR, and IL, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Brunswick River Terminal, Inc., P.O. Box 235, Brunswick, MO 65236. Send protests to: Herbert W. Allen, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 518 Federal Building, Des Moines, IA 50309.

MC 111812 (Sub-539TA), filed October 11, 1978. Applicant: MIDWEST COAST TRANSPORT, INC., P.O. Box 1233, Sioux Falls, SD 57101. Representative: David Peterson, P.O. Box 1233, Sioux Falls, SD 57101. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Meats, meat products, meat by-products and articles distributed by meat packinghouses* as described in Sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 and 766 (except hides and commodities in bulk) from the facilities of Hygrade Food Products Corporation located at or near Storm Lake & Cherokee, IA to points in FL and GA for 180 days. Supporting shipper: Hygrade Food Products Corporation, P.O. Box 4771, Detroit, MI 48219. Send protests to: Mr. James L. Hammond, District Supervisor, Bureau of Operations & Compliance, Interstate Commerce Commission, 455 Federal Building, Pierre, SD 57501.

MC 113024 (Sub-156TA), filed October 11, 1978. Applicant: ARLINGTON J. WILLIAMS, INC., 1398 South DuPont Hwy, Smyrna, DE 19977. Representative: Samuel W. Earnshaw, Esq., 833 Washington Building, Washington, DC 20005. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: (1) *Rubber* (except in bulk), from Louisville, KY, Geismar & LaPlace, LA to McCook, NE. (2) *Crushed oyster shells*, in bags, from Mobile, AL to McCook, NE. (3) *Miscellaneous rubber chemicals* (except in bulk) from Trenton, NJ to McCook, NE, under a continuing contract or contracts with Electric Hose & Rubber Co. for 180 days. Supporting shipper: Fred H. Evick, Director of Distribution, Electric Hose & Rubber Co., P.O. Box 910, Wilmington, DE 19899. Send protests to: William L. Hughes, District Supervisor, Interstate Commerce Commission, 1025 Federal Bldg., Baltimore, MD 21201.

MC113855 (Sub-454TA), filed October 16, 1978. Applicant: INTERNATIONAL TRANSPORT, INC., 2450 Marion Road, S.E., Rochester, MN 55901. Representativ: Richard P. Anderson, 502 First National Bank Building, Fargo, ND 58102. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Building brick*, from ports of entry between the U.S. and CN located at or near Sweetgrass, MT to points in UT, for 180 days. Restricted to traffic originating at the facilities of IXL Industries, Ltd., at or near Medicine Hat, Alberta. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: IXL Industries, Ltd., Box 70, Medicine Hat, Alberta. Send protests to: Delores A. Poe, Transportation Assistant, Interstate Commerce Commission, Bureau of Operations, 414 Federal Building, U.S. Court House, 110 South 4th Street, Minneapolis, MN 55401.

MC 114048 (Sub-3TA), filed October 16, 1978. Applicant: GEBEKE TRANSPORT, INC., P.O. Box 287, Melrose, MN 56352. Representative: Edward C. Gebeke (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum products* from Sauk Centre, MN to the counties of Roberts, Day, Grant and Codington in the state of SD, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Amoco Oil Company, 200 East Randolph Drive, Chicago, IL 60601. Send protests to: Delores A. Poe, Transportation Assistant, Interstate Commerce Commission, Bureau of Operations, 414 Federal Building and U.S. Court House, 110 South 4th Street, Minneapolis, MN 55401.

MC 114211 (Sub-382TA), filed October 18, 1978. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, IA 50704. Representative: Kurt E. Vragel, Jr. (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lumber, lumber products, forest and wood products* from ports of entry of the International Boundary Line between the United States and Canada located in ND and MN to points in MN, ND, SD, NE, KS, IA, WI, IL, IN, MI, OH, MO, and KY, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Southeast Forest Products, Ltd., Blumenort, Manitoba, Canada ROA OCO. Send protests to: Herbert W. Allen, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 518 Federal Building, Des Moines, IA 50309.

MC 114939 (Sub-50TA), filed October 12, 1978. Applicant: BULK CARRIERS LTD., P.O. Box 10, 2421 Cawthra Road, Cooksville Post Office, Mississauga, ON, Canada 2W7. Representative: John W. Ester, 100 West Long Lake Road, Suite 102, Bloomfield Hills, MI 48013. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Wood preservative, class B poison*, in bulk, in tank vehicles, from Memphis, TN to ports of entry on the United States-Canada International Boundary Line located in MI, restricted to foreign commerce, for 180 days. Supporting shipper: Commercial Chemical Co., Division of Osmose Wood Preserving Co., 1172 North Thomas St., P.O. Box 7275, Memphis, TN 38107. Send protests to: Interstate Commerce Commission, Bureau of Operations, 910 Federal Building, 111 West Huron Street, Buffalo, NY 14202.

MC 115364 (Sub-12TA), filed October 16, 1978. Applicant: GOODMAN MOTOR TRANSPORT CO. (1973) LTD., 8510 Jellicoe Street, Vancouver, BC, Canada V5S 3V1. Representative: Robert G. Gleason, 1127 10th East, Seattle, WA 98102. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Machinery and equipment* between points in King and Snohomish Counties, WA and the United States Canadian International Boundary at or near Blaine, Lyden and Sumas, WA, under a continuing contract or contracts with Morgan Power Apparatus (Canada) Ltd., for 180 days. Canadian origin and destination points at Burnaby, BC, Canada. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Morgan Power Apparatus (Canada) Ltd., 7465 Griffiths Avenue, Burnaby, BC, Canada. Send protests to: Hugh H. Chaffee, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 858 Federal Building, 915 Second Avenue, Seattle, WA 98174.

MC 115654 (Sub-119TA), filed September 5, 1978. Applicant: TENNESSEE CARTAGE CO., INC., P.O. Box 23193, Nashville, TN 37202. Representative: Henry E. Seaton, 915 Pennsylvania Building, 425 Thirteenth Street NW., Washington, DC 20004. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Frozen bakery products* from Ashland, KY to Murfreesboro, TN, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Rich Products Corporation, 1145 Niagara Street, Buffalo, NY 14240. Send protests to: Joe J. Tate, District Supervisor, Bureau of Operations, Interstate Commerce Commission, Suite A-422, U.S. Court House, 801 Broadway, Nashville, TN 37203.

MC 118202 (Sub-94TA), filed October 18, 1978. Applicant: SCHULTZ TRANSIT, INC., P.O. Box 406, 323 Bridge Street, Winona, MN 55987. Representative: Robert S. Lee, 1000 First National Bank Building, Minneapolis, MN 55402. Authority sought to operate as a *common carrier*, by motor vehicle over irregular routes, transporting: *Meat, meat products, meat by-products, and articles* distributed by meat packing houses and *foodstuffs* (except hides and commodities in bulk) from the facilities of George A.

Hormel & Co., at Austin, MN and Owatonna, MN to points in AR, OK and TX, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: George A. Hormel & Co., P.O. Box 800, Austin, MN 55912. Send protests to: Delores A. Poe, Transportation Assistant, Interstate Commerce Commission, Bureau of Operations, 414 Federal Building and U.S. Court House, 110 South 4th Street, Minneapolis, MN 55401.

MC 119493 (Sub-235TA), filed October 11, 1978. Applicant: MONKEM CO., INC., West 20th Street Road, P.O. Box 1196, Joplin, MO 64801. Representative: Thomas Boone (same as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Ground clay, floor sweeping compounds and absorbents* (except in bulk) from facilities of Oil Dri Corporation of America at or near Ripley, MS, to points in the U.S. in and east of ND, SD, NE, KS, OK, TX and materials and supplies used in the manufacture, sale and distribution of above named commodities, from destination states named above, to facilities of Oil Dri Corporation of America at or near Ripley, MS, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Oil Dri Corporation of America, Chicago, IL 60611. Send prostests to: District Supervisor, John V. Barry, Rm. 600, 911 Walnut St., Kansas City, MO 64106.

MC 119632 (Sub-80TA), filed October 16, 1978. Applicant: REED LINES, INC., 634 Ralston Avenue, Defiance, OH 43512. Representative: Wayne C. Pence (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Mineral wool insulation* (except in bulk) from the facilities of Guardian Insulation Div. of Guardian Industries at or near Huntington, IN to Kalamazoo, MI, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Guardian Insulation Division of Guardian Industries, 701 North Broadway, Huntington, IN 46750. Send protests to: Interstate Commerce Commission, Bureau of Operations, 313 Federal Office Building, 234 Summit Street, Toledo, OH 43604.

MC 119700 (Sub-47TA), filed October 11, 1978. Applicant: STEEL HAULERS, INC., 306 Ewing Avenue, Kansas City, MO 64125. Representative: Frank W. Taylor, Jr., Suite 600, 1221 Baltimore Avenue, Kansas City, MO 64105. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Wallboard, particleboard, composition board, lumber* (treated or untreated), *insulation, piling posts and poles* (treated or untreated), and, *construction materials* (except in bulk), from the facilities of Temple, Div. Temple-Eastex, Inc. at or near Diboll, TX and Pineland, TX, to points in the States of OK, KS, MO, IL, IN, OH, MS, AR, LA, CO, IA, MN, NE, NM, SD, WI, WY, and MI for 180 days. Supporting shipper: Temple, Div. Temple-Eastex, Inc., P.O. Drawer N, Diboll, TX 75941. Send protests to: Vernon V. Coble, District Supervisor, Interstate Commerce Commission, 600 Federal Office Bldg., 911 Walnut St., Kansas City, MO 64106.

MC 119789 (Sub-522TA), filed October 11, 1978. Applicant: CARAVAN REFRIGERATED CARGO, INC., P.O. Box 226188, Dallas, TX 75266. Representative: James K. Newbold (same as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Meats, meat products and meat by-products and articles* distributed by meat packinghouses, as described in sections A and C of App. I to the Report in Descriptions in Motor Carrier Certificates, 61 M.C.C. 209 and 766 (except hides and commodities in bulk), from facilities of Thies Packing Co. at Great Bend, Topeka and Wichita, KS to AL, FL, GA, KY, MS, NC, SC, and TN, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Thies Packing Co., P.O. Box 49, Great Bend, KS 67530. Send protests to: Opal M. Jones, Transportation Assistant, Interstate Commerce Commission, 1100 Commerce St., Rm. 13C12, Dallas, TX 75242.

MC 124711 (Sub-66TA), filed September 26, 1978. Applicant: BECKER CORP., P.O. Box 1050, El Dorado, KS 67042. Representative: Norman A. Cooper, P.O. Box 1050, El Dorado, KS 67042. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Fertilizer solutions* (not petroleum derived) in bulk, from the facilities of Getty Refining and Marketing Company near Columbus, NE to points in IA, KS, and SD, for 180 days. Supporting shipper: Getty Refining and Marketing Company, P.O. Box 1650, Tulsa, OK 74102. Send protests to: Merlyn E. Taylor, District Supervisor, Bureau of Operations, 101 Litwin Bldg., 110 North Market Street, Wichita, KS 67202.

MC 126276 (Sub-200TA), filed October 12, 1978. Applicant: FAST MOTOR SERVICE, INC., 9100 Plainfield Road, Brookfield, IL 60513. Representative: James C. Hardman, 33 North LaSalle Street, Chicago, IL. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Plastic containers*, from Cleveland, OH to Broadview and Chicago, IL, under a continuing contract or contracts with The Continental Group, Inc., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Thomas D. Corbett, Manager of Traffic, The Continental Group, Inc., One Landmark Square, Stamford, CT 06901. Send protests to: Lois Stahl, Transporting Assistant, Interstate Commerce Commission, 219 S. Dearborn St., Rm. 1386, Chicago, IL 60604.

MC 128527 (Sub-504TA), filed October 12, 1978. Applicant: MAY TRUCKING COMPANY, P.O. Box 400, Payette, ID 83661. Representative: Timothy R. Stivers, Registered Practitioner, P.O. Box 162, Boise, ID 83701. Authority sought to operate in interstate commerce as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foodstuffs*, canned and bottled, from Fruitland, ID and points in its Commercial Zone, to points in Maricopa County, AZ, and points in CA south of Sonoma, Napa, Colusa, Sutter and Placer Counties, for 180 days. Applicant has filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper: Payette Cider, P.O. Box 528, Payette, ID 83661. Send protests to Barney L. Hardin, District Supervisor, Interstate Commerce Commission, 1471 Shoreline Drive, Suite 110, Boise, ID 83706.

MC 128633 (Sub-19TA), filed October 11, 1978. Applicant: LAUREL HILL TRUCKING CO., 614 New County Road, Secaucus, NJ 07094. Representative: William J. Augello, 120 Main St., P.O. Box Z, Huntington, NY 11743. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: (1) *Drugs, medicines, toilet preparations, cleaning, scouring & washing compounds, disinfectants, disposable towels, chemicals, dies, paints, staines, varnishes, pigments, plastics, glass bottles, synthetic fibre and materials, supplies and equipment* used in the manufacture and sale of drugs, medicines and toilet preparations (except in bulk, in tank vehicles); and (2) *emulsifiers*, in bulk, in shipper-owned tank vehicles, (1) between, CT, DE, KS, IL, IN, MD, MA, ME, NH, NJ, NY, OH, PA, RI, VT, VA, WV and DC; and (2) from Philadephia, PA to Rensselaer, NY; restricted to traffic moving to or from plants, warehouses or facilities to operated by or for Sterling Drug, Inc. or its Divisions or Subsidiaries. If a hearing is deemed necessary, applicant requests it be held at either New York, NY or Washington, DC, under a continuing contract or con-

tracts with Sterling Drug, Inc., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Sterling Drug, Inc., 90 Park Avenue, New York, NY 10016. Send protests to: Robert E. Johnston, District Supervisor, Interstate Commerce Commission, 9 Clinton St., Washington, D.C. 20423.

MC 134064 (Sub-13TA), filed October 11, 1978. Applicant: INTERSTATE TRANSPORT, INC., 1820 Atlanta Highway, Gainesville, GA 80501. Representative: Charles M. Williams, Kimball, Williams & Wolfe, P.C., 350 Capitol Life Center, 1600 Sherman Street, Denver, CO 80203. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Candy, confectionery products, and foodstuffs* (except in bulk), from the facilities utilized by the Nestle Co., at or near Burlington, WI, to Memphis, TN; Jacksonville, FL; and Charlotte, NC, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): The Nestle Company, 100 Bloomingdale Road, White Plains, NY 10605. Send protests to: Sara K. Davis, Transportation Assistant, Bureau of Operations, Interstate Commerce Commission, 1252 W. Peachtree Street, N.W., Room 300, Atlanta, GA 30309.

MC 138237 (Sub-7TA), filed October 16, 1978. Applicant: METRO HAULING, INC., 20848 77th Avenue South, Kent, WA 98031. Representative: Jack R. Davis, 1100 IBM Building, Seattle, WA 98101. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Building and construction materials*, between the facilities of Palmer G. Lewis Co., Inc., in WA and OR on the one hand, and, on the other, points in ID, MT, OR and WA, for 180 days. Supporting shipper(s): Palmer G. Lewis Co., Inc., 525 C Street, N.W., Auburn, WA 98002. Send protests to: Hugh H. Chaffee, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 858 Federal Building, 915 Second Avenue, Seattle, WA 98174.

MC 138365 (Sub-3TA), filed August 25, 1978, and published in the FEDERAL REGISTER issue of October 20, 1978, and republished as corrected this issue. Applicant: DOUGLAS RUCKDASCHEL, d.b.a. RUCKDASCHEL TRUCKING, R.R. No. 1, P.O. Box 9, Postville, IA 52162. Representative: Jack H. Blanshan, Attorney-at-law, Suite 200, 205 West Touhy Avenue, Park Ridge, IL 60068. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Meat, meat products, meat byproducts, and articles* distributed by meatpacking houses as described in Sections A and C of Appendix I to the report in Descriptions in Motor Carrier Certificates, 61 M.C.C. 209 and 766 (except commodities in bulk and hides) from the facilities of Hygrade Food Products Corp., at Postville, IA to points in IN, ME, MN, NE, OH, PA, NJ, and NY, restricted to the transportation of traffic originating at the named origin and destined to the named destinations, for 180 days. Supporting shipper(s): Hygrade Food Products, 26300 North Western Highway, Southfield, MI 48075. Send protests to: Herbert W. Allen, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 518 Federal Building, Des Moines, IA 50309. The purpose of this republication is show MI, in lieu of MO, as previously published.

MC 138741 (Sub-58TA), filed October 12, 1978. Applicant: AMERICAN CENTRAL TRANSPORT, INC., 2005 North Broadway, Joliet, IL 60432. Representative: Tom B. Kretsinger, Esq., Kretsinger & Kretsinger, 20 East Franklin, Liberty, MO 64068. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Gypsum, gypsum products and materials and supplies* used in the manufacture, installation and distribution of Gypsum products between the facilities of Georgia-Pacific Corporation, Gypsum Division at Cuba, MO and all points in AL, AR, CO, GA, IA, IL, IN, KS, KY, LA, MI, MS, MO, NE, OH, OK, TN, TX and WI, for 180 days. Supporting shipper(s): Robert A. Cronk, Transportation Supervisor, Georgia-Pacific Corp., 1062 Lancaster Ave, Rosemont, PA 19010. Send protests to: Lois Stahl, Transportation Assistant, Interstate Commerce Commission, 219 S. Dearborn St., Rm. 1386, Chicago, IL 60604.

MC 140006 (Sub-1TA), filed August 15, 1978, and published in the FEDERAL REGISTER issue of October 19, 1978, and republished as corrected this issue. Applicant: JOHN W. GEORGE, d.b.a. HEPNER'S TRUCKING CO., 1810 East Washington Avenue, Vineline, NJ 08360. Representative: Robert B. Pepper, 168 Woodbridge Avenue, Highland Park, NJ 08904. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Floor covering and materials and supplies used in the installation and manufacturing thereof*, except in bulk, between Vineland, NJ and Philadelphia, PA, on the one hand, and, on the other, Atlanta, Dalton, and Rome, GA, and Chattanooga, TN, for 180 days. Supporting shipper(s): There are six (6) statements of support attached to the application which may be examined at the Interstate Commerce Commission in Washington, DC, or copies thereof which may be examined at the field office named below. Send protests to: John P. Lynn, Transportation Specialist, Interstate Commerce Commission, 428 East State Street, Room 204, Trenton, NJ 08608. The purpose of this republication is to show Georgia (GA) in lieu of California (CA) as previously published.

MC 140186 (Sub-30TA), filed October 16, 1978. Applicant: TIGER TRANSPORTATION, INC., P.O. Box 2248, Missoula, MT 59801. Representative: David A. Sutherland, Fullbright & Jaworski, 1150 Connecticut Avenue NW., Washington, DC 20036. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lumber, lumber products, wood and wood products*, from points in CA, OR, and WA to points in IL, IA, KS, MN, MO, MT, NE, ND, SD, and WI for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): There are 10 statements of support attached to the application which may be examined at the Interstate Commerce Commission at Washington, DC, or copies thereof which may be examined at the field office named below. Send protests to: Paul J. Labane, District Supervisor, Interstate Commerce Commission, 2602 First Avenue North, Billings, MT 59101.

MC 140968 (Sub-4TA), filed October 12, 1978. Applicant: VALLEY TRANSPORT, INC., Drayton, ND 58225. Representative: Gene P. Johnson, P.O. Box 2471, Fargo, ND 58108. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *sugar*, except in bulk, from Drayton, ND, to Albert Lea, Alexandria, Austin, Brainerd, Chaska, Duluth, Marshall, Minneapolis, Pipestone, Rochester, St. Cloud, St. Paul, Waseca, White Bear Lake and Worthington, MN, under a continuing contract or contracts with American Crystal Sugar Company, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): American Crystal Sugar Co., 101 3rd St., North, Moorhead, MN 56560. Send protests to: Ronald R. Mau, District Supervisor, Bureau of Operations, Interstate Commerce Commission, Rm. 268 Federal Bldg. and U.S. Post Office, 657 2nd Avenue, North, Fargo, ND 58102.

MC 141804 (Sub-147TA), filed October 16, 1978. Applicant: WESTERN EXPRESS, Division of Interstate Rental, Inc., P.O. Box 3488, Ontario, CA 91761. Representative: Frederick J. Coffman (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular

routes, transporting: *Plastic granules and materials* used in the production of plastic pipe and plastic fittings (except commodities in bulk), from Louisville, KY; Neal, WV; and Avon Lake, OH to Bakersfield, Santa Ana, and Sun Valley, CA, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): R & G Sloane Manufacturing, Inc., 7606 N. Claybourn Avenue, Sun Valley, CA 91352. Send protests to: Irene Carlos, Transportation Assistant, Interstate Commerce Commission, Room 1321 Federal Building, 300 North Los Angeles Street, Los Angeles, CA 90012.

MC 141921 (Sub-24TA), filed October 11, 1978. Applicant: SAV-ON TRANSPORATION, INC., 143 Frontage Rd., Manchester, NH 03108. Representative: John A. Sykas (same as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Plastic film and sheeting, and items related to the sales and distribution thereof* (except in bulk, in tank vehicles) from the facilities of Borden Chemical at North Andover, MA to points in PA, WV, OH, IN, MI, KY, GA, WI, IL, MO, IA, MN, SD, NE, CA, KS and CO, and from the facilities of Borden Chemical at Griffin, GA to points in PA, WV, MA, OH, IN, MI, KY, WI, IL, MO, IA, MN, SD, NE, CA, KS and CO, for 180 days. Supporting shipper(s): Borden Chemical, Division of Borden, Inc., 1 Clark St. No. Andover, MA 01845. Attention: Rudy Bibeau, Traffic Manager. Send protest to: District Supervisor Ross J. Seymour, Bureau of Operations, Interstate Commerce Commission, Rm. 3, 6 Loudon Rd., Concord, NM 03301.

MC 142332 (Sub-4TA), filed October 16, 1978. Applicant MEAT HANDLERS' EXPRESS, INC., 540 42d Avenue West, Camano Island, WA 98199. Representative: Michael D. Duppenthaler, 201 South Washington Street, Seattle, WA 98104. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Materials and supplies* used in the manufacture of grinding wheels, from Niagara and Erie Counties, NY; Worchester County, MA; Bound Brook, Camden, South Brunswick, and South Hackensack, NJ; and Cave-in-Rock, IL; to Marysville, WA, under a continuing contract or contracts with Pacific Grinding Wheel Company, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting Shipper(s): Pacific Grinding Wheel Company, 13120 Hwy 99, Marysville, WA 98270. Send protests to: Hugh H. Chaffee, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 858 Federal Building, 915 Second Avenue, Seattle, WA 98174.

MC 143003 (Sub-3TA), filed July 10, 1978, and published in the FEDERAL REGISTER issue of September 13, 1978, and republished as corrected this issue. Applicant: GEORGE L. MORROW TRUCKING CO., INC., 429 N. Seventh Street, P.O. Box 916, Raymondville, TX 78580. Representative: Harry F. Horak, Room 109, 5001 Brentwood Stair Road, Fort Worth, TX 76112. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Pork pigskins and by products of pork* from St. Paul, MN, Kansas City, MO, Memphis, TN, Louisville, KY, Pittsburgh, PA, Omaha, NE, San Transcisco, CA, Chicago, IL, Roswell, NM, and Oklahoma City, OK to Raymondville, TX, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Cisneros Packing Company, 169 South Fifth Street, Raymondville, TX 78580. Send protests to: Richard H. Dawkins, District Supervisor, Interstate Commerce Commission, Room B-400 Federal Building, 727 E. Durango Street, San Antonia, TX 78206. The purpose of this republication is to show TN, in lieu of TX, as previously published.

MC 143619 (Sub-6TA), filed August 25, 1978, and published in the FEDERAL REGISTER issue of October 20, 1978, and republished as corrected this issue. Applicant: PALS BROS., TRUCKING, INC., R.F.D., Alexander, IA 50430. Representative: James M. Hodge, 1980 Financial Center, Des Moines, IA 50309. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transportating: *Dry feed grade urea* from the Port Neal Industrial Complex in Woodbury County, IA to the facilities of Cargill, Incorporated at Fort Worth and Giddings, TX under continuing contract or contracts with Cargill, Incorporated, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Cargill, Inc. Nutrena Feed Division, Box 9300, Mineapolis, MN 55440. Send protests to: Herbert W. Allen, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 518 Federal Building, Des Moines, IA 50309, under a continuing contract of contracts with Cargill, Inc., The purpose of this republication is to show TX, in lieu of TN, in lieu of TN, as previously published.

MC 143775 (Sub-22TA), filed October 12, 1978. Applicant: PAUL YATES, INC., 6601 W. Orangewood, Glendale, AZ 85301. Representative: Michael R. Burke, 6601 W. Orangewood, Glendale, AZ 85301. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Metal wire and cable*, from Shrewsbury, MA to CA, IL, IA, NV, OH and TX, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Phalo Wire and Cable Co., 530 Borton Tpke., Shrewsbury, MA 01545. Send protests to: Andrew V. Baylor, District Supervisor, Interstate Commerce Commission, Rm. 2020 Federal Bldg., 230 N. First Ave., Phoenix, AZ 85025.

MC 144122 (Sub-24TA), filed August 8, 1978, and published in the FEDERAL REGISTER issued of October 5, 1978, and republished as corrected this issue. Applicant: CARRETTA TRUCKING, INC., S. 160, Route 17 North, Paramus, NJ 07652. Representative: Joseph Carretta (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Tape, tape products, materials, equipment, and supplies* used in the manufacture thereof (except commodities in bulk), from Beacon, NY, and Passaic, NJ, to Carbondale, IL, and from Carbondale, IL, to points in CA; and (2) *springs and spring assemblies, bed frames, materials and equipment and supplies* used in the manufacture thereof, from Carthage, MO, to points in IL, IN, OH, MI, PA, NJ, NY, and GA, for 180 days. Supporting shipper(s): Technical Tape, Inc., 1 Market Street, Passaic, NJ 07055. Send protests to: Joel Morrows, District Supervisor, Interstate Commerce Commission, 9 Clinton Street, Newark, NJ 07102. The purpose of this republication is to complete the commodity description as previously omitted.

MC 144122 (Sub-28TA), filed September 27, 1978. Applicant: CARRETTA TRUCKING, INC., Route 17 North, South 160, Paramus, NJ 07662. Representative: Ronald N. Cobert, Suite 501, 1730 M Street NW., Washington, D.C. 20036. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *General commodities* (except commodities in bulk), those of unusual value, household goods as defined by the Commission, Class A and B explosives, and commodities which require special equipment), from the facilities of West Coast Shippers Association, Inc., at Philadelphia, PA, to Los Angeles, San Francisco and Fresno, CA; Portland, OR; Seattle, WA; Amarillo, Houston, Dallas, Fort Worth and San Antonio, TX; Albuquerque, NM; Phoenix, AZ; Reno and Las Vegas, NV; Denver, CO; and Salt Lake City, UT. Restriction: The authority requested herein is to be restricted to traffic moving on the bills

of lading of shipper's associations, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): West Coast Shipper's Association, Inc., 2000 South 71st Street, Philadelphia, PA 19142 (Robert Tannenbaum). Send protests to: Joel Morrows District Supervisor, Interstate Commerce Commission, 9 Clinton Street, Newark, NJ 07102.

MC 144122 (Sub-29TA), filed October 12, 1978. Applicant: CARRETTA TRUCKING, INC., South 160, Route 17 North, Paramus, NJ 07652. Representative: Charles J. Williams, Esq., 1815 Front Street, Scotch Plains, NJ 07076. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Such commodities* as are dealt in or used by a producer and distributor of paper and plastic products (except commodities in bulk) (1) from the facilities utilized by Continental Groups Inc., at Ft. Worth, TX to points in IL, and (2) from Shelbyville, IL to points in NJ and NY, for 180 days. Supporting shipper(s): Continental Group, 800 E. Northwest Highway, Palatine, IL 60067. Send protests to: District Supervisor Joel Morrows, Interstate Commerce Commission, 9 Clinton St., Newark, NJ 07102.

MC 144239 (Sub-4TA), filed September 27, 1978. Applicant: J.L.T. CORP., 233 Green Village Road, Green Village, NJ 07935. Representative: Charles J. Williams, 1815 Front Street, Scotch Plains, NJ 07076. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Cheese* (in vehicles equipped with mechanical refrigeration), from New Wilmington, PA, to points in IL, IN, MD, MI, MN, NJ, NY, OH and WI; and (2) from Hayfield, MN, to points in PA, MD, DE, DC, VA, CT, MA, RI, NY, and NJ, under a continuing contract or contracts, with Valley Lea Dairies, Inc., for 180 days. Supporting shipper(s): Valley Lea Dairies, Inc., 54501 North Ironwood Road, South Bend, IN 46660. Send protests to: Joel Morrows District Supervisor, Interstate Commerce Commission, 9 Clinton Street, Newark, NJ 07102.

MC 144315 (Sub-2TA), filed October 18, 1978. Applicant: PORT CITY LEASING, INC., 602 20th Street North, Lewiston, ID 83501. Representative: Boyd Hartman, 10655 NE 4th, Suite 210, Bellevue, WA 98004. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lumber, lumber products, particle board and millwork* from points in Spokane, Stevens, and Asotin County, WA and Idaho, Clearwater, Lewis, Nez Perce, Latah, Kootenai, Benewah and Bonner Counties, ID to points in NV, for 180 days. Supporting shipper(s): Dale Daley Forest Products, Inc., P.O. Box 23246, Portland, OR 97223. Bennett Lumber Products, P.O. Box 49, Princeton, ID 83857. Hoff Building Supply, Inc., d.b.a. Western Forest Products, 711 E. Broadway, Meridian, ID 83642. Send protests to: High H. Chaffee, District Supervisor, Bureau of Operations, Interstate Commerce Commission, Room 858 Federal Building, 915 Second Avenue, Seattle, WA 98174.

MC 144759 (Sub-1TA), filed October 16, 1978. Applicant: AIR FREIGHT, INC., Terminal Box No. 2, Casper, WY 82602. Representative: Linda L. McIntosh (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *General commodities* having a prior or subsequent movement by air, between Natrona International Airport and Casper, WY and its commercial zone, Glenrock, Douglas and Midwest, WY and their commercial zones, restricted to traffic having a prior or subsequent movement by air, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): There are approximately (10) statements of support attached to the application which may be examined at the Interstate Commerce Commission in Washington, DC, or copies thereof which may be examined at the field office named below. Send protests to: District Supervisor Paul A. Naughton, Interstate Commerce Commission, Room 105 Federal Building and Court House, 111 South Wolcott, Casper, WY 82601.

MC 144793 (Sub-1TA), Filed October 12, 1978. Applicant: RICHARD PELLETIRE, d.b.a. PELLETIER TRUCKING, 8744 Avalon Street, Alta Loma, CA 91701. Representative: Richard Pelletier, 8744 Avalon St., Alta Loma, CA 91701. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Generators and motors, electric, materials and supplies* used in the manufacture thereof, between the facilities of Reuland Electric Company at City of Industry, CA, on the one hand, and, on the other, Howell, MI, under a continuing contract or contracts with Reuland Electric Co., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Reuland Electric Co., 17969 E. Railroad Ave., Industry, CA 91749. Send protests to: Irene Carlos, Transportation Assistant, Interstate Commerce Commission, Rm. 1321 Federal Building, 300 North Los Angeles St., Los Angeles CA 90012.

MC 145152 (Sub-9TA), filed October 12, 1978. Applicant: BIG THREE TRANSPORTATION, INC., P.O. Box 706, Springfield, AR 72764. Representative: Don Garrison, 324 North Second St., Rogers, AR 72756. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Plastic Film* (except in bulk) in vehicles, equipped with mechanical refrigeration, from the facilities of Resinite Department, Division of Borden, Inc., at or near North Andover, MA; Griffin, GA; Illiopolis, IL; Carson, CA; North Bergen, NJ; Cockeysville, MD; Cloucester City, NJ; Charlotte, NC; Cleveland, OH; Elk Grove, IL; Tampa, FL; Oakland, CA; Seattle, WA; Dallas, TX; and, Minneapolis, MN. To points in the United States (except AK and HI), Restricted to the transportation of traffic originating at the facilities of Resinite Department, Borden Chemical Division of Borden, Inc., for 180 days. Supporting shipper(s): Borden Chemical, Div. of Borden, Inc., 1 Clark St., North Andover, MA 01845. Send protests to: District Supervisor, William H. Land, Jr., 3108 Federal Office Building, 700 West Capitol, Little Rock, AR 72201.

MC 145179 (Sub-2TA), filed October 12, 1978. Applicant: J & J CONTRACT CARRIER, INC., 60 South State Avenue, Indianapolis, IN 46201. Representative: Donald W. Smith, P.O. Box 40659, Indianapolis, IN 46240. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Such merchandise as is dealt in by wholesale, retail, and food business houses and in connection therewith, equipment, materials, and supplies* used in conduct of such business (except commodities in bulk) in vehicles equipped with mechanical refrigeration, from the facilities of The Kroger Co., at Cincinnati, and Columbus, OH on the one hand, and on the other points and places in AR, GA, IL, IN, KY, MI, MO, PA (west of U.S. highway 219), TN, TX, VA, WV. Restriction: restricted to service to be performed under a continuing contract or contracts with The Kroger Co., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): The Kroger Co., 1014 Vine St., Cincinnati, OH 45201. Send protests to: Beverly J. Williams, Transportation Assistant, Interstate Commerce Commission, Federal Bldg. & U.S. Courthouse, 46 East Ohio St., Rm. 429, Indianapolis, IN 46204.

MC 145339 (Sub-2TA), filed October 13, 1978. Applicant: NEBRASKA BEEF EXPRESS, INC., 5521 South 91st Street, Omaha, NE 68127. Representative: Kenneth P. Weiner, 408 Executive Building, Omaha, NE 68102.

Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Meats, meat products and meat by-products and articles* distributed by meat packinghouses, as described in sections A and C of Appendix I to the report in Descriptions in Motor Carrier Certificates 61 MCC 209 and 766 (except hides and commodities in bulk) from Omaha, NE and points in IA to points in NC, SC, FL, TX and Kenosha and Cudahy, WI; and Chicago, IL and their commercial zones, restricted to traffic originating in Omaha, NE and its commercial zone. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Lynn Plambeck, Sales Manager, Missouri Valley Foods, Inc., 11414 W. Center Road, Omaha, NE. Send protests to: Carroll Russell, District Supervisor, Interstate Commerce Commission, Suite 620, 110 No. 14th St., Omaha, NE 68102.

MC 145385TA, filed September 22, 1978. Applicant: SHADE TRANSPORTATION SYSTEMS, INC., 800 Heritage Road, DePere, WI. 54115. Representative: David V. Purcell, 111 E. Wisconsin Avenue, Milwaukee, WI. 53202. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Paper forms and printing paper other than newsprint, and materials, equipment and supplies* used in the manufacture or distribution of paper forms and printing paper other than newsprint (except commodities in bulk), between DePere, WI., on the one hand, and, on the other, points in IL, IN, IA, KS, KY, MI, MN, NY, NC, OH, PA and VA; and (2) From DePere, WI, to Phoenix and Tucson, AZ; Boca Raton, FL; Scoville, ID; Oklahoma City and Tulsa, OK; Ogden and Salt Lake City, UT; Essex Junction, VT, and points in AR, CA, CO, CN, DE, DC, GA, MD, MA, MO, NE, NJ, TX and WA; and (3) from Courtland, AL; Ashdown, AR; Bastrop, LA; Jay, ME, and points in TN, to DePere, WI, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Shade Information Systems, Inc., P.O. Box 730, Green Bay, WI. 54305. Send protests to: Gail Daugherty Transportation Assistant, Interstate Commerce Commission, Bureau of Operations, U.S. Federal Building & Courthouse, 517 East Wisconsin Avenue, Room 619, Milwaukee, WI 53202.

MC 145500TA, filed October 17, 1978. Applicant: EAST TEXAS CARTAGE COMPANY, 3300 West Front Street, P.O. Box 7225, Tyler, TX 75711. Representative: Harry F. Horak, Suite 115, 5001 Brentwood Stair Road, Fort Worth, TX 76112. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *General commodities* having a prior or subsequent movement by air, except those of unusual value, equipment, household goods, and those injurious or contaminating to other lading, between the DFW Airport located in the Dallas-Forth Worth, TX commercial zone, on the one hand, and, on the other, points in Smith, Rusk, Cherokee, Anderson, Henderson, Van Zandt, Wood, Upshur, Morris, Camp, Titus, Harrison, and Gregg Counties, TX, for 180 days. Supporting shipper(s): There are approximately 9 statements of support attached to the application which may be examined at the Interstate Commerce Commission in Washington, DC, or copies thereof which may be examined at the filed office named below. Send protests to: Opal M. Jones, Transportation Assistant, Interstate Commerce Commission, 1100 Commerce St., Room 13C12, Dallas, TX 75242.

MC 145531TA, filed October 11, 1978. Applicant: RAPID TRANSFER, INC., 8726-25th Ave. NW., Seattle, WA 98117. Representative: George R. LaBissoniere, 1100 Norton Bldg., Seattle, WA 98104. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *General commodities* (except in bulk, household goods as defined by the Commission, articles of unusual value, articles, which, because of their size or weight require the use of special equipment and livestock), between points in the Seattle, WA Commercial Zone, restricted to traffic having a subsequent or prior movement by water, for 180 days. Supporting shipper(s): There are approximately 9 statements of support attached to the application which may be examined at the Interstate Commerce Commission in Washington, DC, or copies thereof which may be examined at the filed office named below. Send protests to: Hugh H. Chaffee, District Supervisor, Bureau of Operations, I.C.C. 858 Federal Bldg., Seattle, WA 98174.

MC 145536TA, filed October 16, 1978. Applicant: LARRY HENDERSON, West Railroad Street, Pelham, GA 31779. Representative: Larry Henderson (Same as above). Authority sought to operate as a *contract carrier*, by motor vehicle, over regular routes, transporting: *Bagged and bulk fertilizer* from the facilities of Pelham Phosphate Company, Pelham, GA to points in AL and FL, under a continuing contract or contracts with Pelham Phosphate Co., for 180 days. Supporting shipper(s): Pelham Phosphate Co., P.O. Box 468, Pelham, GA 31779. Send protests to: District Supervisor G. H. Fauss, Jr., Interstate Commerce Commission, Bureau of Operations, Box 35008, 400 W. Bay Street, Jacksonville, FL 32202.

MC 145538TA, filed October 16, 1978. Applicant: J. D. VICKERS TRUCKING, INC., P.O. Box 1201, North Wilkesboro, NC 28659. Representative: J. D. Vickers, 1090 Fairchild Road, Winston-Salem, NC 27105. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Dry fertilizer and dry fertilizer materials* in bags and bulk from Winston-Salem, NC to Campbell, Patrick, Henry, Pittsylvania, Mecklenburg, Franklin, Carroll, Grayson, Floyd, Brunswick, Roanoke and Halifax Counties, VA, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): International Minerals and Chemicals, P.O. Box 4145, Winston-Salem, NC 27105. Send protests to: District Supervisor Terrell Price, 800 Briar Creek Road, Room CC516, Mart Office Building, Charlotte, NC 28205.

MC 145540TA, filed October 12, 1978. Applicant: VILLAGE MOTORS OF CATTARAUGUS COUNTY, INC., 730 East State St., Olean, NY 14760. Representative: S. Michael Richards/Raymond A. Richards, P.O. Box 225, Webster, NY 14580. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Battery chargers rectifiers, transformers and materials, parts, supplies and equipment* used in the manufacture thereof, between Cuba, NY, Lumberton, NC and Salt Lake City, UT, and between Allegany, NY and Salt Lake City, UT, under a continuing contract or contracts with Acme Electric Corp., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days. Supporting shipper(s): Acme Electric Corp., 20 Water Street, Cuba, NY. Send protests to: Interstate Commerce Commission, 910 Federal Bldg., 111 W. Huron St., Buffalo, NY 14202.

MC 145544TA, filed October 12, 1978. Applicant: W & M., INC., P.O. Box 2237, East Chicago, IN 46312. Representative: Samuel Ruff, 2109 Broadway, East Chicago, IN 46312. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Air pollution equipment, materials, and supplies* used in the manufacture, of air pollution equipment for the account of Flex-Kleen Corp. between Chicago, IL and Libertyville, IL, on the one hand and on the other points in the United States over irregular routes. Restricted to transportation for Flex-Kleen Corp, under a continuing contract or contracts with Flex-Kleen Corp., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days

of operating authority. Supporting shipper(s): Roger Selby, General Manger of Material Control & Shipping Flex-Kleen Corp., 222 South Riverside Plaza, Chicago, IL 60606. Send Protests to: Lois Stahl, Transportation Assistant, Interstate Commerce Commission, 219 South Dearborn St., Rm. 1386, Chicago, IL 60604.

MC 145545TA, filed October 16, 1978. Applicant: CENTURY REEFER SERVICE, INC., 8 Main Street, Salisbury, MA 01950. Representative: Chester A. Zyblut, 366 Executive Building, 1030 15th Street, NW., Washington, DC 20005. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Plastic, steel and wire spoke tired wheels* from Seabrook, NH, to Dothan and Union Springs, AL; Compton and North Hollywood, CA; Denver, CO; Freeport and Chicago, IL; Columbus, Seymour, and South Bend, IN; Gardner and Westfield, MA; St. Louis, MO; Englewood, Pennsauken, and Blenheim, NJ; Orangeburg and Rochester, NY; Tarboro, NC; Celina, OH; Bedford, PA; and Delavan, Janesville and Milwaukee, WI and their respective commerical zones, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Spherex, Inc., Walton Road, P.O. Box 530, Seabrook, NH 03874. Send protests to: Max Gorenstein, District Supervisor, Bureau of Operations, Interstate Commerce Commission, Room 501, 150 Causeway Street, Boston, MA 02114.

MC 145571TA, filed October 18, 1978. Applicant: RALPH AARON, JAMES BARTHOLOMEW & AUBRY WILLIS dba ABW TRUCKING COMPANY, Box 113, Scotts Hill, TN 38374. Representative: Mr. Roland M. Lowell, 618 United American Bank Building, Nashville, TN 37219. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Rock, sand, gravel and base materials* from Hardin County, TN to the Yellow Creek Nuclear Plant in Tishomingo County, MS, under a continuing contract or contracts with Clyde Owens Sand and Gravel, Inc., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Clyde Owens Sand and Gravel, Inc., P.O. Box 190, Collierville, TN 38017. Send protests to: Mr. Floyd A. Johnson, Distric Supervisor, Interstate Commerce Commission, 100 North Main Building—Suite 2006, 100 North Main Street, Memphis, TN 38103.

MC 145579TA, filed October 18, 1978. Applicant: D. IRVIN TRANSPORT LIMITED, 3020-52nd Street, SE., Calgary, AB, Canada T2G 2A7. Representative: Charles E. Johnson, P.O. Box 1982, Bismarck, ND 58501. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lumber and wood products* from ports of entry on the International Boundary line between the U.S. and Canada located in ND and MT to points in MN, WI, ND, SD, KS, NE, IL, IN, MI, MO, AK, OK, AL, TX, IA, OH, KY, GA and TN; restricted to traffic originating in AB and BC, Canada, for 180 days. Supporting shipper(s): P. A. Tindle, VP, Ralph S. Plant, Ltd., P.O. Box 2089, MPO, Vancouver, BC, Canada V6B 3T2. Send protests to: District Supervisor Paull J. Labane, Interstate Commerce Commission, 2602 First Avenue North, Billings, MT 59101.

MC 145586TA, filed October 18, 1978. Applicant: DONALD M. MAULDING & DICK M. MAULDING dba MAULDING BROS. TRUCKING, 204 Cincinnati, Box 181, Greenup, IL 62428. Representative: Robert T. Lawley, Attorney, 300 Reisch Building, Springfield, IL 62701. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Concrete slats*, for the account of Brim Slats, Inc., from Casey and Roanoke, IL to points in IN, IA, KY, MO, OH, TN and WI, under a continuing contract or contracts with Brim Slats, Inc., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Jeffrey J. Brim, Mgr., Brim Slats, Inc., Box 65, Casey, IL. Send protests to: Charles D. Little, District Supervisor, Interstate Commerce Commission, 414 Leland Office Building, 527 East Capitol Avenue, Springfield, IL 62701.

PASSENGER CARRIERS

MC 109736 (Sub-43TA), filed September 22, 1978. Applicant: CAPITOL BUS COMPANY, d/b/a CAPITOL TRAILWAYS, 1061 South Cameron Street, Harrisburg, PA 17104. Representative: S. Berne Smith, 100 Pine Street, P.O. Box 1166, Harrisburg, PA 17108. Authority sought to operate as a *common carrier*, by motor vehicle, over regular routes, transporting: *Passengers and their baggage*, and express and newspapers in the same vehicle with passengers, (1) Between Baltimore, MD, and Washington, DC, serving Baltimore for purpose of joinder only, and serving no intermediate points except the junction MD Highway 46 and the Baltimore-Washington Parkway for purposes of joinder only, from Baltimore over MD Highway 3 and Baltimore-Washington Parkway to junction U.S. Highway 50, then over U.S. Highway 50 to Washington, and return over the same route, (2) Between the junction of MD Highway 46 and the Baltimore-Washington Parkway and Baltimore-Washington International Airport, serving no intermediate points, and restricted to traffic moving to or from points north of Baltimore, MD, and serving the junction of MD Highway 46 and the Baltimore-Washington Parkway for purposes of joinder only, from the junction of MD Highway 46 and the Baltimore-Washington Parkway over MD Highway 46 to the Baltimore-Washington International Airport, and return over the same route, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): There are approximately (6) statements of support attached to this application which may be examined at the Interstate Commerce Commission in Washington, DC, or copies thereof which may be examined at the field office named below. Send protests to: Charles F. Myers District Supervisor, P.O. Box 809, Federal Square Station, Harrisburg, PA 17108.

MC 145535TA, filed October 11, 1978. Applicant: JACK BISCEGLIA AND ANNETTE BISCEGLIA dba FRONT RANGE AIRPORT LIMOUSINE SERVICE—a partnership, 4640 East County Road 66, Wellington, CO 80549. Representative: Roy Wittstruck, Manges, and Wittstruck, Attorneys at Law, 315 Canyon Ave., Fort Collins, CO 80521. Authority sought to operate as a *common carrier*, by motor vehicle, over regular routes, transporting: *Passengers, passenger baggage and non-passenger baggage* from Cheyenne, WY to Stapleton International Airport, Denver, CO; Non-passenger baggage and parcels from Fort Collins, Windsor, Greeley, and Loveland, CO to Stapleton International Airport, Denver, CO. (Cheyenne, WY to Stapleton International Airport, Denver, CO, via I-25; stops Fort Collins, CO; Loveland at junction of U.S. 34 and I-25; junction of U.S. 119 and I-25; Windsor CO, via Colorado 392; to Greeley via Colorado 392 and U.S. 85; Greeley to junction U.S. 34 and I-25 via U.S. 34), for 180 days. Supporting shipper(s): Teledyne Water Pik, 1730 E. Prospect, Fort Collins, CO 80521. Woodward Governor Co., P.O. Box 1519, 1000 E. Drake Road, Fort Collins, CO 80525. Send protests to: District Supervisor, Roger L. Buchanan, Interstate Commerce Commission, 492 U.S. Customs House, 721 19th St., Denver, CO 80202.

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-33170 Filed 11-27-78; 8:45 am]

[7035-01-M]

[Notice No. 222]

MOTOR CARRIER TEMPORARY AUTHORITY APPLICATIONS

NOVEMBER 20, 1978.

The following are notices of filing of applications for temporary authority under Section 210a(a) of the Interstate Commerce Act provided for under the provisions of 49 CFR 1131.3. These rules provide that an original and six (6) copies of protests to an application may be filed with the field official named in the FEDERAL REGISTER publication no later than the 15th calendar day after the date the notice of the filing of the application is published in the FEDERAL REGISTER. One copy of the protest must be served on the applicant, or its authorized representative, if any, and the protestant must certify that such service has been made. The protest must identify the operating authority upon which it is predicated, specifying the "MC" docket and "Sub" number and quoting the particular portion of authority upon which it relies. Also, the protestant shall specify the service it can and will provide and the amount and type of equipment it will make available for use in connection with the service contemplated by the TA application. The weight accorded a protest shall be governed by the completeness and pertinence of the protestant's information.

Except as otherwise specifically noted, each applicant states that there will be no significant effect on the quality of the human environment resulting from approval of its application.

A copy of the application is on file, and can be examined at the Office of the Secretary, Interstate Commerce Commission, Washington, D.C., and also in the ICC Field Office to which protests are to be transmitted.

NOTE.—All applications seek authority to operate as a common carrier over irregular routes except as otherwise noted.

MOTOR CARRIERS OF PROPERTY

MC 13569 (Sub-43TA), filed October 20, 1978. Applicant: THE LAKE SHORE MOTOR FREIGHT COMPANY, INC., 1200 South State St., Girard, OH 44420. Representative: John P. Tynan, Esq., 167 Fairfield Rd., P.O. Box 1409, Fairfield, NJ 07006. *Such commodities* as are dealt in by grocery and food business houses. From the facilities of The General Foods Corporation located at Blue Ash, OH, to points in the State of WV, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): General Foods Corp., 250 North St., White Plains, NY 10625. Send protests to: Mary Wehner, District Supervisor, 731 Federal Bldg., 1240 East Ninth St., Cleveland, OH 44199.

MC 22509 (Sub-10TA), filed October 19, 1978. Applicant: MISSOURI-NEBRASKA EXPRESS, INC., 5310 St. Joseph Avenue, St Joseph, MO 64505. Representative: E. Wayne Farmer, 3rd Floor, 900 Walnut St., Kansas City, MO 64106. *Glass containers and closures* therefor, from plantsite of Ball Corporation in Mundelein, IL to Manhattan, Kansas, and other points and places in KS and MO execpt Kansas City, KS, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Ball Corp., 345 So. High St., Muncie, IN 47302. Send protests to: Vernon V. Coble, District Supervisor, 600 Federal Building, 911 Walnut St., Kansas City, MO 64106.

MC 29079 (Sub-96TA), filed October 20, 1978. Applicant: BRADA MILLER FREIGHT SYSTEM, INC., P.O. Box 935, 1210 South Union St., Kokomo, IN 46901. Representative: Richard H. Streeter, 1729 H Street, NW, Washington, DC 20006. *Auto body parts*, From Greencastle, IN, to Wixom and Detroit, MI, for 180 days. Supporting shipper(s): Greencastle Mfg. Co., Division of The Lobdell-Emery Mfg., P.O. Box 508, Greencastle, IN 46135. Send protests to: J. H. Gray, District Supervisor, 343 West Wayne St., Suite 113 , Fort Wayne, IN 46802.

MC 37327 (Sub-11TA), filed October 20, 1978. Applicant: PENN EMPIRE TRANSPORT, INC., P.O. Box 517, Livingston Avenue, Jamestown, NY 14701. Representative: Ronald W. Malin and Kenneth T. Johnson, Bankers Trust Building, Jamestown, NY 14701. (1) *New furniture*, from points in Chautauqua and Cattaraugus Counties, NY to points in OH, MI and IN; and (2) *Voting machines, uncrated and accessories* between OH, MI, IL and IN, on the one hand, and Jamestown, NY, on the other, for 180 days. Supporting shipper(s): Monitor Furniture Co., Inc., 92 Steele Street, Jamestown, NY 14701. Fancher Furniture Co., Inc., 100 Rochester Street, Salamanca, NY 14779. AVM Corporation, P.O. Box 1000, Jamestown, NY 14701. Send protests to: ICC District Supervisor, 910 Federal Building, 111 West Huron Street, Buffalo, NY 14202.

MC 55709 (Sub-5TA), filed October 20, 1978. Applicant: ANDING TRANSIT, INC., P.O. Box 112, Arena, WI 53503. Representatives: James A. Spiegel, Olde Towne Office Park, 6425 Odana Road, Madison, WI 53719. (1) *Yogurt*, and (2) *materials, equipment and supplies used in the manufacture of yogurt*, (1) from the facilities of Elm Grove Dairy Company at Richland Center, WI, to the facilities of Jewel Companys, Inc. at Melrose Park, IL, and (2) from points in IL north of Hwy. I-80 to Richland Center, WI, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Elm Grove Milk Company, Inc., P.O. Box 390, Richland Center, WI 53581. Send protests to: District Supervisor, Ronald A. Morken, 212 East Washington Avenue, Rm. 317, Madison, WI 53703.

MC 55709 (Sub-6TA), filed October 20, 1978. Applicant: ANDING TRANSIT, INC., P.O. Box 112, Arena, WI 53503. Representative: James A. Spiegel, Olde Towne Office Park, 6425 Odana Road, Madison, WI 53719 *Butter*, from points in WI to Browerville, Faribault, Minneapolis, Mountain Lake, New Ulm, and St. Paul, MN, for 180 days. An underlying ETA seeks 90 days authority Supporting shipper(s): Burt Lewis, Inc., 1301 West 22nd St., Oak Brook, IL 60521. Send protests to: District Supervisor, Ronald A. Morken, 212 East Washington Ave., Rm. 317, Madison WI 53703

MC 63387 (Sub-6TA), filed October 18, 1978. Applicant: STANLEY STANLEY d.b.a. ACME EXPRESS, 607 Frelinghuysen Avenue, Newark, NJ 07114 Representative: Thomas F. X. Foley, Esq., State Highway 34, Colts neck, NJ 07722. *Cold finished steel bars*, from the plantsite of Wyckoff Steel Division of Ampco-Pittsburgh Corporation at Newark, NJ to Baltimore, MD, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s) Wycoff-Steel Division, Ampco-Pittsburgh Corp., 722 Frelinghuysen Ave., Newark, NJ 07114. Send protests to District Supervisor, Joel Morrows, 9 Clinton St., Newark, NJ 07102.

MC 71902 (Sub-95TA), filed October 19, 1978. Applicant: UNITED TRANSPORTS, INC., 4900 N. Santa Fe Avenue, P.O. Box 18547, Oklahoma City, OK 73154. Representative: Eric L. Spitler, 4900 N. Santa Fe, P.O. Box 18547, Oklahoma City, OK 73154. *New motor vehicles* (except motor homes, trailers, agricultural and industrial tractors, and attachments for trailers and agricultural and industrial tractors), in secondary movements, in truckaway and driveaway service, restricted to the transportation of shipments having an immediately prior movement by rail or motor carrier, from New Orleans, LA to points in MS, for 180 days. Supporting shipper(s): Chrysler Corp., P.O. Box 1976, Detroit, MI 48231. Send protests to: Connie Stanley, Trans. Assistant Rm. 240 Old Post Office & Court House Bldg., 215 NW 3rd, Oklahoma City, OK 73102.

MC 82063 (Sub-93TA), filed October 19, 1978. Applicant: KLIPSCH HAULING CO., 10795 Watson Rd., Sunset Hills, MO 63127. Representative: W. E. Klipsch (same address as applicant). *Liquid chemicals*, in bulk, in rubber-

lined tank vehicles, between Eldorado, AR and Gulfport, MS, for 180 days. Suporting shipper(s): Velsicol Chemical Corp., 341 E. Ohio St., Chicago, IL 60611. Send protests to: District Supervisor, P. E. Binder, Rm. 1465, 210 N. 12th St., St. Louis, MO 63101.

MC 106398 (Sub-846TA), filed October 19, 1978. Applicant: NATIONAL TRAILER CONVOY, INC., 525 South Main, P.O. Box 3329, Tulsa, OK 74103. Representative: Irvin Tull, 525 South Main, P.O. Box 3329, Tulsa, OK 74103. *Buildings, complete, knocked down or in sections,* from the facilities of Kirby Building Systems in Houston, TX to points in AZ, CA, CO, LA, OK, OR, WA & WY, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Kirby Building Systems, 7101 Renwick, P.O. Box 36425, Houston, TX 77036. Send protests to: Connie Stanley, Trans. Assistant, Rm. 240, Old Post Office & Court House Bldg., 215 NW 3rd, Oklahoma City, OK 73102.

MC 107496 (Sub-1170TA), filed October 20, 1978. Applicant: RUAN TRANSPORT CORPORATION, 666 Grand Avenue, Des Moines, IA 50309. Representative: E. Check (Same as applicant). *Aluminum sulfate* (alum) in bulk, in tank vehicles, from Denver, CO to Amarillo, TX, for 180 days. Supporting shipper(s): Allied Chemical Corp., P.O. Box 1139R, Morristown, NJ 07960. Send protests to: Herbert W. Allen, District Supervisor, 518 Federal Building, Des Moines, IA 50309.

MC 109593 (Sub-5TA), filed October 12, 1978. Applicant: H. R. HILL d.b.a. H. R. HILL TRUCKING COMPANY, Box 875, 2007 West Shawnee, Muskogee, OK 74401. Representative: Max G. Morgan, 223 Ciudad Building, Oklahoma City, OK 73112. Authority sought to operate as a *contract carrier,* by motor vehicle, over irregular routes, transporting: (1) *Carbonated beverages* from the facilities of Shasta Beverages, at or near Houston, TX to points in OK and from the facilities of Shasta Beverages, at or near Lenexa, KS to points in OK, that on and north of I-20 and on and west of I-35, that part of AR on and west of U.S. Hwy 71; and (2) *Equipment, materials, and supplies* used in the processing and distribution of carbonated beverages (except commodities which because of size and weight require special equipment) from points in OK to the facilities of Shasta Beverages at or near Houston, TX and from points in OK those in that part of TX on and north of I-20 and on and west of I-35, and that part of AR on and west of U.S. Hwy 71 to the plantsite of Shasta Beverages at or near Lenexa, KS, under a continuing contract or contracts with Shasta Beverages, for 180 days. Supporting shipper(s): Shasta Beverages, 26901 Industrial Blvd., Hayward, CA 94545. Send protests to: Connie Stanley, Trans. Assistant, Rm. 240 Old Post Office & Court House Bldg., 215 NW 3rd, Oklahoma City, OK 73102.

MC 112962 (Sub-12TA), filed October 19, 1978. Applicant: CRUPPER TRANSPORT CO., INC., 25 South Third, Kansas City, KS 66118. Representative: Tom B. Kretsinger, Esq., Kretsinger & Kretsinger, 20 East Franklin, Liberty, MO 64068. *Iron and steel forms, conveyors and construction materials, equipment and supplies,* between Kansas City, KS and points in CO, IA, IL, LA, MO, NE, OK, and WY. This is a non-radial application. Restricted to transportation for the account of Midwest Conveyor Co., Inc., for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Mid-West Conveyor Co., Inc., 450 E. Donovan Road, Kansas City, KS 66115. Send protests to: Vernon V. Coble, District Supervisor, I.C.C., 600 Federal Building, 911 Walnut St., Kansas City, MO 64106.

MC 114334 (Sub-40TA), filed October 20, 1978. Applicant: BUILDERS TRANSPORTATION COMPANY, 3710 Tulane Road, Memphis, TN 38116. Representative: Mr. Dale Woodall, 900 Memphis Bank Building, Memphis, TN 38103. *Iron and steel and iron and steel articles* from Memphis, TN to a power plant construction site located 10 miles west of Princeton, IN on Indiana Highway 64, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Armco Steel Inc., 1969 Harbor Ave., Memphis, TN 38113. Send protests to: Mr. Floyd A. Johnson, District Supervisor, 100 North Main Building, Suite 2006, 100 North Main St., Memphis, TN 38103.

MC 114569 (Sub-253TA), filed October 20, 1978. Applicant: SHAFFER TRUCKING, INC., P.O. Box 418, New Kingstown, PA 17072. Representative: N. L. Cummins (same as above). *Heating and air-conditioning equipment and parts and accessories therefor* (except commodities the transportation of which because of size or weight requires the use of special equipment) from Nashville, TN to points in IL, IN, OH, MI, MD, NJ, NY, and PA, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Heil Quaker Corp., 1717 Heil Quaker Boulevard, La Vergne, TN 37086. Send protests to: Charles F. Myers, District Supervisor, P.O. Box 869, Federal Square Station, 228 Walnut Street, Harrisburg, PA 17108.

MC 114569 (Sub-254TA), filed October 20, 1978. Applicant: SHAFFER TRUCKING, INC., P.O. Box 418, New Kingstown, PA 17072. Representative: N. L. Cummins (same as above). (1) *Foodstuffs, canned or bottled* (except frozen foods and commodities in bulk, in tank vehicles) from the facilities of Wm. Underwood Co., at or near Hannibal, MO to Great Falls, MT; Los Angeles, Milpitas, and San Jose, CA; Phoenix, AZ; Portland, OR; Salt Lake City, UT; Seattle, WA; El Paso, TX; and Denver, CO, and (2) *Equipment, supplies, and parts utilized in manufacturing and sale of foodstuffs, canned or bottled* from Marion, AL to the facilities of Wm. Underwood Co., at or near Hannibal, MO restricted to traffic originating at or destined to the facilities of Wm. Underwood Co., at or near Hannibal, MO, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Wm. Underwood Co., One Red Devil Lane, Westwood, MA 02090. Send protests to: Charles F. Myers, District Supervisor, P.O. Box 869, Federal Square Station, 228 Walnut Street, Harrisburg, PA 17108.

MC 118142 (Sub-187TA), filed October 20, 1978. Applicant: M. BRUENGER & CO., INC., 6250 North Broadway, Wichita, KS 67219. Representative: Lester C. Arvin, 814 Century Plaza Bldg., Wichita, KS 67202. *Meat, meat products and meat by-products,* from facilities of Riverland Food Corporation, Gonzales, LA, to IL, IN, MN & WI, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Riverland Food Corp., P.O. Box 68, Gonzales, LA 70737. Send protests to: M. E. Taylor, District Supervisor, 101 Litwin Bldg., Wichita, KS 67202.

MC 119493 (Sub-237TA), filed October 20, 1978. Applicant: MONKEM COMPANY, INC., West 20th Street Road, P.O. Box 1196, Joplin, MO 64801. Representative: Thomas D. Boone (same as applicant). *Flour* (except in bulk), from IL and IN to AL, AR, FL, GA, LA, MS, NC, SC, TX, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Gilbert Jackson Co., Inc., Kansas City, MO. Send protests to: District Supervisor, John V. Barry, Rm. 600, 911 Walnut, Kansas City, MO 64106.

MC 121509 (Sub-10TA), filed October 19, 1978. Applicant: DAUFELDT TRANSPORT, INC., 618 Clay Street, Muscatine, IA 52761. Representative: William L. Fairbank, 1980 Financial Center, Des Moines, IA 50309. *Liquid feed,* in bulk, from Olin, IA to points in IL, MN, MO, and WI, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Ralston Purina Company, Checkerboard Square 11T, St. Louis, MO. Send protests to: Herbert W. Allen, District Supervisor, I.C.C., 518 Federal Building, Des Moines, IA 50309.

MC 123407 (Sub-504TA), filed October 12, 1978. Applicant: SAWYER

TRANSPORT, INC., South Haven Square, U.S. Highway 6, Valparaiso, IN 46383. Representative: H. E. Miller, Jr. (same as applicant). *Honeycomb paper products* from the facilities of Hexagon Honeycomb Corporation located in St. Claire County, IL, to Stockton, CA; Douglas, GA; Elkhart, IN; New Orleans, LA; Grand Rapids, MI; Forest City, NC; Cleveland and Upper Sandusky, OH; McKenzie and Milan, TN; Harrisonburg, VA; and Clarksville, TX, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Hexagon Honeycomb Corp., 7803 Clayton Road, Suite 201, St. Louis, MO 63117. Send protests to: Lois Stahl, Trans. Assistant, I.C.C. Everett McKinley Dirksen Building, Rm. 1386, 219 S. Dearborn St., Chicago, IL 60604.

MC 124078 (Sub-895TA), filed October 19, 1978. Applicant: SCHWERMAN TRUCKING COMPANY, 611 South 28 St., Milwaukee, WI 53215. Representative: Richard H. Prevette (same as applicant). *Cement* from Hagerstown, MD to Superior, OH, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Marquette Cement Div., Gulf & Western Natural Resources Group, 2200 First American Center, Nashville, TN 37238. Send protests to: Gail Daugherty, Trans. Assistant U.S. Federal Building & Courthouse, 517 East Wisconsin Ave., Rm. 619, Milwaukee, WI 53202.

MC 12885 (Sub-1TA), filed October 20, 1978. Applicant: M & M TRANSPORT, INC., P.O. Box 455, Mossy Rock, WA 98564. Representative: George R. LaBissoniere, 1100 Norton Building, Seattle, WA 98104. *Sawdust and shavings* from Little Skookum Plantsite and plantsite of Delson Lumber at Olympia, WA to St. Helens, OR, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Delson Lumber Co., P.O. Box 8580, Olympia, WA 98507. Send protests to: R. V. Dubay, District Supervisor, 114 Pioneer Courthouse, Portland, OR 97204.

MC 129032 (Sub-61TA), filed October 19, 1978. Applicant: TOM INMAN TRUCKING, INC., 6015 S. 49th West Avenue, Tulsa, OK 74107. Representative: David R. Worthington (same as applicant). *Candy and confectionery* (except in bulk) moving in vehicles equipped with mechanical refrigeration, from the facilities of E. J. Brach & Sons at or near Chicago, IL to points in TX and OK, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): E. J. Brach & Sons Div. of American Home Products Corporation, 4656 W. Kinzie, Chicago, IL 60644. Send protests to: Connie Stanley, Trans. Assistant, Rm. 240, Old Post Office & Court House Bldg., 215 NW 3rd, Oklahoma City, OK 73102.

MC 133095 (Sub-207TA), filed October 20, 1978. Applicant: TEXAS CONTINENTAL EXPRESS, INC., P.O. Box 434, Euless, TX 76039. Representative: Kim G. Meyer, P.O. Box 872, Atlanta, GA 30301. *Petroleum and petroleum products in packages* from the facilities of Texaco, Inc. in Jefferson County, TX to points in OH, IN, IL, MI, IA, NE, LA, MO, KY, TN, MS & WI, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Texaco, Inc., 1111 Rusk, Houston, TX 77052. Send protests to: Robert J. Kirspel, District Supervisor, Rm. 9A27, Federal Bldg., 819 Taylor St., Ft. Worth, TX 76102.

MC 134286 (Sub-85TA), filed October 20, 1978. Applicant: ILLINI EXPRESS, INC., P.O. Box 1564, Sioux City, IA 51102. Representative: Kenneth L. Ackerman (same as above). *Meat, meat products, meat by-products, and articles distributed by meat packinghouses as described in Sections A and C of Appendix I to the report in Descriptions in Motor Carrier Certificates, 61 MCC 209 and 766* (except hides and commodities in bulk), from the facilities of Iowa Beef Processors, Inc., located at or near Dakota City, NE, and Sioux City, IA, to points in CA, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Glen Echelbarger, Transportation Rate Analyst, Iowa Beef Processors, Inc., Dakota City, NE 68731. Send protests to: Carroll Russell, District Supervisor, Suite 620, 110 North 14th Street, Omaha, NE 68102.

MC 135070 (Sub-14TA), filed October 20, 1978. Applicant: JAY LINES, INC., 720 N. Grand, Amarillo, TX 79120. Representative: Gailyn Larsen, 521 South 14th Street, Lincoln, NE 68501. *Meats, meat products, meat by-products, and articles distributed by meat packinghouses,* (except in bulk and hides), from the facilities of Royal Packing Company, at or near National Stockyards, IL and St. Louis, MO, to points in CT, MD, MA, NJ, NY, PA, RI, and DC, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Royal Packing Company, P.O. Box 156, National City, IL 62071. Send protests to: Haskell E. Ballard, District Supervisor, Box F-13206 Federal Building, Amarillo, TX 79101.

MC 135070 (Sub-15TA), filed October 20, 1978. Applicant: JAY LINES, INC., 720 N. Grand, Amarillo, TX 79120. Representative: Gailyn Larsen, 521 South 14th Street, Lincoln, NE 68501. *Candy and confectionery* (except in bulk), from the plantsite and warehouse facilities of or utilized by E. J. Brach & Sons at or near Chicago, IL to points in MD, NJ, NY, OK, PA, TX, and VA, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): E. J. Brach & Sons, 4656 West Kinzie St., Chicago, IL 60644. Send protests to: Haskell E. Ballard, District Supervisor, Box F-13206 Federal Building, Amarillo, TX 79101.

MC 135082 (Sub-33TA), filed October 19, 1978. Applicant: ROADRUNNER TRUCKING, INC., P.O. Box 26748, 415 Rankin Road NE., Albuquerque, NM 87125. Representative: Randall R. Sain (same as applicant). *Brick and tile,* and the commodities used in the installation thereof, from Los Angeles and Elsinore, CA, to points in AR, LA, and OK, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Pacific Clay Building Products, 9500 South Norwalk Blvd., Santa Fe Springs, CA 90607. Send protests to: I.C.C. District Supervisor, 1106 Federal Office Bldg., 517 Gold Ave. SW., Albuquerque, NM 87101.

MC 135810 (Sub-4TA), filed October 19, 1978. Applicant: BRUCE CART<AGE CO., INC., 8399 Zionsville Road, Indianapolis, IN 46268. Representative: Donald W. Smith, Suite 945, 9000 Keystone Crossing, Indianapolis, IN 46240. Authority sought to operate as a *contract carrier,* by motor vehicle, over irregular routes, transporting: *Electrical goods and household appliances and parts thereof,* from the facilities of ADI at Indianapolis, IN to points in KY. Restriction: Restricted to traffic originating at the facilities of ADI at Indianapolis, IN under a continuing contract or contracts with ADI of Indianapolis, IN, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): ADI, 8399 Zionsville Road, Indianapolis, IN 46268. Send protests to: Beverly J. Williams, Trans. Assistant, I.C.C., Federal Bldg. and U.S. Courthouse, 46 East Ohio St., Rm. 429, Indianapolis, IN 46204.

MC 136315 (Sub-41TA), filed October 20, 1978. Applicant: OLEN BURRAGE TRUCKING, INC., Route 9, Box 22-A, Philadelphia, MS 39350. Representative: Fred W. Johnson, Jr., 1500 Deposit Guaranty Plaza, P.O. Box 22628, Jackson, MS 39205. (1) *Lumber* from the facilities of Weyerhaeuser Company at or near Millport, AL to points in IL, IN, KY, MI, MN, OH, PA, and WI; (2) and *equipment, materials and supplies* (except in bulk) from points in the above named states to the facilities of Weyerhaeuser Company at or near Millport, AL, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Weyerhaeuser Co., P.O. Box 577, Bruce, MS 38915. Send protests to: Alan C. Tarrant, District Su-

pervisor, I.C.C., Rm. 212, 145 East Amite Building, Jackson, MS 39201.

MC 138388 (Sub-3TA), filed October 20, 1978. Applicant: CHESTER CAINE, JR., d.b.a. CAINE TRANSFER, 255 Beaver Dam St., Lowell, WI 53557. Representative: Thomas P. Shannon, 622 N. Water St., Milwaukee, WI 53202. *Bagged feed or feed* in bulk which excludes all chemical or liquid commodities from the Town of Emmet, County of Dodge, WI to points located within IL, IN, MI and MN, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s):. Provimi, Inc., Provimi Road, Watertown, WI. Send protests to: Mrs. Gail Daugherty, Trans. Assistant, U.S. Federal Building and Courthouse, 517 East Wisconsin Avenue, Rm. 619, Milwaukee, WI 53202.

MC 138567 (Sub-2TA), filed October 19, 1978. Applicant: R. L. PAQUETTE, INC., Box 162, Middlebury, VT 05753. Representative: Roger Paquette, Jr., Dog Team Road, New Haven, VT 05472. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Plastic brushes*, from Middlebury, VT to Sheffield, PA, under a continuing contract or contracts with Tucel Industries, Inc., for 180 days. An underlying ETA seeks 90 days authority. Supporting shippper(s): Tucel Industries, Inc., Maple Street, Middlebury, VT 05753. Send protests to: District Supervisor, David A. Demers, P.O. Box 548, 87 State St., Montpelier, VT 05602.

MC 129495 (Sub-392TA), filed October 20, 1978. Applicant: NATIONAL CARRIERS, INC., 1501 E. 8th Street, P.O. Box 1358, Liberal, KS 67901. Representative: Herbert Alan Dubin, Sullivan & Dubin, 1320 Fenwick lane, Silver Spring, MD 20910. *Adhesives, sealants, solvents, stains, wood preservatives, and accessories, equipment, materials, and supplies used in the installation, maintenance, and distribution of floors, floor coverings, walls and wall coverings*, in vehicles equipped with mechanical refrigeration, from the facilities of Roberts Consolidated industries located at or near City of Industry, Monrovia, and Southgate, CA to points in the United States (except AK, HI, and CA), for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Roberts Consolidated Industries, 600 N. Baldwin Park Boulevard, City of Industry, CA 91749. Send protests to: M. E. Taylor, District Supervisor, 101 Litwin Building, Wichita, KS 67202.

MC 140820 (Sub-9TA), filed October 19, 1978. Applicant: A & R TRANSPORT, INC., an Illinois corporation, 2996 N. Illinois 71, Route 3, Ottawa, IL 61350. Representative: James R. Madler, 120 West Madison St., Chicago, IL 60602. *Sulfuric acid*, from DePue, IL to points in IA, IN, KS, KY, MI, MO, OH and WI, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): T. C. Welch, Vice President, Chemical Interchange Company, 11 S. Meramec, Suite 1104, St. Louis, MO 63105. Send protests to: Lois M. Stahl, Trans. Assistant, 219 South Dearborn St., Rm. 1386, Chicago, IL 60604.

MC 143812 (Sub-6TA), filed October 19, 1978. Applicant: MARTIN E. VAN DIEST, d.b.a. M. VAN DIEST CO., 8087 Victoria Avenue, Riverside, CA 92504. Representative: William J. Monheim, P.O. Box 1756, Whittier, CA 90609. *Liquid foodstuffs*, in bulk, from points in Kern County, CA, to points in Washington, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Delano Growers Cooperative Winery, Route 1, Box 283, Delano, CA 93215. Send protests to: Irene Carlos, Trans. Assistant, Rm. 1321, Federal Building, 300 North Los Angeles St., Los Angeles, CA 90012.

MC 143988 (Sub-4TA), filed October 19, 1978. Applicant: JAMES W. TATE, d.b.a. JAMAR TRUCKING, 5377 Fleetway Avenue, Memphis, TN 38118. Representative: Mr. Thomas A. Stroud, 2008 Clark Tower, 5100 Poplar Ave., Memphis, TN 38137. *Foodstuffs* (except commodities in bulk) from the facilities of Green Giant Company at or near Belvidere, IL to points in the states of TN, MO, MS and KY, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Green Giant Company, Le Sueur, MN 56058. Send protests to: Mr. Floyd A. Johnson, District Supervisor, 100 North Main Building, Suite 2006, 100 North Main Street, Memphis, TN 38103.

MC 144264 (Sub-2TA), filed October 17, 1978. Applicant: MOHR TRUCKING CO., INC., Route 1, Box 198, Barboursville, WV 25526. Representative: John M. Friedman, 2930 Putnam Avenue, Hurricane, WV 25526. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Crushed stone and limestone aggregate*, in bulk, in dump vehicles, from points in Adams County, OH to points in Boone, Cabell, Jackson, Kanawha, Lincoln, Logan, Mason, Mingo, Putnam, Roane, Wayne, and Wirt Counties, WV, under a continuing contract or contracts with Plum Run Stone Div. of Davon Inc., for 180 days. Supporting shipper(s): Plum Rum Stone Div of Davon Inc. 4281 Roush Road, Hillsboro, OH 45133. Send protests to: ICC District Supervisor, 3108 Federal Building, 500 Quarrier Street, Charleston, WV 25301.

MC 145152 (Sub-11TA), filed October 18, 1978. Applicant: BIG THREE TRANSPORTATION, INC., P.O. Box 706, Springdale, AR 72764. Representative: Don Garrison, 324 North Second Street, Rogers, AR 72756. *Canned foods*, from Napoleon, OH to Paris, TX, for 180 days. Supporting shipper(s): Campbell Soup Company, East Maumee Avenue, Napoleon, OH 43545. Send protests to: District Supervisor, William H. Land, Jr., 3108 Federal Office Building, 700 West Capitol, Little Rock, AR 72201.

MC 145152 (Sub-12TA), filed October 18, 1978. Applicant: BIG THREE TRANSPORTATION, INC., P.O. Box 706, Springdale, AR 72764. Representative: Don Garrison, 324 North Second Street, Rogers, AR 72756. *Such commodities as are dealt in or used by wholesale and retail discount and variety stores*, from points in the States of IL and PA to the facilities of Wal-Mart Stores, Inc., at or near Bentonville and Searcy, AR, for 180 days. Supporting shipper(s): Wal-Mart Stores, Inc., P.O. Box 116, Bentonville, AR 72712. Send protests to: District Supervisor William H. Land, Jr., 3108 Federal Office Building, 700 West Capitol, Little Rock, AR 72201.

MC 145152 (Sub-13TA), filed October 20, 1978. Applicant: BIG THREE TRANSPORTATION, INC., P.O. Box 706, Springdale, AR 72764. Representative: Don Garrison, 324 North Second Street, Rogers, AR 72756. *Canned goods*, from Napoleon, OH to Paris, TX; Camden, NJ; Chicago, IL; and points in NY, PA, KY, WV, IN, NC, and SC, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Campbell Soup Co., East Maumee Ave., Napoleon, OH 43545. Send protests to: District Supervisor William H. Land, Jr., 3108 Federal Office Building, 700 West Capitol, Little Rock, AR 72201.

MC 145409 (Sub-2TA), filed October 18, 1978. Applicant: STA-GREEN TRANSPORTATION CO., INC., 321 North Anniston Avenue, Sylacauga, AL 35150. Representative: Robert E. Tate, P.O. Box 517, Evergreen, AL 36401. (1) *Fertilizer and fertilizer ingredients, seed, insecticides, herbicides, and fungicides*, from the facilities utilized by Parker Fertilizer Co., Inc., in Talladega County, AL to all points in the United States (except AK and HI); and (2) *equipment, materials, and supplies used in the manufacture or distribution of fertilizer and fertililzer ingredients, seed, insecticides, herbicides, and fungicides*, from all points in the United States (except AK and HI) to the facilities utilized by Parker Fertilizer Co., Inc., to Talladega County, AL, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Parker Fertilizer Co., Inc., P.O. Box 540 Sylacauga, AL 35150. Send protests to: Mabel E.

Holston, Trans. Asst., Room 1616, 2121 Building, Birmingham, AL 35203.

MC 145573TA, filed October 18, 1978. Applicant: ELBERT R. RANEY, d.b.a. RANEY'S TRUCKING, 634 East Olive, Oxnard, CA 93030. Representative: William J. Monheim, P.O. Box 1756, Whittier, CA 90609. *Expanded shale and bentonite*, in bulk, from Lightweight Processing Co. plant sites, at or near Frazier Park and Ventura, CA to points in AZ and NV, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Lightweight Processing Co., 715 North Central Avenue, Suite 321, Glendale, CA 91203. Send protests to: Irene Carlos, Trans. Asst., Room 1321, Federal Building, 300 North Los Angeles Street, Los Angeles, CA 90012.

No. MC 145574TA, filed October 19, 1978. Applicant: RUSS'S MOTOR SERVICE, INC., 5070 Lake Street, Melrose Park, IL 60160. Representative: Albert A. Andrin, 180 North LaSalle Street, Chicago, IL 60601. *General commodities* having a prior or subsequent movement by rail and empty trailers or containers, between Chicago, IL on the one hand, and, on the other Waukegan, IL and Kenosha, Racine, and Milwaukee, WI, for 180 days. Supporting shipper(s): C. V. Murphy, Manager, Intermodal Operations, Chicago & Northwestern Transportation Company, Inc., Rm. 100, 500 W. Madison St., Chicago, IL 60606. Send protests to: Lois M. Stahl, Trans. Assistant, ICC, 219 South Dearborn St., Rm. 1386, Chicago, IL 60604.

MC 145578TA, filed October 18, 1978. Applicant: CHEVALLEY MOVING & STORAGE OF LAWTON, INC., P.O. Box 627, Lawton, OK 73501. Representative: Billy R. Reid, P.O. Box 9093, Ft. Worth, TX 76107. *Used household goods*, between points in Commanche, Kiowa, Caddo, McLain, Carter, Grady, Garvin, Murray and Stephens Counties, OK, for 180 days. Restriction: The operations authorized are restricted to the transportation of traffic having a prior or subsequent movement, in containers, beyond the points authorized, and further restricted to the performance of pickup and delivery service in connection with packing, crating and containerization, or unpacking, uncrating and decontainerization of such traffic. Supporting shipper(s): Sunpak Movers, Inc., 100 West Harrison Plaza, Seattle, WA 98119. Imperial Van Lines International, Inc., 2805 Columbia Street, P.O. Box 2949, Torrance, CA 90503. Send protests to: Robert J. Kirspel, District Supervisor, Room 9A27, Federal Building, 819 Taylor Street, Ft. Worth, TX 76102.

MC 145580TA, filed October 18, 1978. Applicant: GAINER'S TOWING, INC., 4321 SE. Hawthorne Boulevard, Portland, OR 97215. Representative: Richard James Spielman (same as above). *Mobile offices, restrooms and storage trailers* by towing (1) from Portland, OR and Vancouver, WA serving all intermediate points and off route points within fifty (50) airline miles of Portland, OR and Vancouver, WA. (2) From Portland, OR and Vancouver, WA, on the one hand, and, on the other, points in OR, WA, ID and MT, for 180 days. Supporting shipper(s): There are (5) statements of support attached to the application which may be examined at the Interstate Commerce Commission in Washington, DC, or copies thereof which may be examined at the field office named below. Send protests to: R. V. Dubay, District Supervisor, 114 Pioneer Courthouse, Portland, OR 97204.

MC 145581TA, filed October 17, 1978. Applicant: HAROLD L. HOOD, d.b.a. HOOD TRUCKING, R.R. No. 1, Rushville, IL 62681. Representative: Robert T. Lawley, Attorney, 300 Reisch Building, Springfield, IL 62701. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Feed and feed ingredients*, for the account of Kent Feeds, Inc., between Beardstown, IL, on the one hand, and, on the other, points in IN, IA and MO, under a continuing contract or contracts with Kent Feeds, Inc., for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Thomas D. Donis, Director of Transp., Kent Feeds, Inc., 1600 Oregon Street, Muscatine, IA. Send protests to: Charles D. Little, District Supervisor, 414 Leland Office Building, 527 East Capitol Avenue, Springfield, IL 62701.

MC 145583TA, filed October 18, 1978. Applicant: XPRESS TRUCK LINES, INC., 4325 Bath Street, Philadelphia, PA 19137. Representative: Anthony A. Cerone (same as above). *Iron and steel articles* having a prior movement by water, between points in PA, DE, CT, NY, NJ, MD, VA within 250 miles of Philadelphia, PA for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Nasco Steel, Inc., Milnor and Bleigh Streets, Philadelphia, PA 19136. Send protests to: T. M. Exposito, Trans. Asst., 600 Arch Street, Room 3238, Philadelphia, PA 19106.

MC 145584TA, filed October 18, 1978. Applicant: SOUTHLAND TRANSPORTATION, INC., P.O. Box 7760, Washington, DC 20044. Representative: Henry E. Seaton, 929 Pennsylvania Building, 425 13th Street NW., Washington, DC 20004. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Such articles* as are dealt in by variety and department stores, and newspaper supplements when moving in mixed loads with the above, between the facilities of Kuhn's Big K Stores at Nashville, TN, on the one hand, and, on the other, its retail outlets at Brunswick and Savannah, GA and points in SC, under a continuing contract or contracts with Kuhn's Big K Stores Corporation, for 180 days. An underlying ETA seeks 90 days authority. Supportng shipper(s): Kuhn's Big K Stores Corporation, 245 Great Circle Drive, Nashville, TN 37228. Send protests to: T. M. Esposito, Trans. Asst., 600 Arch Street, Room 3238, Philadelphia, PA 19106.

MC 145654TA, filed October 10, 1978. Applicant: RICAR, INC., 106 Crown Court, Lancaster, OH 43130. Representative: Robert W. Gardier, Jr., 100 East Broad Street, Columbus, OH 43215. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Fireplace coal, fireplace supplies and accessories, and materials used in the manufacture, distribution or sale thereof*, between the facilities of the Hearthland Corp., located at or near Columbus, OH, on the one hand, and, on the other, points in CA, CO, DE, DC, IL, IN, KY, MD, MA, MI, MO, NH, NY, PA, RI, TN, TX, VT, VA and WI, and the following points: Albuquerque, NM; Atlanta, GA; Coyers, GA; Englewood, CO; Kansas City, KS; Lincoln, NE; Little Rock, AR; Metarie, LA; Minneapolis, MN; St. Paul, MN; Salt Lake City, UT; and Tampa, FL, for 180 days. Restricted: To service performed under continuing contract or contracts with Hearthland Corp., of Columbus, OH. An underlying ETA seeks 90 days authority. Supporting shipper(s): Hearthland Corp., P.O. Box 15361, Columbus, OH 43215. Send protests to: Frank L. Calvary, District Supervisor, 220 Federal Building and U.S. Courthouse, 85 Marconi Boulevard, Columbus, OH 43215.

PASSENGER CARRIER

MC 145548 (Sub-1TA), filed October 20, 1978. Applicant: COMMUNITY TRANSIT LINES, INC., 315 Howe Avenue, Passaic, NJ 07055. Representative: J. G. Dail Jr., P.O. Box LL, McLean, VA 22101. *Passengers and their baggage*, between the junction of the Garden State Parkway and New Jersey Highway 3 in Clifton, NJ and New York, NY, serving all intermediate points between the junction of the Garden State Parkway and New Jersey Highway 3 and the Hackensack River: From junction Garden State Parkway and New Jersey Highway 3 over New Jersey Highway 3 to junction Interstate 495 in North Bergen, NJ, then over Interstate Highway 495 through the Lincoln Tunnel to New York, and return over the same route, for 180 days. An underlying ETA seeks

90 days authority. Supporting shipper(s): There are approximately 5 statements of support attached to the application which may be examined at the Interstate Commerce Commission in Washington, DC, or copies thereof which may be examined at the filed office named below. Send protests to: District Supervisor Joel Morrows, I.C.C., 9 Clinton St., Newark, NJ 07102.

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-33171 Filed 11-27-78; 8:45 am]

[7035-01-M]

[Notice No. 134]

MOTOR CARRIER BOARD TRANSFER PROCEEDINGS

The following publications include motor carrier, water carrier, broker, and freight forwarder transfer applications filed under Sections 212(b), 206(a), 211, 312(b), and 410(g) of the Interstate Commerce Act.

Each application (except as otherwise specifically noted) contains a statement by applicants that there will be no significant effect on the quality of the human environment resulting from approval of the application.

Protests against approval of the application, which may include request for oral hearing, must be filed with the Commission with 30 days after the date of this publication. Failure seasonably to file a protest will be construed as a waiver of opposition and participation in the proceeding. A protest must be served upon applicants' representative(s), or applicants (if no such representative is named), and the protestant must certify that such service has been made.

Unless otherwise specified, the signed original and six copies of the protest shall be filed with the Commission. All protests must specify with particularity the factual basis, and the section of the Act, or the applicable rule governing the proposed transfer which protestant believes would preclude approval of the application. If the protest contains a request for oral hearing, the request shall be supported by an explanation as to why the evidence sought to be presented cannot reasonably be submitted through the use of affidavits.

The operating rights set forth below are in synopses form, but are deemed sufficient to place interested persons on notice of the proposed transfer.

MC-FC-77794, filed August 1, 1978. Transferee: DELIVERY SERVICE CORPORATION, d.b.a. DELIVERY SERVICE, INC., 155 Bignall Street, Warwick, RI 02888. Transferor: Mr. Messenger, Inc., 10 Messenger Drive, Warwick, RI 02888. Representative: John E. Fuyat, Attorney at Law, 1345 Warwick Avenue, Warwick, RI 02888. Authority sought for purchase by transferee of the operating rights of transferor as set forth in Certificates Nos. MC-117243 and MC-117243 (Sub-No. 4), issued January 31, 1972, and May 23, 1975, respectively, as follows: Photo film and photo finishers handling materials (excepting transportation of motion picture film, between Providence, RI, and the Theodore Francis Green Airport, Warwick, RI, and between Providence, RI, and the Theodore Francis Green Airport, Warwick, RI on the one hand, and, on the other points in CT and MA within 25 miles of the Rhode Island State line, restricted to shipments having a prior or subsequent movement by air or rail; dental, medical, and optical supplies, in shipments not exceeding 35 pounds in weight, in retail delivery service, between Providence, RI on the one hand, and, on the other, points in Massachusetts and Connecticut within 25 miles of the Rhode Island State line; and such merchandise as is dealt in retail stores, in retail delivery service, between points in Rhode Island and Connecticut, and points in Bristol, Norfolk, Plymouth, Worcester, and Barnstable Counties, MA and Boston, MA. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under Section 210a(b).

MC-FC-77829, filed August 30, 1978. Transferee: BILL HEAD TRUCKING, INC., 1281 Pine Tree Drive, Birmingham, AL 35235. Transferor: Caravan Refrigerated Cargo, Inc., P.O. Box 6188, Dallas, TX 75222. Representative: John W. Cooper, Attorney at Law, 1927 First Ave. No., 200 Woodward Building, Birmingham, AL 35203. Authority sought for purchase by transferee of portion of the operating rights of transferor as set forth in Certificate No MC-119789 issued August 19, 1963, as follows: Bananas, from Gulfport, MS to points in Alabama (except Montgomery) with no transportation for compensation on return except as otherwise authorized. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under Section 210a(b).

MC-FC-77847, filed September 13, 1978. Transferee: AIM INDUSTRIES, INC., 330 Manhattan Ave., Jersey City, NJ 07307. Transferor: Transloric Trucking Corp., 720 Tonelle Ave., Jersey City, NJ 07307. Representative: Salvatore Guasto, President, Aim Industries, Inc., 330 Manhattan Ave., Jersey City, NJ 07307. Authority sought for purchase by transferee of the operating rights of transferor set forth in Certificate No. MC-134085 issued September 13, 1971, as follows: General commodities (except noninflammable liquids, in bulk, in tank vehicles; automobiles, trucks, chassis, bodies, and cabs; and classes A and B explosives), between points in that part of the New York, NY, Commercial Zone, as defined by the Commission, within which local operations may be conducted pursuant to the partial exemption of Section 203(b)(8) of the Interstate Commerce Act (the "exempt" zone), restrictive to the transportation of traffic having an immediately prior or subsequent movement by water. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under Section 210a(b).

MC-FC-77879, filed September 26, 1978. Transferee: JENSEN TRUCKING CO., INC., P.O. Box 402, American Fork, UT 84003. Transferor: Hi-Line Transport, Inc., 572 East 1700 South, Salt Lake City, UT 84105. Representative: Jack L. Jensen, President-Jensen Trucking Co., In., P.O. Box 402, American Fork, UT 84003. Authority sought for purchase by transferee of the operating rights of transferor as set forth in Certificate No. MC-117415 (Sub-No. 1) issued April 10, 1961, as follows: Lumber, from points in Del Norte, Nodoc, Siskiyou, Lassen, Shasta, Humboldt, Tehama, Butte, Sonoma, Mendocino, and Plumas Counties, CA to points in Box Elder, Cache, Rich, Weber, Morgan, Davis, Wasatch, Summit, Salt Lake, Utah, Duchesne, Uintah, Carbon, Sanpete, Juab, Millard, and Sevier Counties, UT; and returned shipments of lumber, and exempt agricultural commodities moving the same vehicle with returned shipments of lumber, from points in the above named destination counties to points in the above named origin counties. Transferee holds authority in Certificate No. MC-129991 (Sub-No. 1). Application has not been filed for temporary authority under Section 210a(b).

MC-FC-77887, filed October 17, 1978. Transferee: RBL, INC., 325 North Second Street, Terre Haute, IN 47807. Transferor: Ray Wilson, Inc., Hattiesburg, MS 39401. Representative: A. Charles Tell, Attorney at Law, 100 East Broad Street, Columbus, OH 43215. Authority sought for purchase by transferee of the operating rights of transferor as set forth in Certificate No. MC-117998 and the Permit in No. MC-139751 issued July 24, 1961 and March 12, 1975, respectively, as follows: Bananas, from New Orleans, LA to Terre Haute and Indianapolis, IN, DeKalb, IL, and Springfield and St. Louis, MO, from Mobile, AL to Terre

Haute, IN, and from Tampa, FL to Terre Haute, IN; and metal containers ends, from the facilities of Rockford Can Company, at Rockford, IL to Pascagoula, MS. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under Section 210a(b).

MC-FC-77904, filed October 24, 1978. Transferee: FOURWAY EXPRESS, INC., 5 Henshaw Street, Woburn, MA 10801. Transferor: Great East Trucking Corp., 5 Henshaw Street, Woburn, MA 10801. Representative: Mary E. Kelley, Attorney at Law, 11 Riverside Avenue, Medford, MA 02155. Authority sought for purchase by transferee of the operating rights of transferor as set forth in Certificate of Registration No. MC-120847, issued May 15, 1974, as follows: General commodities anywhere within Massachusetts. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under Section 210a(b).

MC-FC-77912, filed October 26, 1978. Transferee: J. B. O. L., INC., 10050 West Roosevelt Road, Westchester, IL 60153. Transferor: Freight Brokers, Inc., 10050 West Roosevelt Road, Westchester, IL 60153. Representative: Eugene L. Cohn, Attorney at Law, One North LaSalle Street, Chicago, IL 60602. Authority sought for purchase by transferee of the operating rights of transferor as set forth in License No. MC-78948 issued April 30, 1959, authorizing transferor to engage in the transportation of general commodities as a broker at Chicago, IL. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under Section 210a(b).

MC-FC-77918, filed October 31, 1978. Transferee: FRATE SERVICE, INC., R.R. 1, East Peoria, IL 61611. Transferor: C.P.T. Freight, Inc., 2600 Calument Avenue, Hammond, IN 46320. Representatives: Eugene L. Cohn, Attorney for transferor, One North LaSalle Street, Chicago, IL 60602; Samuel G. Harrod, Attorney for transferee, Professional Building, Eureka, IL 61530. Authority sought for purchase by transferee of the operating rights of transferor as set forth in Certificate No. MC-1042 (Sub-No. 5), issued March 19, 1968, as follows: Iron and steel articles, from the facility of Jones & Laughlin Steel Corporation, located in Putnam County, IL, to points in Indiana; and materials, equipment, and supplies used in the manufacture and processing of iron and steel articles, from points in Indiana, to the facility of Jones & Laughlin Steel Corporation, located in Putnam County, IL, restricted against the transportation of commodities in bulk. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under Section 210a(b).

H. G. Homme, Jr.,
Secretary.

[FR Doc. 78-33172 Filed 11-27-78; 8:45 am]

[7035-01-M]

[Finance Docket No. 28583 (Sub-No. 22F)]

STANLEY E. G. HILLMAN, TRUSTEE OF THE PROPERTY OF CHICAGO, MILWAUKEE, ST. PAUL AND PACIFIC RAILROAD CO.

Debtor-Trackage Rights Over Burlington Northern, Inc., Between Miles City, MT and Big Sky and Kuehn, MT, a Distance of 138.9 Miles

November 21, 1978.

Stanley E. G. Hillman, Trustee of the Property of Chicago, Milwaukee, St. Paul and Pacific Railroad Company, Debtor (Milwaukee Road), 516 West Jackson Boulevard, Chicago, IL 60606, represented by Thomas H. Ploss, General Solicitor, and William C. Sippel, Attorney, each of the foregoing address hereby gives notice that on November 3, 1978, he filed with the Interstate Commerce Commission at Washington, D.C. an application under section 11344 of Title 49—Transportation, Public Law 95-473 (1978) for an order approving and authorizing a grant trackage rights to permit Milwaukee Road to operate its own locomotives, cars, and trains with its own crews between Miles City and Big Sky and Kuehn, MT, over trackage of Burlington Northern, Inc. (BN), a distance of approximately 138.9 miles. The transaction proposed by Milwaukee Road is subject to the execution of an appropriate agreement between Milwaukee Road and BN. This application is a major market extension and has been accepted and assigned Finance Docket No. 28583 (Sub-No. 22F).

This application has been filed in response to Finance Docket No. 28583 (Sub-No. 1F), Burlington Northern, Inc.—Control and Merger—St. Louis-San Francisco Railway Company. It will be consolidated with Finance Docket No. 28583 (Sub-No. 1F). Milwaukee Road is seeking imposition of these trackage rights as a condition in the event the BN-Frisco merger is approved by the Commission in order to reduce its operating costs and gain additional revenues which would enhance its reorganization on an income basis.

Milwaukee Road operates approximately 9,891 miles of railroad in the States of Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Montana, Nebraska, North Dakota, Oregon, South Dakota, Washington, and Wisconsin.

Milwaukee Road is under the sole control of the U.S. District Court for the Northern District of Illinois, Eastern Division, Judge Thomas R. McMillen, and the trusteeship of Stanley E. G. Hillman. The Chicago Milwaukee Corp. owns 96 percent of the Milwaukee Road's outstanding stock.

Interested persons may participate formally in a proceeding by submitting written comments in regard to the application. Such submissions shall indicate the proceeding designation (F.D. No. 28583 (Sub-No. 22F)), and the original and two copies thereof shall be filed with the Secretary, Interstate Commerce Commission, Washington, D.C. 20423, not later than January 2, 1979. Such written comments shall include the following: the person's position—e.g. party protestant or party in support, regarding the proposed transaction—and specific reasons why approval would or would not be in the public interest. This proceeding has been set for oral hearing. Additionally, interested persons who do not intend to participate formally in a proceeding but who desire to comment thereon, may file such statements and information as they may desire, subject to the filing and service requirements specified herein. Persons submitting written comments to the Commission shall, at the same time, serve copies of such written comments upon applicant, the Secretary of Transportation, the Attorney General, and all parties of record in Finance Docket No. 28583 (Sub-No. 1F).

Dated: November 20, 1978.

By the Commission, Chairman O'Neal, Vice Chairman Christian, Commissioners Brown, Stafford, Gresham, and Clapp. Vice Chairman Christian absent and not participating.

H. G. Homme, Jr.,
Secretary.

[FR Doc. 78-33177 Filed 11-27-78; 8:45 am]

[7035-01-M]

[ICC Order No. P-13]

ATCHISON, TOPEKA & SANTA FE RAILWAY CO.

Passenger Train Operation

November 21, 1978.

It appearing, That the National Railroad Passenger Corporation (Amtrak) has established through passenger train service between Chicago, Illinois, and St. Louis, Missouri; that the operation of these trains requires the use of the tracks and other facilities of the Illinois Central Gulf Railroad Company (ICG) between Chica-

go, Illinois, and St. Louis, Missouri; that these tracks of the ICG are temproarily out of service because of a plant fire; that an alternate route between these points is available via The Atchison, Topeka and Santa Fe Railway Company between Chicago, Illinois, and Joliet, Illinois, thence via ICG from Joliet to St. Louis, Missouri; that the use of such alternate route is necessary in the interest of the public and the commerce of the people; that notice and public procedure herein are impracticable and contrary to the public interest; and that good cause exists for making this order effective upon less than thirty days' notice.

It is ordered,

(a) Pursuant to the authority vested in me by order of the Commission served December 10, 1976, and of the authority vested in the Commission by section 402(c) of the Rail Passenger Service Act of 1970 (45 USC § 562(c)), The Atchison, Topeka and Santa Fe Railway Company is directed to permit use of its tracks and facilities for the movement of trains of the National Railroad Passenger Corporation between Chicago, Illinois, and Joliet, Illinois.

(b) In executing the provisions of this order, the common carriers involved shall proceed even though no agreements or arrangements now exist between them with reference to the compensation terms and conditions applicable to said transportation. The compensation terms and conditions shall be, during the time this order remains in force, those which are voluntarily agreed upon by and between said carriers; or upon failure of the carriers to agree, the compensation terms and conditions shall be as hereafter fixed by the Commission upon petition of any or all of the said carriers in accordance with pertinent authority conferred upon it by the Interstate Commerce Act and by the Rail Passenger Service Act of 1970, as amended.

(c) *Application.* The provisions of this order shall apply to intrastate, interstate and foreign traffic.

(d) *Effective date.* This order shall become effective at 9:30 a.m., CST, November 9, 1978.

(e) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., CST, November 10, 1978, unless otherwise modified, changed or suspended by order of this Commission.

This order shall be served upon The Atchison, Topeka and Santa Fe Railway Company, and upon the National Railroad Passenger Corporation and a copy shall be filed with the Director, Office of the Federal Register.

Issued at Washington, D.C., November 9, 1978.

INTERSTATE COMMERCE COMMISSION,
ROBERT S. TURKINGTON,
Agent.

[FR Doc. 78-33175 Filed 11-27-78; 8:45 am]

[7035-01-M]

[2d Rev. S.O. 1332; Exception 3]

CHICAGO, MILWAUKEE, ST. PAUL AND PACIFIC RAILROAD CO.

Exception to Service Order

NOVEMBER 21, 1978.

Decided November 9, 1978.

By the Board:

The Maine Central Railroad Company (MEC) has purchased one hundred-fifty (150) new boxcars which will be delivered to Chicago, Milwaukee, St. Paul and Pacific Railroad Company (MILW) at Portland, Oregon, for movement to the MEC. MEC has allowed MILW to load these cars on the west coast for movement to the MEC. Reduced loadings of these cars on the MILW to destinations as directed by MEC means the MILW will hold some of the cars beyond the 60 hours permitted in Section (a)(2)(ii) of this order prior to placing of cars for loading.

Order. Pursuant to the authority vested in the Railroad Service Board by Section (a)(1)(v) of Second Revised Service Order No. 1332, Chicago, Milwaukee, St. Paul and Pacific Railroad Company, is authorized to assemble and hold up to one hundred-fifty (150) new Maine Central Railroad Company (MEC) boxcars for loading as directed by MEC, regardless of the provisions of Section (a)(2)(ii) of this order.

These cars shall become fully subject to all provisions of Second Revised Service Order No. 1332 when loading is completed and instructions for forwarding are received from the shipper.

Effective November 9, 1978.

Expires November 30, 1978.

ROBERT S. TURKINGTON,
Acting Chairman,
Railroad Service Board.

[FR Doc. 78-33174 Filed 11-27-78; 8:45 am]

[7035-01-M]

[2d Rev. S.O. 1332; Exception 4]

MARYLAND AND PENNSYLVANIA RAILROAD CO.

Exception to Service Order

NOVEMBER 21, 1978.

Decided November 14, 1978.

By the Board.

The Columbus and Greenville Railway Company (CAGY) has purchased four hundred (400) new boxcars which will be delivered to Maryland and Pennsylvania Railroad Company (MPA) at York, Pennsylvania, for movement to the CAGY. CAGY has allowed MPA to load these cars for movement to the CAGY. Reduced loadings of these cars on the MPA to destinations as directed by CAGY means the MPA will hold some of the cars beyond the 60-hours permitted in Section (a)(2)(ii) of this order prior to placing of cars for loading.

Order. Pursuant to the authority vested in the Railroad Service Board by Section (a)(1)(v) of Second Revised Service Order No. 1332, Maryland and Pennsylvania Railroad Company (MPA) is authorized to assembled and hold up to four hundred (400) new Columbus and Greenville Railway Company (CAGY) boxcars for loading as directed by CAGY, regardless of the provisions of Section (a)(2)(ii) of this order.

These cars shall become fully subject to all provisions of Second Revised Service Order No. 1332 when loading is completed and instructions for forwarding are received from the shipper.

Effective November 15, 1978.

Expires November 30, 1978.

JOEL E. BURNS,
Chairman,
Railroad Service Board.

[FR Doc. 78-33176 Filed 11-27-78; 8:45 am]

[7035-01-M]

[2nd Rev. S.O. No. 1332; Exception 2]

ST. LOUIS SOUTHWESTERN RAILWAY CO. AND SOUTHERN PACIFIC TRANSPORTATION CO.

Exception to Service Order

NOVEMBER 21, 1978.

Decided November 9, 1978.

By the Board.

Because of recent work stoppage on the St. Louis Southwestern Railway Company (SSW) and on other connections of the Southern Pacific Transportation Company (SP), and due to * derailments at Pine Bluff, Arkansas, New Orleans, Louisiana, Klamath Falls, Oregon, and in the vicinity of Roseville, California, the SP and the SSW are temporarily unable to forward all cars within 60 hours as required by Section (a)(4)(i) of Second Revised Service Order No. 1332.

It is ordered, Pursuant to the authority vested in the Railroad Service Board by Section (a)(1)(v) of Second Revised Service Order No. 1332, the SSW and the SP are required to forward loaded cars or empty foreign or private cars from the points named below within 72 hours.

* Change.

SSW	SP
Pine Bluff, Ark	Eugene, Oreg. Roseville, Calif. XXX. West Colton, Calif. XXX. Houston, Tex.

XXX Los Angeles, California, San Antonio, Tex., eliminated.

Effective November 10, 1978.

Expires 11:59 p.m., November 24, 1978.

ROBERT S. TURKINGTON,
Acting Chairman,
Railroad Service Board.

[FR Doc. 78-33173 Filed 11-27-78; 8:45 am]

sunshine act meetings

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
Commodity Credit Corporation	1
Commodity Futures Trading Commission	2
Consumer Product Safety Commission	3, 4
Equal Employment Opportunity Commission	5
Federal Communications Commission	6, 7, 8, 9
Federal Deposit Insurance Corporation	10, 11
Federal Energy Regulatory Commission	12
Federal Reserve System	13
International Trade Commission	14
Nuclear Regulatory Commission	15
Parole Commission	16
Postal Rate Commission	17
Railroad Retirement Board	18
Tennessee Valley Authority	19

[3410-05-M]

1

COMMODITY CREDIT CORPORATION.

TIME AND DATE: 3 p.m., December 5, 1978.

PLACE: Room 218-A, Administration Building, U.S. Department of Agriculture, Washington, D.C.

STATUS: Open meeting.

MATTERS TO BE CONSIDERED:

1. Minutes of CCC Board meeting on October 26, 1978.
2. Docket UCP 101a and UCP 176a re Wool and Mohair payment programs for the 1978 to 1981 marketing years.
3. Docket UCP 72a re 1979 cotton loan and payment program (upland cotton).
4. Docket UCP 72a re 1979 cotton loan program (extra long staple).
5. Docket UCP 105 re 1979-crop soybean loan and purchase program.
6. Docket UCP 137a re 1979-crop barley, corn, oats, rye, and sorghum loan, purchase, payments, set-aside and land diversion programs.
7. Docket UMD 3a re Section 32 diversion of potatoes.
8. Consideration of proposals for pilot industrial hydrocarbon and alcohol projects.

CONTACT PERSON FOR MORE INFORMATION:

Bill Cherry, Secretary, Commodity Credit Corporation, Room 202-W, Administration Building, U.S. Department of Agriculture, Washington, D.C. 20013, telephone 202-447-7583.

[S-2390-78 Filed 11-24-78; 11:37 am]

[6351-01-M]

2

COMMODITY FUTURES TRADING COMMISSION.

TIME AND DATE: 3 p.m., November 27, 1978.

PLACE: 2033 K Street NW., Washington, D.C., 8th floor conference room.

STATUS: Closed.

MATTERS TO BE CONSIDERED. Personnel.

CONTACT PERSON FOR MORE INFORMATION:

Jane Stuckey, 254-6314.

[S-2393-78 Filed 11-24-78; 12:05 pm]

[6355-01-M]

3

CONSUMER PRODUCT SAFETY COMMISSION.

DATE AND TIME: Wednesday, November 29, 1978, 10 a.m.

LOCATION: Room 456, Westwood Towers Bldg., Bethesda, Md.

STATUS: partly open, partly closed.

MATTERS TO BE CONSIDERED:

AGENDA

OPEN TO THE PUBLIC

1. *Briefing on cellulose insulation labeling rule.* The staff will brief the Commission on issues related to a draft labeling and notification for cellulose insulation, to be issued under section 27(e) of the Consumer Product Safety Act.

2. *Briefing on Denver insulation petition.* In October 1976, the Metropolitan Denver District Attorney's Office petitioned the Commission to set standards for home insulation. The Commission has granted the petition as to cellulose insulation. At this briefing, the staff will brief the Commission on the remaining issues of the petition, plastic foam and fibrous glass insulation.

CLOSED TO THE PUBLIC

3. *Enforcement of sharp points/edges technical requirements.* The staff will discuss issues related to enforcement of the technical requirements the Commission has issued for sharp points and sharp edges on toys and other children's products. (Closed under exemption 9: possible significant frustration of agency action.)

Agenda approved November 17, 1978.

CONTACT PERSON FOR ADDITIONAL INFORMATION:

Sheldon B. Butts, Assistant Secretary, Office of the Secretary, Consumer Product Safety Commission, Suite 300, 1111 18th Street NW., Washington, D.C. 20207, telephone 202 634-7700.

[S-2394-78 Filed 11-24-78]

[6355-01-M]

4

CONSUMER PRODUCT SAFETY COMMISSION.

DATE AND TIME: Thursday, November 30, 1978, 9:30 a.m.

LOCATION: Third floor hearing room, 1111 18th Street NW., Washington, D.C. 20207.

STATUS: Open.

MATTERS TO BE CONSIDERED.

AGENDA

OPEN TO THE PUBLIC

1. *Decision on Christmas tree lights.* The Commission will consider options for action on a recommended product safety rule for miniature Christmas tree lights. The staff briefed the Commission on this matter at the November 15 briefing.

2. *Decision on definition of "glazed panels".* The Commission will consider issues related to the definition of "glazed panel" in its Safety Standard for Architectural Glazing Materials. This will include consideration of two related petitions. CP 78-10 from Elwood Buck, and CP 78 18 from the National Glass Dealers Association. The staff and representatives of building codes organizations briefed the Commission on these issues at the November 15 briefing.

3. *Recommendation to accept corrective action plan: Bassett Furniture Industries, Inc., full-size cribs, ID 78-51.* The staff has recommended that the Commission accept and monitor the corrective action plan which Bassett has implemented to deal with possible hazards associated with certain cribs Bassett manufactured.

4. *Recommendation to accept corrective action plan: AMF/Harley Davidson Motor Co. golf cars, ID 78-100.* The staff has recommended that the Commission accept the corrective action plan which this firm has implemented to deal with possible hazards associated with certain golf cars it manufactures.

Agenda approved November 17, 1978.

CONTACT PERSON FOR ADDITIONAL INFORMATION:

Sheldon D. Butts, Assistant Secretary, Office of the Secretary, Consumer Product Safety Commission, Suite 300, 1111 18th Street NW., Washington, D.C. 20207, telephone 202-634-7700.

[S-2395-78 Filed 11-24-78; 3:04 pm]

[6570-06-M]

5

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: S-2334-78 and S-2354-78.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 9:30 a.m. (eastern time), Monday, November 27, 1978.

CHANGE IN THE MEETING: Canceled.

The only matter scheduled for this meeting was consideration of final affirmative action guidelines. The matter is postponed until further notice.

CONTACT PERSON FOR MORE INFORMATION:

Marie D. Wilson, Executive Officer, Executive Secretariat, at 202-634-6748.

This notice issued November 22, 1978.

[S-2401-78 Filed 11-24-78; 3:04 pm]

[6712-01-M]

6

FEDERAL COMMUNICATIONS COMMISSION.

TIME AND DATE: 9 a.m., Wednesday, November 29, 1978.

PLACE: Room 856, 1919 M Street NW., Washington, D.C.

STATUS: Special closed Commission meeting.

MATTERS TO BE CONSIDERED:

Agenda, Item No., and Subject

General—1—Commission briefing on the CCIR Special Preparatory Meeting for WARC 1979.

General—2—Subpoena of FCC records by A.T. & T. in connection with *United States* v. *A.T. & T. et al.*, Civil Action No. 74-1698 (D.D.C.).

This meeting may be continued the following workday to allow the Commission to complete appropriate action.

Additional information concerning this meeting may be obtained from the FCC Public Information Office, telephone 202-632-7260.

Issued: November 24, 1978.

[S-2398-78 Filed 11-24-78; 3:04 pm]

[6712-01-M]

7

FEDERAL COMMUNICATIONS COMMISSION.

TIME AND DATE: 9:30 a.m., Thursday, November 30, 1978.

PLACE: Room 856, 1919 M Street NW., Washington, D.C.

STATUS: Closed Commission meeting.

MATTERS TO BE CONSIDERED:

Agenda, Item No., and Subject

Hearing—1—Questions addressed to the Commission by the United States Court of Appeals for the District of Columbia Circuit concerning the Beaufort, S.C., AM revocation proceeding (Docket No. 19886).

Hearing—2—Certification to the Commission in the Eaton, Ohio, Construction permit proceeding (Docket No. 20832).

Hearing—3—Petition to terminate hearing and for other belief in the Centerville, Utah, FM proceeding for construction permit (Docket No. 20460).

General—1—Instructions to Bureau Chiefs and Staff Officers regarding internal Affirmative Action for Minorities and Women.

This meeting may be continued the following workday to allow the Commission to complete appropriate action.

Additional information concerning this meeting may be obtained from FCC Public Information Office, telephone 202-632-7260.

Issued: November 24, 1978.

[S-2399-78 Filed 11-24-78; 3:04 pm]

[6712-01-M]

8

FEDERAL COMMUNICATIONS COMMISSION.

TIME AND DATE: 9:30 a.m., Thursday, November 30, 1978.

PLACE: Room 856, 1919 M Street NW., Washington, D.C.

STATUS: Open Commission meeting.

MATTERS TO BE CONSIDERED:

Agenda, Item No., and Subject

Hearing—1—Motion for stay in the Omaha, Nebrasha/Council Bluffs, Iowa consolidated AM/FM comparative licensing proceeding (Docket Nos. 78-33-78-345).

General—1—Rule adjustments in light of the Sunshine Act.

General—2—Renewal of the Advisory Committee for Cable Signal Leakage and the Radio Technical Commission for Marine Services as Federal Advisory Committees.

General—3—Petitions for Special Relief filed by Citizens Communications Center requesting approval of reimbursement provisions contained in certain licensee-citizens group agreements.

General—4—Amendment of Parts 1, 81 and 83 of the Commission's Rules to implement a system of temporary authorizations for ship stations in the Maritime Services.

General—5—Report to the Commission regarding public participation in FCC Rulemaking Proceeding Workshops.

Safety and Special Radio Services—1—Applications for review of action taken which dismissed applications of Arthur W. Brothers for authorization of new public coast class III-B stations at Boulder Peak and Boulder City, Nevada.

Common Carrier—1—Petition for Rulemaking (RM-2875) filed by Common Cause on April 1, 1977.

Common Carrier—2—Memorandum Opinion and Order denying an application for review filed by ITT World Communications, Inc., directed against a delegated action by the Chief, Common Carrier Bureau granting the joint application of Telenet Communications Corp. and Hawaiian Telephone Co.

Common Carrier—3—Petition for Partial Reconsideration of *American Television Relay, Inc. (ATRII).*

Common Carrier—4—Reconsideration of ATR Refund.

Common Carrier—5—Extension of Time Limit for Adoption of Rules and Technical Standards for Cellular Mobile Radio Communications Systems.

Common Carrier—6—Regulation of domestic satellite receive-only earth stations.

Common Carrier—7—Applications of All America Cables and Radio, Inc., to construct an additional antenna and associated equipment, acquire, install and operate channelizing equipment at the Cayey, P.R., Earth station, (File Nos. 20-DSE-P-74 and DS-AA-1) and application of Communications Satellite Corp. to discontinue service via the Cayey, P.R., Earth station and to transfer ownership to All Amercia Cables and Radio, Inc. (File No. I-P-D-5).

Cable Television—1—"Petition for Special Relief" (CSR-1287) filed by the New York State Commission on Cable Television.

Cable Television—2—Edward Dunn (McKean County, Pa.) CT Docket No. 78-109.

Assignment and Transfer—1—Application of North Dakota Broadcasting Co., Inc., to transfer control of North American Communications Corp., KXJB-TV, Valley City, N. Dak., to Central Minnesota Television Co., and a Petition to Deny filed by Spokane Television Inc., licensee of Television Station KTHI-TV, Valley City, N. Dak.

Renewal—1—Up-dated EEO programs which include minority/female hiring goals.

Renewal—2—Petition to deny the application of the Georgia State Board of Education for renewal of license for WVAN-TV, Savannah-Pembroke, Ga., filed by the Savannah Branch of the National Association for the Advancement of Colored People.

Renewal—3—Renewal applications of Communico Oceanic Corp. for Stations KPOI and KHSS(FM) Honolulu, Hawaii, and Pe-

tition for Emergency and Extraordinary Relief, filed by licensee on October 4, 1978.

Renewal—4—Petition for reconsideration of decision granting B & H Broadcasting Co. waiver of the ascertainment documentation and reporting requirements for Stations WHMI-AM-FM, Howell, Mich.; Requests of seven other licensees for waivers and small market exemption—evaluation to date.

Aural—1—Application to construct a new daytime commercial AM station filed by Dennis F. Doelitzsch, Johnston City, Ill.; petition to deny application by Meredith Corp., KCMO(AM), Kansas City, Mo., and petition to deny application by Greentree Broadcasting Co., WJPF (AM), Herrin, Ill.

Complaints and Compliance—1—Violation by United Broadcasting Co. Station WOOK(FM), Washington, D.C.

Complaints and Compliance—2—Requests for a declaratory ruling concerning the meaning of the phrase "program or any part thereof" in Section 325(a) of the Act.

This meeting may be continued the following workday to allow the Commission to complete appropriate action.

Additional information concerning this meeting may be obtained from FCC Public Information Office, telephone 202-632-7260.

Issued: November 24, 1978.

[S-2400-78 Filed 11-24-78; 3:04 pm]

[6712-01-M]

9

FEDERAL COMMUNICATIONS COMMISSION.

TIME AND DATE: 9:30 a.m., 10:30 a.m. and 2 p.m., Tuesday, November 28, 1978.

PLACE: Room 856, 1919 M Street NW., Washington, D.C.

STATUS: Oral arguments and closed instructions following oral arguments.

MATTERS TO BE CONSIDERED:

The Commission will hold a closed meeting on Tuesday, November 28, 1978, for the purpose of issuing instructions to the staff following oral arguments on Walton Broadcasting, Inc., Tucson, Ariz., standard broadcast station renewal proceeding (Docket No. 20287); WHAM and WHFM, Rochester, N.Y., broadcast renewal proceeding (Docket No. 20477) and renewal application of New Mexico Broadcasting Co., Inc. for television station KGGM-TV, Albuquerque, N. Mex. (Docket No. 20540).

Oral argument, which is open to the public, is scheduled to start at 9:30 a.m. on KGGM-TV, 10:30 a.m. on Walton Broadcasting, Inc., and 2 p.m. on WHAM and WHFM, in Room 856, 1919 M Street NW., Washington, D.C.

Additional information concerning this meeting may be obtained from the FCC Public Information Office, telephone 202-632-7260.

Issued: November 21, 1978.

[S-2389-78 Filed 11-24-78; 11:37 am]

[6714-01-M]

10

FEDERAL DEPOSIT INSURANCE CORPORATION.

TIME AND DATE: 2 p.m., November 30, 1978.

PLACE: Board Room, 6th floor, FDIC Building, 550 17th Street NW., Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Disposition of minutes of previous meetings.

Request by the Comptroller of the Currency for a report on the competitive factors involved in the proposed merger of National Bank & Trust Co. of Gloucester County, Woodbury, N.J., and the National Bank of Mantua, Sewell, N.J.

Recommendation regarding liquidation of a bank's assets acquired by the Corporation in its capacity as receiver, liquidator or liquidating agent of those assets:

Case No. 43,721-L—Bank of Black Mountain, Black Mountain, N.C.

Recommendations with respect to payment for legal services rendered and expenses incurred in connection with receivership and liquidation activities:

Schall, Boudreau & Gore, San Diego, Calif., in connection with the receivership of United States National Bank, San Diego, Calif.

Bronson, Bronson & McKinnon, San Francisco, Calif., in connection with the liquidation of First State Bank of Northern California, San Leandro, Calif. (two memorandums).

Powell, Goldstein, Frazer & Murphy, Atlanta, Ga., in connection with the liquidation of the Hamilton Bank & Trust Co., Atlanta, Ga.

Chapman & Cutler, Chicago, Ill., in connection with the liquidation of the Drovers' National Bank of Chicago, Chicago, Ill.

Patterson & Patterson, Whitfield, Manikoff & White, Bloomfield Hills, Mich., in connection with the receivership of Birmingham Bloomfield Bank, Birmingham, Mich.

Kaye, Scholer, Fierman, Hays & Handler, New York, N.Y., in connection with the receivership of American Bank & Trust Co., New York, N.Y.

Atkinson, Mueller & Dean, New York, N.Y., in connection with the liquidation of Franklin National Bank, New York, N.Y.

Kaye, Scholer, Fierman, Hays & Handler, New York, N.Y., in connection with the liquidation of Franklin National Bank, New York, N.Y.

Schneider, Smeltz, Huston & Bissell, Cleveland, Ohio, in connection with the liquidation of Northern Ohio Bank, Cleveland, Ohio.

O'Neill & Borges, Hato Rey, P.R., in connection with the liquidation of Banco Credito y Ahorro Ponceno, Ponce, P.R. (five memorandums).

Hansell, Post, Brandon & Dorsey, Atlanta, Ga., in connection with the liquidation of the Hamilton National Bank of Chattanooga, Chattanooga, Tenn.

Strasburger & Price, Dallas, Tex., in connection with the liquidation of the Hamilton National Bank of Chattanooga, Chattanooga, Tenn.

Meredith, Donnell & Edmonds, Corpus Christi, Tex., in connection with the liquidation of Northeast Bank of Houston, Houston, Tex.

Memorandum and resolution proposing the adoption of a statement of policy, and the publication for comment of proposed amendments to Part 337 of the Corporation's rules and regulations, regarding income derived from the sale by bank insiders of credit life, health or accident insurance to loan customers of insured State nonmember banks.

Resolution authorizing a contribution by the Corporation to the "Minority Bank Development Program."

Proposed amendments to the current delegations of authority relating to the Manning Table and to the Budget of Administrative Expenses.

Reports of committees and officers:

Minutes of the actions approved by the Committee on Liquidations, Loans and Purchases of Assets pursuant to authority delegated by the Board of Directors.

Reports of the Director of the Division of Bank Supervision with respect to applications or requests approved by him and the various Regional Directors pursuant to authority delegated by the Board of Directors.

Reports of security transactions authorized by the Acting Chairman.

CONTACT PERSON FOR MORE INFORMATION:

Alan R. Miller, Executive Secretary, 202-389-4446.

[S-2396-78 Filed 11-24-78; 3:04 pm]

[6714-01-M]

11

FEDERAL DEPOSIT INSURANCE CORPORATION.

TIME AND DATE: 2:30 p.m., November 30, 1978.

PLACE: Board Room, 6th floor, FDIC Building, 550 17th Street, NW., Washington, D.C.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Applications for Federal deposit insurance:

Growers & Merchants State Bank, a proposed new bank to be located at the southwest corner of the McCall Village Shopping Center, 3700 North McCall Avenue, Selma, Calif., for Federal deposit insurance.

Bank of Gibson City, a proposed new bank to be located at the junction of U.S. Route 54 and Illinois Routes 47 and 9, Gibson City, Ill., for Federal deposit insurance.

Colonial Banking Co., a proposed new bank to be located at 3600 Merlin Road, Grants Pass (Merlin), Oreg., for Federal deposit insurance.

Peoples Bank of Crossville, a proposed new bank to be located on Route 11, Tennessee Highway 127, approximately one-half mile south of the county courthouse, Crossville, Tenn., for Federal deposit insurance.

Citizens Bank of Marysville, a proposed new bank to be located at the southeast corner of 10th and State Avenue, Marysville, Wash., for Federal deposit insurance.

Marshall County Industrial Financing Corp., and operating industrial loan company converting to an industrial bank, located at 526 Seventh Street, Moundsville, W. Va., for Federal deposit insurance.

Applications for consent to establish branches:

Lloyds Bank California, Los Angeles, Calif., for consent to establish branches in the vicinity of the intersection of Dublin Boulevard and Golden Gate Drive, Dublin, Calif., and at the intersection of North Texas Street and Atlantic Avenue, Fairfield, Calif.

Application for consent to purchase assets, assume liabilities, and establish a branch:

Bank of Sonoma County, Santa Rosa, Calif., an insured State nonmember bank, for consent to purchase the assets of and assume the liability to pay deposits made in the Healdsburg branch of the First National Bank of Cloverdale, Cloverdale, Calif., and for consent to establish the Healdsburg branch as a branch of Bank of Sonoma County.

Applications for consent to merge and establish branches:

La Jolla Bank & Trust Co., La Jolla, Calif., an insured State nonmember bank, for consent to merge, under its charter and title, with West Coast National Bank, Oceanside, Calif., and for consent to establish the five offices of West Coast National Bank as branches of the resultant bank.

First American Bank of North Palm Beach, North Palm Beach, Fla., an insured State nonmember bank, for consent to merge under its charter, and with the title of "First American Bank of Palm Beach County," with First American Bank of Lake Worth, National Association, Lake Worth, Fla., and for consent to establish the main office and three branches of First American Bank of Lake Worth, National Association, as branches of the resultant bank.

Flagship Bank of Orlando, Orlando, Fla., an insured State nonmember bank, for consent to merge under its charter and title with Flagship Bank of West Orlando, N.A., Orlando, Fla., and for consent to establish the sole office of Flagship Bank of West Orlando, N.A., as a branch of the resultant bank.

Flagship Peoples Bank of Tallahassee, Tallahassee, Fla., an insured State nonmember bank, for consent to merge under its charter and title with Flagship American Bank of Tallahassee, Tallahassee, Fla., and for consent to establish the sole office of Flagship American Bank of Tallahassee as a branch of the resultant bank.

Burlington County Trust Co., Moorestown, N.J., an insured State nonmember bank, for consent to merge with Bank of West Jersey, Delran Township (P.O. Delran), N.J., under the charter and title of Burlington County Trust Co., and for consent to establish the four offices of Bank of West Jersey as branches of the resultant bank.

Recommendations regarding the liquidation of a bank's assets acquired by the Corporation in its capacity as receiver, liquidator, or liquidating agent of those assets:

Case No. 42,971-L (Addendum)—Algoma Bank, Algoma, Wis.

Case No. 43,699-L—State Bank of Clearing, Chicago, Ill.

Case No. 43,707-L—American Bank & Trust, Orangeburg, S.C.

Case No. 43,709-L—Bank of Commerce, Tonkawa, Okla.

Case No. 43,710-L—American Bank & Trust, Orangeburg, S.C.

Case No. 43,713-L—The Hamilton National Bank of Chattanooga, Chattanooga, Tenn.

Case No. 43,716-L—American City Bank & Trust Co., National Association Milwaukee, Wis.

Case No. 43,718-NR—United States National Bank, San Diego, Calif.

Case No. 43,719-L—Wilcox County Bank, Camden, Ala.

Case No. 43,722-L—The Drovers' National Bank of Chicago, Chicago, Ill.,

Memorandum re Franklin National Bank, New York, N.Y.

Memorandum re Northern Ohio Bank, Cleveland, Ohio.

Recommendations with respect to payment for legal services rendered and expenses incurred in connection with receivership and liquidation activities:

Bronson, Bronson & McKinnon, San Francisco, Calif., in connection with the receivership of United States National Bank, San Diego, Calif.

Sullivan & Worcester, Boston, Mass., in connection with the receivership of Surety Bank & Trust Co., Wakefield, Mass. (3 memorandums).

Recommendations with respect to the initiation or termination of cease-and-desist proceedings, termination-of-insurance proceedings, or suspension or removal proceedings against certain insured banks or officers or directors thereof:

Names of persons and names and locations of banks authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(6), (c)(8), and (c)(9)(A)(ii) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(6), (c)(8), and (c)(9)(A)(ii)).

Personnel actions regarding appointments, promotions, administrative pay increases, reassignments, retirements, separations, removals, etc.:

Names of employees authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(2) and (c)(6) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(2) and (c)(6)).

Reports of committees and officers:

Audit Report: Franklin National Bank Liquidation, New York, N.Y., dated August 4, 1978.

Audit Report: Travel Voucher Process—Phase II, Processing Procedures and Financial Reporting, dated August 11, 1978.

Audit Report: Service Branch Purchasing Function, dated August 25, 1978.

Audit Report: Asset No. R-328, Treetops Condominiums, Hamilton National Bank Liquidation, dated November 2, 1978.

CONTACT PERSON FOR MORE INFORMATION:

Alan R. Miller, Executive Secretary, 202-389-4446.

[S-2397-78 Filed 11-24-78; 3:04 pm]

[6740-02-M]

12

FEDERAL ENERGY REGULATORY COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 43 FR 55055, published November 24, 1978.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 10 a.m., November 27, 1978.

CHANGE IN THE MEETING: The meeting scheduled for November 27, 1978, at 10 a.m. has been changed to November 27, 1978, at 9 a.m.

KENNETH F. PLUMB,
Secretary.

[S-2391-78 Filed 11-24-78; 11:37 am]

[6210-01-M]

13

FEDERAL RESERVE SYSTEM (BOARD OF GOVERNORS).

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 43 FR 53897, November 17, 1978.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Following 10 a.m. open portion, Wednesday, November 22, 1978.

CHANGES IN THE MEETING: One of the items announced for inclusion at this meeting was consideration of any agenda items carried forward from a previous meeting; the following such closed item was added:

Proposed salary structure adjustments at Federal Reserve Banks. (This matter was originally announced for a meeting on Friday, November 17, 1978.)

CONTACT PERSON FOR MORE INFORMATION:

Mr. Joseph R. Coyne, Assistant to the Board, 202-452-3204.

Dated: November 22, 1978.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[S-2385-78 Filed 11-24-78; 11:37 am]

[7020-02-M]

14

[USITC SE-78-59]

INTERNATIONAL TRADE COMMISSION.

TIME AND PLACE: 10 a.m., Thursday, December 7, 1978.

PLACE: Room 117, 701 E Street NW., Washington, D.C. 20436.

STATUS: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

Portions open to the public:

1. Agenda.
2. Minutes.
3. Ratifications.
4. Petitions and complaints (if necessary).
6. Any items left over from previous agenda.

Portions closed to the public:

5. Status report on Investigation 332-101 (MTN Study), if necessary.

CONTACT PERSON FOR MORE INFORMATION:

Kenneth R. Mason, Secretary, 202-523-0161.

[S-2392-78 Filed 11-24-78; 11:34 am]

[7590-01-M]

15

NUCLEAR REGULATORY COMMISSION.

TIME AND DATE: Week of November 27, 1978 (includes changes).

PLACE: Commissioners' Conference Room, 1717 H Street NW., Washington, D.C.

STATUS: Open and Closed.

MATTERS TO BE CONSIDERED:

MONDAY, NOVEMBER 27 (REVISED) 1:30 P.M.

1. Discussion of personnel matter (approximately 1½ hours, closed—exemption 6).
2. Discussion of proposed Commission response to IRG Report on Waste Management (approximately 1 hour, public meeting).

TUESDAY, NOVEMBER 28; 10 A.M.

1. Briefing by American Electric Power Co. on new nuclear projects (approximately 1 hour, public meeting).
2. Briefing on Reactor licensing schedules (approximately 1 hour, public meeting).

FRIDAY, DECEMBER 1:10 A.M.

1. Briefing on report of the NRC/EPA Task Force on Emergency Planning (approximately 1 hour, public meeting).

CONTACT PERSON FOR MORE INFORMATION:

Walter Magee, 202-634-1410.

ADDITIONAL INFORMATION: The executive branch briefing scheduled for Friday, November 17, was held as scheduled and continued on Monday, November 20.

WALTER MAGEE,
Office of the Secretary.

[S-2387-78 Filed 11-24-78; 11:37 a.m.]

[4410-01-M]

16

PAROLE COMMISSION (National Commissioners—the Commissioners presently maintaining offices at Washington, D.C. Headquarters).

TIME AND DATE: 9:30 a.m., November 21, 1978.

PLACE: Room 500, 320 First Street NW., Washington, D.C.

STATUS: Open or closed pursuant to a vote to be taken at the beginning of the meeting.

CHANGES IN THE MEETING: On November 21, 1978, the Commission determined that the date and time for the above meeting be changed to Wednesday, November 22, 1978, at 9:30 a.m.; and that the above change be announced at the earliest practicable time.

CONTACT PERSON FOR MORE INFORMATION:

Lee H. Chait, Analyst, 202-724-3117.

[S-2402-78 Filed 11-24-78; 3:04 pm]

[7715-01-M]

17

POSTAL RATE COMMISSION.

TIME AND DATE: 2 p.m., Tuesday, November 28, 1978.

PLACE: Conference Room, Room 500, 2000 L Street NW., Washington, D.C.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Draft opinion and recommended decision in Docket No. MC77-2. Closed pursuant to 5 U.S.C. 552b(c)(10).

CONTACT PERSON FOR MORE INFORMATION:

Ned Callan, Information Officer, Postal Rate Commission, Room 500, 2000 L Street NW., Washington, D.C. 20268, telephone 202-254-5614.

[S-2403-78 Filed 11-24-78; 3:04 pm]

[7905-01-M]

18

RAILROAD RETIREMENT BOARD.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: November 20, 1978.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 9:30 a.m., November 28, 1978.

CHANGES IN THE MEETING: Additional item to be considered at the closed meeting:

(12) Appeal from referee's denial of disability annuity application, Robert E. Bigger.

CONTACT PERSON FOR MORE INFORMATION:

R. F. Butler, Secretary of the Board, COM No. 312-751-4920; FTS No. 387-4920.

[S-2388-78 Filed 11-24-78; 11:37 am]

[8120-01-M]

19

TENNESSEE VALLEY AUTHORITY.

TIME AND DATE: 10:30 a.m. (C.S.T.), Thursday, November 30, 1978.

PLACE: Auditorium of TVA's National Fertilizer Development Center, Muscle Shoals, Ala.

STATUS: Open.

MATTERS FOR ACTION:

OLD BUSINESS

No. 1. Quarterly rate review and proposal for elimination of monthly fuel cost and purchased power adjustment.

No. 2. Project Authorization No. 3390—Develop nuclear spent fuel storage alternatives (Phase I).

No. 3. Revised TVA policy codes to implement changes in policy discussed by the Board at the November 16 meeting regarding reclamation requirements in coal purchase contracts.

No. 4. Sale at public auction of 13.93 acres of land on White Bridge Road in Davidson County, Tennessee, acquired by TVA for a power service center site—Tract XNVSC-8.

NEW BUSINESS

B—Consulting and personal service contracts

1. Renewal of consulting contract with Sheppard T. Powell Associates, Baltimore, Md., for advice and assistance in the field of chemical engineering, requested by the Office of Engineering Design and Construction.

C—Purchase awards

1. Req. 823912—Furnish all necessary labor, tools, equipment, and materials to construct reinforced drilled pier foundations for the proposed Yellow Creek Nuclear Plant.
2. Req. No. 572850—Indefinite quantity term contract for carbon steel sheets, coils and strips (nuclear) for various TVA projects and warehouses.
3. Amendment to contracts 76K38-86163-1 with Atwood and Morrill Co., Inc.; 76K38-86163-2 with Rockwell International Corp.; 76K38-86163-3 with BIF-A Unit of General Signal Corp.; and 77K38-86163-8 with Nuclear Valve Division, Borg-Warner Corp. for motor-operated and manual valves for the Bellefonte Nuclear plant.
4. Amendment to contract 78P-42-T30 with Falcon Coal Co., Inc., for coal for TVA steam plants.
5. Req. No. 822080 (Reissue)—Requirement contract for metal cable trays and fittings for the Hartsville and Phipps Bend Nuclear Plants.

6. Rejection of bids received in response to Invitation No. 824481 for spent fuel storage racks for Bellefonte Nuclear Plant.

D—Project authorizations

1. No. 3392—Pilot-plant production of granular fertilizer by the pipecross granulation process.

2. No. 511.7—Continuation of farm test demonstrations outside the Valley as part of the TVA fertilizer program.

3. No. 3388—Convert the East Bowling Green-Scottsville, Ky., 69-kV transmission line to 161-kV operations.

E—Fertilizer items

1. Supplemental letter agreement between TVA and the International Fertilizer Development Center covering arrangements for library services.

F—Power items

1. New power contract with Blue Ridge Mountain Electric Membership Corp.

2. New power contract with Tallahatchie Valley Electric Power Association.

3. New power contract with the city of Humboldt, Tenn.

4. New power contract with the Mayor and Aldermen of Ripley, Tenn.

5. Amendment to lease and amendatory agreement TV-44653A with Gibson County Electric Membership Corp. providing for exercise of option to purchase TVA's Rutherford 69-kV Substation site; and deed covering sale of the substation site to the Gibson County Electric Membership Corp.

6. Proposed agreements and bonding arrangements to facilitate continued milling of TVA ore at Federal-American Partners uranium mill in Gas Hills area of Wyoming.

G—Real property transactions

1. Grant of 30-year easement to Union County, Tenn., for commercial recreation facilities, affecting approximately 50 acres of Norris Reservoir Land—Tract XTNR-82RE.

2. Grant of 30-year public recreation easement to Meigs County, Tenn., for a county park, affecting approximately 240 acres of Watts Bar Reservoir Land—Tract XTWBR-129RE.

3. Filing of condemnation suits.

H—Unclassified

1. Letter agreement with the Department of Energy covering arrangements for Oak Ridge National Laboratory to conduct fluidized bed combustion studies for TVA.

2. Interagency agreement with the Department of Energy covering arrangements for studies to analyze the impact of wind-powered generation on the electric power system.

[S-2386-78 Filed 11-24-78; 11:37 am]

Federal Register

TUESDAY, NOVEMBER 28, 1978
PART II



DEPARTMENT OF HEALTH EDUCATION, AND WELFARE

Office of Human Development Services

■

RUNAWAY YOUTH PROGRAM

Administration Requirements

[4110-92-M]

Title 45—Public Welfare

CHAPTER XIII—OFFICE OF HUMAN DEVELOPMENT SERVICES, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PART 1351—RUNAWAY YOUTH PROGRAM

AGENCY: Office of Human Development Services, HEW.

ACTION: Final rule.

SUMMARY: These regulations establish the requirements that govern the administration of the Runaway Youth Program grants. They provide information necessary for grantees and potential grantees, and runaway or otherwise homeless youth and their families, to clearly understand the purpose of the Runaway Youth Program. Written comments, suggestions, and objections to the Notice of Proposed Rulemaking published in the FEDERAL REGISTER on February 23, 1978 (43 FR 7600) were carefully considered in developing these final regulations. Decisions reached and changes made are explained. The basis for these regulations is the Runaway Youth Act, Title III, Juvenile Justice and Delinquency Prevention Act of 1974, as amended by the Juvenile Justice Amendments of 1977.

DATE: November 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Mrs. Patricia T. Jefferson, Youth Development Bureau, Administration for Children, Youth and Families, Office of Human Development Services, DHEW, 330 Independence Avenue, SW., Washington, D.C. 20201, 202-245-2862

SUPPLEMENTARY INFORMATION: The Runaway Youth Act provides financial assistance to develop or strengthen proposed or existing runaway youth projects. These projects are community-based facilities designed to take care of the immediate needs (temporary shelter, counseling, and aftercare services) of runaway or otherwise homeless youth, and their families. The law mandates that grantee organizations or agencies be outside the law enforcement structure and the juvenile justice system. The statute also makes provision for technical assistance and short-term training. Those eligible for grants are: States, localities, and private nonprofit agencies, and coordinated networks of private nonprofit agencies. HEW is revising its Runaway Youth Program regulations (41 FR 54296), December 13, 1976, (45 CFR Part 1351) in order to:

(1) Implement the Juvenile Justice Amendents of 1977 relating to the Runaway Youth Program;

(2) Clarify and simplify the existing regulations under HEW's Operation Common Sense. The aim of Operation Common Sense is to produce readable and understandable regulations which reflect Congressional intent and which do not unnecessarily regulate consumers and providers, including State and local governments; and

(3) Carry out the goals of the President's zero-based review of Federal planning requirements. The purpose of the zero-based review is to eliminate unnecessary, burdensome requirements.

1977 RUNAWAY YOUTH ACT AMENDMENTS

The 1977 Amendments give priority to applicants whose grant request to provide services to runaway or otherwise homeless youth is less than $100,000. Priority is also given to applicants whose total project budgets, considering all funding sources, are less than $150,000. Previously these dollar thresholds were $75,000 and $100,000, respectively. The amendments also require that crisis care services be provided to otherwise homeless youth, as well as runaway youth and their families. HEW is also authorized to provide short-term training to runaway or otherwise homeless youth service providers. Coordinated networks of nonprofit private agencies are now eligible for grant assistance in addition to States, localities, and individual nonprofit private agencies.

In the original Act, client records could only be released with the consent of the parent or legal guardian. However, the Department included in the regulations published in the FEDERAL REGISTER on December 13, 1976, provisions for the consent of the youth and parents or legal guardians prior to the release of records. In the amendments, Congress acknowledged and affirmed the Department's decision for joint consent through legislative mandate in Section 7(a)(3) of the 1977 amendments (which amends Section 312(b)(6) of the original Act.

SUBPARTS

For the purposes of clarity, the final regulations for Part 1351, the Runaway Youth Program, are divided into three basic subparts. These subparts, and significant regulations contained in them, are discussed separately to describe any changes made to the Notice of Proposed Rulemaking published in the FEDERAL REGISTER on February 23, 1978. The purpose of the subpart and its basis is also given.

Subpart A, *Definition of Terms*, defines significant terms used in the Act and these regulations. This subpart includes new terms—for example, "coordinated networks of agencies", "homeless youth", and "short-term training". It deletes certain definitions which are unnecessary or redundant. Other definitions have been revised to clarify administrative policy and to reaffirm particular administrative decisions reflected in the proposed regulations published in the FEDERAL REGISTER on February 23, 1978.

The definition for "coordinated networks of agencies" was revised to mean only private nonprofit agencies. This is based on an analysis of public comments and a legal opinion within the Department.

The provisions of Subpart B, *Runaway Youth Program Grant*, pertain to the purpose of the Runaway Youth Act and provide rules regarding grant applications and the use of grant funds.

Section 1351.14 incorporates provisions regarding application for continued grant support. These provisions were not included in the proposed rulemaking because the Department was re-examining the advantages and disadvantages of awarding grants competitively each year versus providing continued financial support to current grantees during a maximum project period of three years. Based on its review, the Department will continue to adhere to policies in the regulations (Section 1351.12) published in the FEDERAL REGISTER on December 13, 1976.

Section 1351.17 informs applicants that the criteria used in rating grant applications will be published annually in the FEDERAL REGISTER as a part of the official program announcement.

Section 1351.18 describes the involvement of both the youth and the parent or legal guardian in the development of plans for case disposition. It also includes provisions for the contact of parents or legal guardians within a preferred time frame. Section 1351.19 describes provisions regarding the confidentiality of client information. The provisions in Sections 1351.18 and 1351.19 were inadvertantly omitted from the proposed rulemaking; however, the Department considers these policies proper and reasonable and has included them as a part of these final regulations.

Subpart C, *Additional Requirements*, explains administrative requirements affecting grantees and potential grantees. These requirements are acceptance of technical assistance and short-term training; coordination with a 24-hour National toll-free communication system; and submission of statistical reports profiling clients served. The purpose of this subpart is to outline the nature of these requirements and to describe the types of assistance and training that will be available.

The requirements for technical assistance and short-term training are based on the Department's intent to improve the administration of the Runaway Youth Program by increasing the capability of the runaway service providers to deliver services. The requirement for coordination with the 24-hour toll-free communication system is based on the need to assure that runaway or otherwise homeless youth are aware of the availability of services and can be referred for assistance regardless of their whereabouts. The statistical reporting requirements are based on the legislative mandate in Section 312(b)(6) of the Act which states that "runaway youth projects shall keep adequate statistical records profiling the children and parents which it serves. . . ." This information is provided in the Annual Report to Congress on the Runaway Youth Program.

PUBLIC COMMENTS

Comments received in response to the proposed regulations were carefully considered. Revisions have been made where appropriate. These changes and significant areas of comment are described below. The decisions made after review of public comments are explained.

1. *Definitions*—(a) *Youth:* Several comments suggested that the definition of a youth as "a person who has not yet reached the legal age of majority" was vague, confusing, contradictory, and could present problems in providing services. State laws vary on the "age of majority" and this could result in grantees having to serve two significantly distinct groups because of the different legal relationships between parents and youth in the age range of 18 to 21. Also, the level of maturity for the 18 to 21 group is different. Their needs are more acute and they require longer-term services and greater staff expertise than runaway youth projects are designed to provide. Given these substantive needs differences and the varying legal relationships, it would not be possible for runaway youth projects to accomplish the intent and goals of the Act, such as reuniting youth with their families. Accordingly, revisions have been made to the proposed definitions of "runaway youth" and "homeless youth". The definitions describe these youth as persons under 18 years of age. The Department will continue to adhere to the age ceiling set forth in the regulations published in the FEDERAL REGISTER on December 13, 1976.

(b) *Technical Assistance:* Concern was expressed that the proposed definition of technical assistance was not adequate because it could be confused with that of "short-term training". The nature of technical assistance places emphasis on problem resolution and increases the overall capability of grantee organizations to administer an effective program. Current grantees report frustration because of an unclear understanding of the nature and function of technical assistance. To take care of this concern, the Department has revised the definition used in the past and has presented additional examples of technical assistance and removed those related to short-term training.

(c) *Short-term Training:* Numerous comments noted that short-term training is the development of staff skills to strengthen the effective delivery of services. Comments also indicated that allowing the training to be State, local or regionally-based will contribute to making the training more useful and accessible to grantee organizations. The Department agrees with these suggestions and has revised Section 1351.20(a) and the definition of "short-term training" in Section 1351.1(m).

(d) *Temporary Shelter:* It was recommended that the present definition be revised to include a specific time frame to define short-term room and board. Since it is not the Department's intention to establish group homes for permanent or long-term care of runaway or otherwise homeless youth, the Department accepts this recommendation. It was decided that a maximum time frame of 15 days would be appropriate. This is based on the average length of stay by a youth in a local runaway youth project as indicated through statistical reporting requirements placed on grantees over the past three years.

2. *Standard for capacity:* A few comments recommended that a standard which requires a minimum residential capacity of four be added to the Program Performance Reporting Requirements placed on grantees in September 1976. The Department has decided to establish a minimum residential capacity to assure a quantifiable standard for measuring whether a runaway youth project is in fact complying with the Act and these regulations regarding shelter. The decision to establish a particular minimum capacity of four is based on limited resources available to runaway youth projects. Therefore, Section 1351.17(d) has been revised.

3. *Indian eligibility:* One comment recommended that Indian tribes be specifically mentioned as eligible to apply for grants as they are considered local units of government. 45 CFR Section 74.3 notes that Federally recognized Indian tribes are presently eligible to apply as localities. All other Indian tribes and Indian organizations are eligible to apply for grants as private nonprofit organizations. These regulations have been revised to include a specific reference to these groups in the definition of "locality" in Section 1351.1(i).

A second recommendation was made to earmark 10 percent of the appropriation specifically for Indian tribes and organizations. The Runaway Youth Act does not permit set-asides for any group of runaway or otherwise homeless youth. The regulations have not been revised in this regard.

4. *Accreditation of local private nonprofit agencies:* One comment suggested that these applicants be awarded grants if accredited by an independent body designated by the Department. This accreditation, would establish whether or not the agency has met acceptable professional standards. All runaway youth projects funded by the Department are required to adhere to local licensing requirements for shelter facilities. These requirements address minimum professional standards in such areas as administration, personnel, training, physical facilities, and records and reports. Therefore, the Department believes that a regulation requiring private nonprofit applicants to be accredited is unnecessary.

5. *Technical Changes:* In addition to the revisions described above, the Department has incorporated various suggestions regarding minor technical changes designed to clarify the language and intent of the regulations.

(Catalog of Federal Domestic Assistance 13.623—Runaway Youth)

Dated: August 23, 1978.

ARABELLA MARTINEZ,
Assistant Secretary for Human Development Services.

Approved: November 8, 1978.

HALE CHAMPION,
Acting Secretary.

Chapter XIII of Title 45 of the Code of Federal Regulations (CFR), Part 1351 is amended as follows:

Subpart A—Definition of Terms

Sec.
1351.1 Significant Terms.

Subpart B—Runaway Youth Program Grant

1351.10 What is the purpose of the Runaway Youth Program grant?
1351.11 Who is eligible to apply for a Runaway Youth Program grant?
1351.12 Who gets priority for the award of a Runaway Youth Program grant?
1351.13 What are the Federal and non-Federal participation requirements under a Runaway Youth Program grant?
1351.14 What is the period for which a grant will be awarded?
1351.15 What costs are supportable under a Runaway Youth Program grant?
1351.16 What costs are not allowable under a Runaway Youth Program grant?
1351.17 How is application made for a Runaway Youth Program grant?

1351.18 What criteria has HEW established for deciding which Runaway Youth Program grant applications to fund?
1351.19 What additional information should an applicant or grantee have about a Runaway Youth Program grant?

Subpart C—Additional Requirements

1351.20 What are the additional requirements under a Runaway Youth Program grant?

AUTHORITY: 91 Stat. 1058 (42 U.S.C. 5711)

Subpart A—Definition of Terms

§ 1351.1 Significant terms.

For the purposes of this part:

(a) "Aftercare services" means the provision of services to runaway or otherwise homeless youth and their families, following the youth's return home or placement in alternative living arrangements which assist in alleviating the problems that contributed to his or her running away or being homeless.

(b) "Area" means a specific neighborhood or section of the locality in which the runaway youth project is or will be located.

(c) "Coordinated networks of agencies" means an association of two or more nonprofit private agencies, whose purpose is to develop or strengthen services to runaway or otherwise homeless youth and their families.

(d) "Counseling services" means the provision of guidance, support and advice to runaway or otherwise homeless youth and their families designed to alleviate the problems which contributed to the youth's running away or being homeless, resolve intrafamily problems, to reunite such youth with their families, whenever appropriate, and to help them decide upon a future course of action.

(e) "Demonstrably frequented by or reachable" means located in an area in which runaway or otherwise homeless youth congregate or an area accessible to such youth by public transportation or by the provision of transportation by the runaway youth project itself.

(f) "Homeless youth" means a person under 18 years of age who is in need of services and without a place of shelter where he or she receives supervision and care.

(g) "Juvenile justice system" means agencies such as, but not limited to juvenile courts, law enforcement, probation, parole, correctional institutions, training schools, and detention facilities.

(h) "Law enforcement structure" means any police activity or agency with legal responsibility for enforcing a criminal code including, police departments and sheriffs offices.

(i) "A locality" is a unit of general government—for example, a city, county, township, town, parish, village, or a combination of such units. Federally recognized Indian tribes are eligible to apply for grants as local units of government.

(j) "A nonprofit private agency" is any agency, organization, or institution whose net earnings do not benefit any private shareholder, governing board member, or individual and which agrees to be legally responsible for the operation of a runaway youth project. It may include agencies which are fully controlled by private boards or persons. Non-Federally recognized Indian tribes and Indian organizations are eligible to apply for grants as nonprofit private agencies.

(k) "Runaway youth project" means a locally controlled human service program facility outside the law enforcement structure and the juvenile justice system providing temporary shelter, either directly or through other facilities, counseling and aftercare services to runaway or otherwise homeless youth.

(l) "Runaway youth" means a person under 18 years of age who absents himself or herself from home or place of legal residence without the permission of parents or legal guardian.

(m) "Short-term training" means the provision of local, State, or regionally based instruction to runaway or otherwise homeless youth service providers in skill areas that will directly strengthen service delivery.

(n) "A State" includes any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and any territory or possession of the United States.

(o) "Technical assistance" means the provision of expertise or support for the purpose of strengthening the capabilities of grantee organizations to deliver services.

(p) "Temporary shelter" means the provision of short-term (maximum of 15 days) room and board and core crisis intervention services, on a 24-hour basis, by a runaway youth project.

Subpart B—Runaway Youth Program Grant

§ 1351.10 What is the purpose of the Runaway Youth Program grant?

The purpose of the Runaway Youth Program grant is to establish or strengthen existing or proposed community-based runaway youth projects to provide temporary shelter and care to runaway or otherwise homeless youth who are in need of temporary shelter, counseling and aftercare services. The Department is concerned about the increasing numbers of youth who leave, and stay away from, their homes without permission of their parents or legal guardian. There is also national concern about runaway youth who have no resources, who live on the street, and who represent law enforcement problems in the communities to which they run. The problems of runaway or otherwise homeless youth should not be the responsibility of already overburdened police departments and juvenile justice authorities. Rather, Congress intends that the responsibility for locating, assisting, and returning such youth should be placed with low-cost, community-based human service programs.

§ 1351.11 Who is eligible to apply for a Runaway Youth Program grant?

(a) States, localities, nonprofit private agencies and coordinated networks of private nonprofit agencies are eligible to apply for a Runaway Youth Program grant unless they are part of the law enforcement structure or the juvenile justice system.

§ 1351.12 Who gets priority for the award of a Runaway Youth Program grant?

In making Runaway Youth Program grants, HEW gives priority to those private agencies which have had past experience in dealing with runaway or otherwise homeless youth. HEW also gives priority to applicants whose total grant requests for services to runaway or otherwise homeless youth are less than $100,000 and whose project budgets, considering all funding sources, are smaller than $150,000. Past experience means that a major activity of the agency has been the provision of temporary shelter, counseling, and referral services to runaway or otherwise homeless youth and their families, either directly or through linkages established with other community agencies.

§ 1351.13 What are the Federal and non-Federal Financial Participation requirements under a Runaway Youth Program grant?

HEW will pay 90 percent of the costs of operating a runaway youth project for any fiscal year. Grantees must pay 10 percent of the costs of operating a runaway youth project for any fiscal year.

§ 1351.14 What is the period for which a grant will be awarded?

(a) The initial notice of grant award specifies how long HEW intends to support the project without requiring the project to recompete for funds. This period, called the project period, will not exceed three years.

(b) Generally the grant will initially be for one year. A grantee must

submit a separate application to have the support continued for each subsequent year. Continuation awards within the project period will be made provided the grantee has made satisfactory progress, funds are available, and HEW determines that continued funding is in the best interest of the Government.

§ 1351.15 What costs are supportable under a Runaway Youth Program grant?

Costs which can be supported include, but are not limited to, temporary shelter, referral services, counseling services, aftercare services, and staff training. Costs for acquisition and renovation of existing structures may not normally exceed 15 percent of the grant award. HEW may waive this limitation upon written request under special circumstances based on demonstrated need.

§ 1351.16 What costs are not allowable under a Runaway Youth Program grant?

A Runaway Youth Progam grant does not cover the cost of constructing new facilities.

§ 1351.17 How is application made for a Runaway Youth Program grant?

HEW publishes annually in the FEDERAL REGISTER a program announcement of grant funds available under the Runaway Youth Program Act. The program announcement states the amount of funds available, program priorities for funding, and criteria for evaluating applications in awarding grants. The announcement also describes specific procedures for receipt and review of applications. An applicant should:

(a) Obtain a program announcement from the FEDERAL REGISTER or from one of HEW's 10 Regional Offices in Boston, New York, Philadelphia, Atlanta, Chicago, Dallas, Kansas City, Denver, San Francisco, and Seattle;

(b) Obtain an application package from one of HEW's Regional Offices; and

(c) Upon fulfillent of the requirements of OMB-Circular A-95 which can also be obtained at one of HEW's Regional Offices, submit a completed application to the Grants Management Office at the appropriate Regional Office.

§ 1351.18 What criteria has HEW established for deciding which Runaway Youth Program grant applications to fund?

In reviewing applications for a Runaway Youth Program grant, HEW takes into consideration a number of factors, including:

(a) Whether the application meets one or more of the program's funding priorities; (see § 1351.12)

(b) The need for Federal support based on the number of runaway or otherwise homeless youth in the area in which the runaway youth project is or will be located;

(c) The availability of services to runaway or otherwise homeless youth in the area in which the runaway youth project is located;

(d) Whether there is a minimum residential capacity of four and a maximum residential capacity not to exceed 20 youth with a ratio of staff to youth sufficient to assure adequate supervision and treatment;

(e) Plans for meeting the best interests of the youth involving, when possible, both the youth and the parent or legal guardian. These must include contacts with parents or legal guardian. This contact should be made within 24 hours, but must be made no more than 72 hours following the time of the youth's admission into the runaway youth project. The plans must also include assuring the youth's safe return home or to local government officials or law enforcement officials and indicate efforts to provide appropriate alternative living arrangements.

(f) Plans for the delivery of aftercare or counseling services to runaway or otherwise homeless youth and their parents or legal guardians;

(g) Whether the estimated cost to the Department for the runaway youth project is reasonable considering the anticipated results;

(h) Whether the proposed personnel are well qualified and the applicant agency has adequate facilities and resources;

(i) Whether the proposed project design, if well executed, is capable of attaining program objectives;

(j) The consistency of the grant application with the provisions of the Act and these regulations.

§ 1351.19 What additional information should an applicant or grantee have about a Runaway Youth Program grant?

(a) Several other HEW rules and regulations apply to applicants for or recipients of Runaway Youth Program grants. These include:

(1) The provisions of 45 CFR Part 74 pertaining to the Administration of Grants;

(2) The provisions of 45 CFR Part 16, Departmental Grants Appeal Process, and the provisions of Informal Grant Appeal Procedures (Indirect Costs) in volume 45 CFR Part 75;

(3) The provisions of 45 CFR Part 80 and 45 CFR Part 81 pertaining to nondiscrimination under programs receiving Federal assistance, and hearing procedures;

(4) The provisions of 45 CFR Part 84 pertaining to discrimination on the basis of handicap;

(5) The provisions of 45 CFR Part 46 pertaining to protection of human subjects.

(b) Several program policies regarding confidentiality of information, treatment, conflict of interest and State protection apply to recipients of Runaway Youth Program grants. These include:

(1) *Confidential information.* All information including lists of names, addresses, photographs, and records of evaluation of individuals served by a runaway youth project shall be confidential and shall not be disclosed or transferred to any individual or to any public or private agency without written consent of the youth and parent or legal guardian. Youth served by a runaway youth project shall have the right to review their records; to correct a record or file a statement of disagreement; and to be apprised of the individuals who have reviewed their records. Procedures shall be established for the training of project staff in the protection of these rights and for the secure storage of records.

(2) *Medical, psychiatric or psychological treatment.* No youth shall be subject to medical, psychiatric or psychological treatment without the consent of the youth and parent or legal guardian unless otherwise permitted by State law.

(3) *Conflict of interest.* Employees or individuals participating in a program or project under the Act shall not use their positions for a purpose that is, or gives the appearance of being, motivated by a desire for private gain for themselves or others, particularly those with whom they have family, business or other ties.

(4) *State law protection.* HEW policies regarding confidential information and experimentation and treatment shall not apply if HEW finds that State law is more protective of the rights of runaway or otherwise homeless youth.

(c) Nothing in the Runaway Youth Act or these regulations gives the Federal Government control over the staffing and personnel decisions regarding individuals hired by a runaway youth project receiving Federal funds.

Subpart C—Additional Requirements

§ 1351.20 What are the additional requirements under a Runaway Youth Program grant?

(a) To improve the administration of the Runaway Youth Program by increasing the capability of the runaway youth service providers to deliver services, HEW will require grantees to

accept technical assistance and short-term training as a condition of funding for each budget period.

(1) Technical assistance may be provided in, but not limited to, such areas as:

- Program Management,
- Fiscal Management,
- Development of coordinated networks of private nonprofit agencies to provide services, and
- Low cost community alternatives for runaway or otherwise homeless youth.

(2) Short-term training may be provided in, but not limited to, such areas as:

- Shelter facility staff development,
- Aftercare services or counseling,
- Fund raising techniques,
- Youth and Family counseling, and
- Crisis intervention techniques.

(b) Grantees will be required to coordinate their activities with the 24-hour National toll-free communication system which links runaway youth projects and other service providers with runaway or otherwise homeless youth.

(c) Grantees will also be required to submit statistical reports profiling the clients served. The statistical reporting requirements are mandated by the Act which states that "runaway youth projects shall keep adequate statistical records profiling the children and parents which it serves . . .".

[FR Doc. 78-32473 Filed 11-27-78; 8:45 am]

Federal Register

TUESDAY, NOVEMBER 28, 1978
PART III



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

MEDICAL DEVICES

Proposals on Development of Classification of Neurological Devices

[4110-03-M]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 882]

[Docket No. 78N-1000]

CLASSIFICATION OF NEUROLOGICAL DEVICES

Development of General Provisions

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The agency is proposing general rules applicable to the classification of all neurological devices. The Medical Device Amendments of 1976 requires the Food and Drug Administration (FDA) to classify all medical devices intended for human use into three categories: Class I, general controls; class II, performance standards; and class III, premarket approval. In the preamble to this proposal, FDA describes the development of the proposed regulations classifying individual neurological devices, which are being published elsewhere in this issue of the FEDERAL REGISTER. The preamble also describes the activities of the Neurological Device Classification Panel, an FDA advisory committee that makes recommendations to FDA concerning the classification of neurological devices.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposed become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, Md. 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

DEVICE CLASSIFICATION SYSTEM

The Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295) establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) establishes three catogories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories are as follows: class I, general controls; class II, performance standards; class III, premarket approval.

Most devices are not classified under section 513 of the act until after FDA has (1) received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. These steps must precede the classification of any device that was in commercial distribution before May 28, 1976 (the date of enactment of the amendments) and that was not previously regarded by FDA as a new drug under section 505 of the act (21 U.S.C. 355). A device that is first offered for commercial distribution after May 28, 1976, and is substantially equivalent to a device classified under this scheme, is also classified in the same class as the device to which it is substantially equivalent.

A device that FDA previously regarded as a new drug, or a newly offered device that is not substantially equivalent to a device that was in commercial distribution before the amendments, is classified by statute into class III. These two types of devices are classified into class III without any FDA rulemaking proceedings. The agency determines whether new devices are substantially equivalent to previously offered devices by means of the premarket notification in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807).

RELATED REGULATIONS

In the FEDERAL REGISTER of July 28, 1978 (43 FR 32988), the Commissioner issued final regulations describing the procedures for classifying devices intended for human use. These regulations, which were proposed in the FEDERAL REGISTER of September 13, 1977 (42 FR 46028), supplement the agency's regulations in Part 14 (21 CFR Part 14) governing the use of advisory committees. The agency also issued interim device classification procedures in a notice published in the FEDERAL REGISTER of May 19, 1975 (40 FR 21848).

ACTIVITIES OF PANEL

Anticipating enactment of the amendments, FDA established several advisory committees to make preliminary recommendations on device classification. The Neurological Device Classification Panel (the Panel) was originally chartered on October 15, 1974, as the Panel on Review of Neurological Devices. On January 26, 1976, FDA placed a report of the Panel's tentative classification recommendations on file with the office of the Hearing Clerk (HFA-305), Food and Drug Administration, and announced the availability of the report to the public by notice published in the FEDERAL REGISTER of June 25, 1976 (41 FR 26245).

On August 9, 1976, the Panel and other preamendments device classification panels were rechartered to reflect their new responsibilities under the amendments. The agency directed each panel to reconsider its preamendments classification recommendations in light of the new requirements. In 1976 and 1977, the Panel reviewed all devices that FDA had referred to it to make certain that its recommendations were in accord with the amendments.

Throughout the Panels deliberations, interested persons were given an opportunity to present their views, data, and other information concerning the classification of neurological devices. The Panel also invited experts to testify and sought information on many devices from the published literature.

In October 1977, the Panel submitted to FDA a preliminary report of its recommendations. The report included a roster of current and previous Panel members and consultants and listed all meeting dates. The agency placed a copy of the report in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, and announced its availability to the public by notice published in the FEDERAL REGISTER of November 29, 1977 (42 FR 60792). At meetings held on January 13, 1978 and April 21, 1978, the Panel changed its previous recommendations concerning the clasification of several devices. An addendum to the Panel report showing these changes has been placed in the office of the Hearing Clerk, Food and Drug Administration. Also available in the office of the Hearing Clerk are summary minutes from all Panel meetings, verbatim transcripts of meetings held after May 28, 1976 (the date of enactment of the amendments), and all references cited in individual neurological device proposed classification regulations. Interested persons may review these documents in the office at the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, between 9 a.m. and 4 p.m., Monday through Friday.

LIST OF NEUROLOGICAL DEVICES

In 1972 FDA surveyed device manufacturers to identify the devices for which classification regulations would be needed. Following this survey, FDA developed a list of neurological devices. The Panel supplemented the list utilizing its members' knowledge of

neurological devices in use. Devices that were solely for experimental or investigational use or that were not generally available were not included.

The Commissioner is proposing to establish a new Part 882 in Title 21 of the Code of Federal Regulations. Part 882 will consist of sections identifying each neurological device with a brief narrative description and stating the classification of that device. A list of the neurological devices appears elsewhere in this preamble.

Individual Neurological Device Classification Regulation

Elsewhere in this issue of the Federal Register, the Commissioner is issuing 103 individual proposed regulations to classify each neurological device. The Commissioner is proposing to classify 26 neurological devices into class I (general controls), 66 neurological devices into class II (performance standards), and 11 neurological devices into class III (premarket approval). The Commissioner also is publishing the recommendations of the Panel regarding these devices, as required by section 513(c)(2) and (d)(1) of the act (21 U.S.C. 360c(c)(2) and (d)(1)).

Published Panel Recommendations

Each published Panel recommendation concerning a neurological device includes the information described below.

1. *Identification.* The Panel recommendation and proposed FDA classification regulation each include a brief narrative identification of the device. The identification statement is necessarily broad because it applies to a category or type of device rather than to a specific device. As explained in proposed § 882.1, manufacturers who submit premarket notification submissions under section 510(k) of the act and Part 807 of the regulations cannot show merely that a newly offered device is accurately described by the section title and identification provisions of a classification regulation. although a new device may be described accurately by the title and identification in a classification regulation, it is nevertheless in class III under section 513(f) of the act of it is not substantially equivalent to a preamendment device (or to a postamendment device that has already been reclassified from class III into class I or class II). It is not practical for FDA to publish an identification of each type of device that is so detailed as to anticipate every product feature that may be relevant in determining whether a new device is substantially equivalent to previous devices classified by the regulation. The commissioner believes that this problem was recognized in, and addressed by, the premarket notification procedures in section 510(k) of the act. Accordingly, any manufacturer who submits a premarket notification submission should state why the manufacturer believes the device is substantially equivalent to other devices in commercial distribution, as required by § 807.87 (21 CFR § 807.87), and whether the device is described in a classification regulation.

2. *Recommended classification.* Each Panel's recommendation describes whether the device is recommended for classification into class I (general controls), class II (performance standards), or class III (premarket approval).

For each device recommended for classification into class I, the Panel considered whether the device should be exempt from any requirements under certain sections of the act: section 510 (21 U.S.C. 360, registration), section 519 (21 U.S.C. 360i, records and reports), and section 520(f) (21 U.S.C. 360j(f), good manufacturing practice requirements). Although the Panel did not recommend that any device be exempted at this time from section 510 or section 519 of the act, the panel did recommend that the manufacturers of several class I devices be exempted from good manufacturing practice regulations (and thus from the records and reports requirements in these regulations) in the manufacture of these devices. The Commissioner's policy concerning these exemption recommendations is discussed below in the section of this proposal concerning "Exemptions for Class I Devices."

A Panel recommendation that a device be classified into class II includes the Panel's recommended priority ("high" or "low") for establishing a performance standard for the device. Similarly, each Panel recommendation that a device be classified into class III includes the Panel's recommended priority ("high" or "low") for application of premarket approval requirements to that device. As explained below in the section of this notice concerning "Priorities for Class II and III Devices," the Commissioner is not, however, proposing the establishment of FDA priorities at this time.

3. *Summary of reasons for recommendation.* The summary of reasons for the Panel's recommendation explains why the Panel believes a particular device meets the statutory criteria for classification into class I, II, or III.

Except in those instances in which FDA's classification proposal differs from an advisory committee's recommendation, the Commissioner is adopting the committee's summary of reasons as the agency's statement of the reasons for issuing the regulations, as required by section 517(f) of the act (21 U.S.C. 360g(f)).

The summary of reasons for a recommendation identifies any device that is an implant or a life-supporting or life-sustaining device. The summary of reasons for any implant or life-supporting or life-sustaining device that is not recommended for classification into class III also explains why the Panel determined that classification of the device into class III is not necessary to provide reasonable assurance of its safety and effectiveness. The agency provides a similar explanation in the "Proposed Classification" section of the preamble to any proposal to classify an implant or a life-supporting or life-sustaining device into a class other than class III.

4. *Summary of data on which the recommendation is based.* In many cases, the Panel based its recommendations on Panel members' personal knowledge of, and familiarity with, the devices under review. Reliance upon clinical experience and judgement was particularly common when the Panel considered a simple device that had been used extensively and was accepted widely before the amendments were enacted. The legislative history of the amendments provides that the term "data" has a special meaning in section 513(a)(2) of the act, which requires that a Panel recommendation summarize the data upon which a recommendation is based. As used in this section, "data" refers not only to the results of scientific experiments, but also to less formal evidence, other scientific information, or judgments of experts (House Committee on Interstate and Foreign Commerce, Medical Device Amendments of 1976, H. Rept. 94-853, 94th Congress, 2d Session 40 (1976)). The Commissioner has determined that clinical experience and judgment are valid scientific evidence for classifying certain devices.

In many cases, FDA sought data and information concerning the classification of a device in addition to that cited by the Panel. References to these data and information are found in the "Proposed Classification" section of the preambles to individual neurological device regulations. The Commissioner is adopting, as the agency's statement of the basis for issuing the regulation under section 517(f) of the act, the Panel's summary of the data on which a recommendation to classify a device is based, together with any additional data and information cited in the preamble to the proposed classification regulation.

5. *Risks to health.* In identifying the risks to health presented by neurological devices, the Panel recognized that few devices are completely free of risk. The Panel listed the risks it considered most significant, especially those that are unique to the use of a device.

In some cases, FDA has identified additional risks to health presented by a device. These additional risks are set out in the section of the preamble concerning the "Proposed classification" of a particular device.

Because the classification recommendations and FDA regulations do not identify all risks to health presented by neurological devices, future regulations establishing performance standards under section 514 of the act (21 U.S.C. 360d) and future regulations requiring premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)) may identify risks to health to be addressed by FDA requirements in addition to those identified in the classification recommendations and regulations.

Proposed Classification

Each proposed regulation to classify a neurological device states whether FDA agrees with the Panel's recommendation, describes the agency's proposed classification of the device, and proposes a new section in Part 882 in which the device classification will be codified.

The Commissioner cautions that the final classification of a device may differ from the proposal. Factors that may cause such a change include comments, the agency's reconsideration of existing data and information, and the agency's consideration of new data and information.

Priorities for Class II and Class III Devices

For a device that the Panel recommends to be classified into class II or class III, section 513(c)(2)(A) of the act requires that the Panel recommendation include, to the extent practicable, a recommendation for the assignment of a priority for application to the device of a performance standard or premarket approval requirements. In developing its advice concerning priorities ("high" or "low") of devices recommended for classification into class II or class III, the Panel compared the device with other neurological devices, based on information available to the Panel members concerning the relative importance of use of the device and the relative risks presented by the device. The Panel recommended assignment of a "high priority" only to those class II or class III devices that the Panel believed should receive the agency's immediate attention.

The Commissioner is not proposing at this time to establish priorities for development of performance standards for class II devices or application of premarket approval requirements to class III devices. Section 513(d)(3) of the act authorizes, but does not require, establishment of these priorities. At a later date, however, the Commissioner will establish priorities for the development of standards for class II devices and the application of premarket approval requirements to class III devices. These priorities will be based on the classification panels' recommendations, available resources, and other relevant factors. The agency's priorities will be reflected in the agency's annual budget request and other publicly available documents and may be published in the Federal Register.

The agency intends to proceed as quickly as the statute and classification panel resources permit to require premarket approval of devices classified into class III. There are two factors affecting the length of time necessary before FDA requires submission of premarket approval applications for any particular device that is classified by an FDA regulation into class III: the number of devices reviewed by a panel and the priority of a particular device in relation to other class III devices considered by a classification panel. For example, where FDA classifies into class III only a few devices within a Panel's specialty area, FDA may at the same time also publish regulations under section 515(b) of the act requiring premarket approval for many of the class III devices considered by the Panel, regardless of whether of a high or a low priority. Where practical, FDA will publish these section 515(b) regulations during the grace period (30 months) following classification during which a device classified into class III by FDA regulation may lawfully remain on the market without a premarket approval application. The grace period is provided for in section 501(f) of the act (21 U.S.C. 351(f)).

Exemptions for Class I Devices

The Panel recommended that several neurological devices that are recommended for classification into class I be exempted from the good manufacturing practice (GMP) regulation. The GMP regulation was published in final form in the Federal Register of July 21, 1978 (43 FR 31508). At the time of the Panel's recommendation, the GMP regulation had not been promulgated, and the agency had not yet developed criteria for exempting a class I device from the GMP regulation.

The Commissioner has decided that the agency will consider exempting a class I device from the GMP regulations if any one of the following requirements is met:

1. Based on adequate information about current practices in the manufacture of the device and about user experience with the device, the agency has determined that application of the GMP regulation will not improve the safety and effectiveness of the device.

2. The agency has determined that all possible defects relating to the safety and effectiveness of the device are readily detectable before use, either through visual examination by the user or through testing that is done routinely before use, e.g., testing a clinical laboratory reagent with positive and negative controls.

3. The agency has determined that any defect in the device that is not readily detectable will not result in a device failure that could have an adverse effect on the patient or other user.

List of Neurological Devices

The following is a list of neurological devices that shows the section in the Code of Federal Regulations under which the regulation classifying the device will be codified, the docket number of the proposed classification regulation, and the proposed classification of each device.

Section	Device	Docket No.	Class
	Subpart B—Neurological Diagnostic Devices		
882.1020	Rigidity analyzer	78N-1001	II
882.1030	Ataxiagraph	78N-1002	I
882.1200	Two-point discriminator	78N-1003	I
882.1240	Echoencephalograph	78N-1004	II
882.1275	Electroconductive media	78N-1005	II
882.1310	Cortical electrode	78N-1006	II
882.1320	Cutaneous electrode	78N-1007	II
882.1330	Depth electrode	78N-1008	II
882.1340	Nasopharyngeal electrode	78N-1009	II
882.1350	Needle electrode	78N-1010	II
882.1400	Electroencephalograph	78N-1011	II
882.1410	Electroencephalograph electrode/lead tester	78N-1012	II
882.1420	Electroencephalogram (EEG) signal spectrum analyzer	78N-1013	I
882.1430	Electroencephalograph test signal generator	78N-1014	I
882.1460	Nystagmograph	78N-1015	II
882.1480	Neurological endoscope	78N-1016	II
882.1500	Esthesiometer	78N-1017	I

Section	Device	Docket No.	Class
	Subpart B—Neurological Diagnostic Devices—Continued		
882.1525	Tuning fork	78N-1018	I
882.1540	Galvanic skin response measurement device	78N-1019	I
882.1550	Nerve conduction velocity measurement device	78N-1020	II
882.1560	Skin potential measurement device	78N-1021	II
882.1570	Powered direct-contact temperature measurment device	78N-1022	II
882.1610	Alpha monitor	78N-1023	II
882.1620	Intracranial pressure monitoring device	78N-1024	II
882.1700	Percussor	78N-1025	I
882.1750	Pinwheel	78N-1026	I
882.1790	Ocular plethysmograph	78N-1027	III
882.1825	Rheoencephalograph	78N-1028	III
882.1835	Physiological signal amplifier	78N-1029	II
882.1845	Physiological signal conditioner	78N-1030	II
882.1855	Physiological signal telemetry system	78N-1031	II
882.1870	Evoked response electrical stimulator	78N-1032	II
882.1880	Evoked response mechanical stimulator	78N-1033	II
882.1890	Evoked response photic stimulator	78N-1034	II
882.1900	Evoked response auditory stimulator	78N-1035	II
882.1925	Ultrasonic scanner calibration test block	78N-1036	I
882.1950	Tremor transducer	78N-1037	II
	Subparts C—D [Reserved]		
	Subpart E—Neurological Surgical Devices		
882.4030	Skull plate anvil	78N-1038	I
882.4060	Ventricular cannula	78N-1039	I
882.4100	Ventricular catheter	78N-1040	II
882.4125	Neurosurgical chair	78N-1041	I
882.4150	Scalp clip	78N-1042	II
882.4175	Aneurysm clip applier	78N-1043	II
882.4190	Clip forming/cutting instrument	78N-1044	I
882.4200	Clip removal instrument	78N-1045	I
882.4215	Clip rack	78N-1046	I
882.4250	Cryogenic surgical device	78N-1047	II
882.4275	Dowel cutting instrument	78N-1048	I
882.4300	Manual drill, burr, trephine, and accessories	78N-1049	II
882.4305	Powered compound drill, burr, trephine, and accessories	78N-1050	II
882.4310	Powered simple drill, burr, traphine, and accessories	78N-1051	II
882.4325	Drill handpiece (brace)	78N-1052	II
882.4360	Electric drill motor	78N-1053	II
882.4370	Pneumatic drill motor	78N-1054	II
882.4400	Radiofrequency lesion generator	78N-1055	II
882.4440	Neurosurgical headrest	78N-1057	I
882.4460	Neurosurgical head holder (skull clamp)	78N-1058	II
882.4500	Cranioplastry material forming instrument	78N-1059	I
882.4525	Microsurgical instrument	78N-1061	I
882.4535	Nonpowered neurosurgical instrument	78N-1062	I
882.4545	Shunt system implantation instrument	78N-1063	I
882.4560	Stereotaxic instrument	78N-1064	II
882.4600	Leukotome	78N-1065	I
882.4650	Nrurosurgical suture needle	78N-1066	I
882.4700	Cottonoid paddie	78N-1067	II
882.4725	Radiofrequency lesion probe	78N-1068	II
882.4750	Skull punch	78N-1069	I
882.4800	Self-retaining retractor	78N-1070	II
882.4840	Manual rongeur	78N-1071	II
882.4845	Powered rongeur	78N-1072	II
882.4900	Skullplate screwdriver	78N-1073	I
882.4925	Sponge for internal use	78N-1074	II
	Subpart F—Neurological Therapeutic Devices		
882.5030	Methyl methacrylate for aneurysmorrhaphy	78N-1075	II
882.5050	Biofeedback device	78N-1076	II
882.5070	Bite block	78N-1077	II
882.5150	Intravascular occluding catheter	78N-1078	III
882.5175	Carotid artery clamp	78N-1079	II
882.5200	Aneurysm clip	78N-1080	II
882.5225	Implanted malleable clip	78N-1081	II
882.5335	Aversive conditioning device	78N-1082	II
882.5250	Burr hole cover	78N-1083	II
882.5275	Nerve cuff	78N-1084	III
882.5300	Methyl methacrylate for cranioplasty	78N-1085	II
882.5320	Preformed alterable cranioplasty plate	78N-1086	II
882.5330	Preformed nonalterable cranioplasty plate	78N-1087	II
882.5360	Cranioplasty plate fastener	78N-1088	II
882.5500	Lesion temperature monitor	78N-1089	II
882.5550	Central nervous system fluid shunt and components	78N-1090	II
882.5800	Cranial electrotherapy stimulator	78N-1091	III
882.5810	External functional neuromuscular stimulator	78N-1092	II
882.5820	Implanted cerebellar stimulator	78N-1093	III
882.5830	Implanted diaphragmatic/phrenic nerve stimulator	78N-1094	III
882.5840	Implanted intracerebral/subcortical stimulator for pain relief	78N-1095	III
882.5850	Implanted spinal cord stimulator for bladder evacuation	78N-1096	III
882.5860	Implanted neuromuscular stimulator	78N-1097	III
882.5870	Implanted peripheral nerve stimulator for pain relief	78N-1098	II
882.5880	Implanted spinal cord stimulator for pain relief	78N-1099	II
882.5890	Transcutaneous electrical nerve stimulator for pain relief	78N-1100	II
882.5900	Preformed craniosymostosis strip	78N-1101	II
882.5910	Dura substitute	78N-1102	II

Section	Device	Docket No.	Class
	SUBPART F—NEUROLOGICAL THERAPEUTIC DEVICES—Continued		
882.5940	Electroconvulsive therapy device	78N-1103	II
882.5950	Artificial embolization device	78N-1104	III
882.5960	Skull tong for traction	78N-1105	II

DEVICES CONSIDERED BY TWO OR MORE PANELS

Many devices were reviewed by two or more device classification panels. For these devices, FDA will publish each panel's recommendations and a single proposed classification regulation. The following devices were considered by the Neurological Device Classification Panel and by other panels:

1. The Physical Medicine Device Classification Panel recommended that the two-point discriminator esthesiometer and the touch discriminator esthesiometer be classified into class I. The Neurological Device Classification Panel recommended that the two-point discriminator be classified into class I. The Commisssioner has determined that these devices are essentially the same. Therefore, the Commissioner is proposing a single regulation classifying the two-point discriminator into class I, and is publishing the two panels' recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

2. The Physical Medicine Device Classification Panel recommended that the battery-powered skin resistance meter be classified into class I and that the AC-powered skin resistance meter be classified into class II. The Neurological Device Classification Panel recommended that the neurodermamometer for galvanic skin response measurement, whether battery-powered or AC-powered, be classified into class II. The Commissioner has determined that these devices are essentially the same. Therefore, the Commissioner is proposing a single regulation classifying the galvanic skin response measurement device into class II, and is publishing the two panels' recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

3. The Physical Medicine Device Classification Panel recommended that the external functional neuromuscular stimulator be classified into class II. The Neurological Device Classification Panel recommended that the external neuromuscular stimulator be classified into class II. The Commissioner has determined that these devices are essentially the same. Therefore, the Commissioner is proposing a single regulation classifying the external functional neuromuscular stimulator into class II, and is publishing the two panel's recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

4. The Anesthesiology Device Classification Panel recommended that the electrophrenic pacer be classified into class III. The Neurological Device Classification Panel recommended that the implanted diaphragmatic/phrenic nerve stimulator be classified into class III. The Commissioner has determined that these devices are the same. Therefore, the Commissioner is proposing a single regulation classifying the implanted diaphragmatic/phrenic nerve stimulator into class III and is publishing the two panels' recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

5. The Orthopedic Device Classification Panel recommended that the implanted peroneal stimulator be classified into class II. The Neurological Device Classification Panel recommended that the implanted neuromuscular stimulator be classified into class III. The Commissioner has determined that these devices are the same. Therefore, the Commissioner is proposing a single regulation classifying the implanted neuromuscular stimulator into class III and is publishing the two panels' recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

6. The Neurological Device Classification Panel and the other panels listed below made classification recommendations concerning the following devices:

Device	Other panel(s)
Chronaximeter	Physical medicine.
Dynamometer	Physical medicine; orthopedic; anesthesiology.
Electromyograph	Physical medicine.
Computed tomography X-ray scanner.	Radiology.
Angiographic catheter	Radiology; cardiovascular.
Angiographic wire guide and accessories.	Do.
Angiographic needle	Do.
Fiberoptic surgical field illuminator.	General and plastic surgery.
Surgical microscope system.	General and plastic surgery; ophthalmic; ear, nose, and throat.
Electrosurgical apparatus.	Cardiovascular; general and plastic surgery; anesthesiology; gastroenterology and urology; dental.
Ligature-passing and knot-tying instrument.	General and plastic surgery.
Neurosurgical headlight	General and plastic surgery; ear, nose, and throat; dental.
Ultrasonic bone-cutting instrument.	Orthopedic.
Pneumoencephalographic chair.	Radiology.
Manual saw and accessories.	Cardiovascular; orthopedic; ear, nose, and throat; general and plastic surgery.
Powered saw and accessories.	Cardiovascular; orthopedic; dental; ear, nose, and throat.
Sponge (external use)	General and plastic surgery; dental; ophthalmic.
Manual retractor	Dental; ear, nose, and throat; gastroenterology and urology; ophthalmic; orthopedic; general and plastic surgery; obstetrics and gynecology.
Hemostatic clip applier	General and plastic surgery.
Electroanesthesia stimulator.	Anesthesiology.

The Commissioner is not at this time publishing the Neurological Device Classification Panel's recommendations to classify the devices listed above. The Commissioner will publish these recommendations, and proposed classification regulations, when FDA publishes the recommendations of other panels that reviewed the devices.

TISSUE ADHESIVES

At a future date, FDA will publish in the FEDERAL REGISTER a final regulation stating that one neurological device (tissue adhesives for aneurysmorrhaphy) is classified into class III (premarket approval) because of transitional provisions of the act in section 520(1) (21 U.S.C. 360j(1)). The transitional provisions classify into class III any device previously regarded by FDA as a new drug. At the time FDA publishes this regulation, the agency also will publish the Panel's recommendations regarding tissue adhesives for aneurysmorrhaphy and for general neurosurgical use.

ENVIRONMENTAL IMPACT

The Commissioner has carefully considered the environmental effects of proposed § 882.1 and of the proposed neurological device classification regulations and because the proposed actions will not significantly affect the quality of the human environment has concluded that an environmental impact statement is not required. A

copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration (address above).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)), and under authority delegated to the Commissioner (21 U.S.C. 5.1), the Commissioner proposes that Chapter I of Title 21 of the code of Federal Regulations be amended by adding new Part 882, Subpart A, to read as follows:

PART 882—NEUROLOGICAL DEVICES

Subpart A—General Provisions

Sec.
882.1 Scope.

AUTHORITY: Secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c and 701(a)).

Subpart A—General Provisions

§ 882.1 Scope.

(a) This part sets forth the classification of neurological devices intended for human use.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 of this chapter cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87 of this chapter.

(c) To avoid duplicative listings, a neurological device that has two or more types of uses (e.g., use both as a diagnostic device and as a therapeutic device) is listed in the subpart representing one use of the device, rather than in two or more subparts.

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding proposed § 882.1. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32858 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1001]

MEDICAL DEVICES

Classification of Rigidity Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rigidity analyzers into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medcial Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the hearing Clerk (HFA-305), Food and Drug Administraion, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of rigidity analyzers:

1. Identification: A rigidity analyzer is a device for quantifying the extent of the rigidity of a patient's limb to determine the effectiveness of drugs or other treatment.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the rigidity analyzer be classified into class II (performance standards) to require that the performance characteristics be maintained at a satisfactory level. The Panel believes that general controls will not provide sufficient control over these characteristics. The function of this device is to quantify a physiological measurement; therefore, the Panel believes that the device should provide accurate and repeatable measurements. The Panel also recommends that FDA require the labeling of this device to indicate the limitations of the device. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: Rigidity analyzers have been in use for many years. The Panel members based their recommendation on their experience with these rigidity analyzers.

5. Risks to health: Incorrect treatment. If the device measurements are not sufficiently accurate, the assessment of the patient's response to therapy may be in error, and the physician may prescribe incorrect treatment.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the rigidity analyzer be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act 9 (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to add a new Part 882 as follows:

PART 882—NEUROLOGICAL DEVICES

Subpart A—[Reserved]

Subpart B—Neurological Diagnostic Devices

§ 882.1020 Rigidity analyzer.

(a) *Identification.* A rigidity analyzer is a device for quantifying the extent of the rigidity of a patient's

limb to determine the effectiveness of drugs or other treatments.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32859 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1002]

MEDICAL DEVICES

Classification of Ataxiagraphs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ataxiagraphs into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by Janurary 29, 1979. the Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of ataxiagraphs:

1. Identification: An ataxigraph is a device used to determine the extent of ataxia (failure of muscular coordination) by measuring the amount of swaying of the body when the patient is standing erect and with eyes closed.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class I (general controls) because it make no electrical contact with the patient and presents no inherent hazards. It is used to help quantify clinical observations only and does not replace subjective evaluation. Because no particular precision is required, the Panel believes that a performance standard is not necessary and that general controls are sufficient to assure the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience in evaluating ataxia and familiarity with these devices.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the ataxiagraph be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1030 as follows:

§ 882.1030 Ataxiagraph.

(a) *Identification.* An ataxiagraph is a device used to determine the extent of ataxia (failure of muscular coordination) by measuring the amount of swaying of the body when the patient is standing erect and with eyes closed.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32860 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1003]

MEDICAL DEVICES

Classification of Two-Point Discriminators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying two-point discriminators into class I (general controls). The FDA is also publishing the recommendations of the Neurological Device Classification Panel and the Physical Medicine Device Classification Panel that the device by classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel and the Physical Medicine Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of two-point discriminators:

1. Identification: A two-point discriminator is a device with points used for testing a patient's touch discrimination.

2. Recommended Classification: Class I (general controls). The Neurological Device Classification Panel recommends that the device be exempted from good manufacturing practice regulations under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)). The Physical Medicine Device Classification Panel recommended no exemptions.

3. Summary of reasons for recommendation: The two-point discriminator is an extremely simple mechanical device which is routinely used in neurological examinations. It presents no hazards to health and requires no special materials or properties. The panel members noted that an ordinary object such as a paper clip will often serve the same purpose as this device. Because the Neurological Device Classification Panel believes that the functional capabilities and qualities of the device are easily determined by examination of the device itself, the Panel believes that control of manufacturing methods for manufacturing the device is unnecessary.

4. Summary of data on which the recommendation is based: The panel members based their recommendation on their familiarity with this device and its routine use in neurological examinations.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that two-point discriminators be classified into class I (general controls) because the Commissioner believes that general controls are sufficient to provide a reasonable assurance of the safety and effectiveness of the device.

The Commissioner is also proposing that two-point discriminators be exempted from good manufacturing practice regulations under section 520(f) of the act and from recordkeeping and reporting requirements in good manufacturing regulations, because all defects related to the safety and effectiveness of the device are readily detectable prior to use. The FDA's good manufacturing practice regulations for medical devices (21 CRF Part 820) were published in the FEDERAL REGISTER of July 21, 1978 (43 FR 31508).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1200 as follows:

§ 882.1200 Two-point discriminator.

(a) *Identification.* A two-point discriminator is a device with points used for testing a patient's touch discrimination.

(b) *Classification.* Class I (general controls). Exempt from the good manufacturing practice regulations in Part 820 of this chapter, including recordkeeping and reporting requirements in Part 820 of this chapter.

Interested persons may, on or before January 29, 1978; submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32861 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1004]

MEDICAL DEVICES

Classification of Echoencephalographs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying echoencephalographs into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, Md. 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of echoencephalographs:

1. Identification: An echoencephalograph is an ultrasonic scanning device (including A-scan, B-scan, or doppler systems) that uses noninvasive transducers for measuring intracranial interfaces and blood flow velocity to and in the head.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that echoencephalographs be classified into class II (performance standards) to control the hazards of excessive ultrasonic power output, electric shock, and explosive environments and to assure usable resolution (image quality) and accuracy. The Panel believes that records and images obtained from this device are valuable aids in the diagnosis of various cranial disorders. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their knowledge and experience with ultrasonic diagnostic instruments. Dr. Mark Dyken, a Panel member, stated that laboratory experiments to determine the adverse effects on the eyes produced by the highest level of clinically used ultrasound had been conducted. The results (Ref. 1) indicated no adverse effects.

5. Risks to health: a. Excessive ultrasonic output: An excess level of power could cause tissue damage by cavitation (bubble formation and activity), thermal effects, or nonthermal mechanisms.

b. Electric shock. Failure of the transducer insulation could allow high voltage to reach the patient.

c. Explosion. If the device is not explosion proof it might cause an explosion if used in an environment having flammable gases.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the echoencephalograph be classifed into class II (performance standards). Stratmeyer's review (Ref. 2) of the possible biological effects of ultrasound includes references to two investigations showing that exposures of ultrasonic energy similar to those used in echoencephalography may cause alterations in the central nervous system of dogs (Ref. 3) and nonhuman primates (Ref. 4). Although those investigations are cause for concern, the Commissioner regards them as inconclusive at this time. The studies have yet to be verified, and some investigators question the methods or findings of these investigations or their applicability to humans.

The Biological Effects of Ultrasound Subcommittee of FDA's Obstetrical and Gynecological Device Classification Panel has also reviewed the possible adverse effects of diagnostic ultrasound devices. (The Subcommittee was established because of FDA's special concerns about the obstetrical use of ultrasound, based upon several studies involving laboratory animals that showed various biological effects from prenatal ultrasound exposures (Ref. 2).) The Subcommittee concluded that there is sufficient information available to establish a standard for diagnostic ultrasound devices generally (Refs. 5, 6, and 7).

FDA will soon publish a notice of intent in the FEDERAL REGISTER announcing that it is considering an action program to reduce exposure to diagnostic ultrasound as much as practicable, consistent with the need for essential diagnostic information. One action the agency will consider taking is promulgation of a performance standard under the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602, 42 U.S.C. 2636 et seq.).

The Commissioner believes that a performance standard under the Radiation Control for Health and Safety Act may be necessary for the echoencephalograph because general controls by themselves are insufficient to control the risks to health. The Commissioner also believes that there is sufficient information to establish a standard that will provide reasonable assurance of the safety and effectiveness of the device.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Rm. 4-65, 5600 Fisheries Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday:

1. Maroon, J., R. L. Campbell, and M. Dyken, *Stroke*, 1:122-127, 1970.

2. Stratmeyer, M. E., "Research Directions in Ultrasound Bioeffects—a Public Health View," Proceedings of a Symposium on Biological Effects and Characterization of Ultrasound Sources, HEW publication (FDA) 78-8044, 1978.

3. Tsutsumi, Y., K. Sano, T. Kuwabara, T. Takakura, K. Hayakawa, T. Suzuki, and M. Katanuma, "A New Portable Echo-encephalograph, Using Ultrasonic Transducers and its Clinical Application," *Medical Electronics and Biological Engineering*, 2:21-29, 1964.

4. Hu, J. H. and W. D. Ulrich, "Effects of Low-Intehsity Ultrasound on the Central Nervous System of Primates" *Aviat. Space Environ, Med.*, pp. 640-643, June, 1976.

5. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB-GYN Device Classification Panel (First Meeting), Jan. 22-23, 1976.

6. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB-GYN Device Classification Panel (Second Meeting), Oct. 28, 1976.

7. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB-GYN Device Classification Panel (Third Meeting), Oct. 4, 1977.

Therefore, under the Federal Food, Drug, and Comestic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1240 as follows:

§ 882.1240 Echoencephalograph.

(a) *Identification.* An echoencephalograph is an ultrasonic scanning device (including A-scan, B-scan, and doppler systems) that uses noninvasive transducers for measuring intracranial interfaces and blood flow velocity to and in the head.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32862 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1005]

MEDICAL DEVICES

Classification of Electroconductive media

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electroconductive media into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD. 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD. 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electroconductive media:

1. Identification: Electroconductive media are the conductive creams or gels used with external electrodes to reduce the impedance

(resistance to alternating current) of the contact between the electrode surface and the skin.

2. Recommended classification; Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that electroconductive media be classified into class II (performance standards) becuase the material is applied to the patient's skin and carries electrical current and the Panel believes that performance standards are necessary to control the material's electrical conductivity and compatibility with the skin. The need for specifying an adequate acid/base buffer to avoid skin burns was also noted by the Panel. The Panel believes that general controls will not provide sufficient control of the device characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: Various substances have been used as electroconductive media for many years in conjunction with cutaneous electrodes. The Panel members based their recommendation on their experience ith these electroconductive media.

5. Risks to health: a. Chemical skin burn casued by pH change: The electrical current can produce adverse chemical changes in the conductive media unless the media contain a buffer.

b. Toxic reactions: A toxic substance in the media could attack the skin or be absorbed through the skin.

c. Unacceptable recording quality: Material which does not maintain sufficiently low resistance to the electrical current may impair the quality of the recorded signal.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the electroconductive media be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding New § 882.1275 to read as follows:

§ 882.1275 Electroconductive media.

(a) *Identification.* Electroconductive media are the conductive creams or gels used with external electrodes to reduce the impedance (resistance to alternating current) of the contact between the electrode surface and the skin.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32863 filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1006]

MEDICAL DEVICES

Classification of Cortical Electrodes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cortical electrodes into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. these actions are being taken under the medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cortical electrodes:

1. Identification: A cortical electrode is an electrode which is temporarily placed on the surface of the brain for stimulating the brain or recording the brain's electrical activity.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the cortical electrode be classified into class II (performance standards because the device uses materials that come into contact with the body and should be controlled, and the device has performance characteristics which should be maintained at an acceptable level. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel also recommends that the method of sterilization be stated in the device labeling. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: Cortical electrodes have been in use for many years. The Panel members based their recommendation on their experience with these electrodes.

5. Risks to health: a. Sterility: If not sterilized, the device may introduce contaminants into the brain.

b. Local irritation: The electrode materials may cause toxic or adverse reactions when placed in contact with brain tissue.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the cortical electrode be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513,

701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1310 to read as follows:

§ 882.1310 Cortical electrode.

(a) *Identification:* A cortical electrode is an electrode which is temporarily placed on the surface of the brain for stimulating the brain or recording the brain's electrical activity.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32864 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1007]

MEDICAL DEVICES

Classification of Cutaneous Electrodes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cutaneous electrodes into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cutaneous electrodes:

1. Identification: A cutaneous electrode is an electrode which is applied directly to a patient's skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the cutaneous electrode be classified into class II because the electrical properties of the device must be controlled to assure that when physiological signals are recorded, they are adequately reproduced; to prevent burns when the device is used to apply stimulation; and to assure that only materials with known and acceptable properties are used in electrodes. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: Cutaneous electrodes have been in use for many years. The Panel members based their recommendation on their experience with these electrodes.

5. Risks to health: a. Burns. Poor design or incorrect application of the electrodes could result in skin burns when the electrodes are used for stimulation.

b. Toxic reactions. Material or substances in the electrodes that are in contact with the skin could produce adverse reactions.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the cutaneous electrodes be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1320 to read as follows:

§ 882.1320 Cutaneous electrode.

(a) *Identification.* A cutaneous electrode is an electrode that is applied directly to a patient's skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32865 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1008]

MEDICAL DEVICES

Classification of Depth Electrodes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying depth electrodes into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the

future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of depth electrodes:

1. Identification: A depth electrode is an electrode used for temporary stimulation of, or recording electrical signals at, subsurface levels of the brain.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that depth electrodes be classified into class II (performance standards) because they use materials that come into contact with the brain and because the geometric configuration and performance characteristics of this device must be controlled to assure that the device is safe and effective. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with these electrodes.

5. Risks to health: a. Local irritation: Improper materials in the electrode can adversely react with the tissue.

b. Damage to brain tissue: The electrode geometry must be such that it spreads rather than cuts tissue during insertion.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the depth electrode be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1330 as follows:

§ 882.1330 Depth electrode.

(a) *Identification.* A depth electrode is an electrode used for temporary stimulation of, or recording electrical signals at, subsurface levels of the brain.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32866 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1009]

MEDICAL DEVICES

Classification of Nasopharyngeal Electrodes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nasopharyngeal electrodes into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of nasopharyngeal electrodes:

1. Identification: A nasopharyngeal electrode is an electrode which is temporarily placed in the nasopharyngeal region for the purpose of recording electrical activity.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the nasopharyngeal electrode be classified into class II (performance standards) to assure that when physiological signals are recorded, they are adequately reproduced and to control the materials used in the electrode to prevent injury to the sensitive internal surface of the nose or the pharynx. The Panel believes that general controls alone will not be sufficient to control these properties. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience with devices of this type.

5. Risks to health: a. Improper positioning: If the device is poorly designed or is not accompanied by adequate directions for use, an accurate reproduction of the physiological signal may not be obtained.

b. Tissue damage: If the device is poorly designed or is made from inflexible material, the device could injure the inside of the nose or the pharynx.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the nasopharyngeal electrode be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1340 as follows:

§ 882.1340 Nasopharyngeal electrode.

(a) *Identification.* A nasopharyngeal electrode is an electrode which is temporarily placed in the nasopharyngeal region for the purpose of recording electrical activity.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32867 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1010]

MEDICAL DEVICES

Classification of Needle Electrodes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying needle electrodes into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of needle electrodes:

1. Identification: A needle electrode is a device which is placed subcutaneously to stimulate or to record electrical signals.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the needle electrode, because it penetrates the skin, be classified into class II (performance standards) to assure that the device is sterile. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard should require that the device be capable of being sterilized. The Panel recommends that FDA require that the manufacturer furnish users with adequate instructions for achieving sterile use and that the labeling indicate the maximum safe stimulating current that can be applied to a specific electrode. The Panel believes further tht the conducting and insulating materials of the electrode should meet standards to reduce the risk of toxic effects. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device, and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: Needle electrodes have been used for many years. The Panel members based their recommendation on their experience with these electrodes.

5. Risks to health: a. High current-density burns: Burns may result if the exposed conducting surface area is too small for the stimulation current being used.

b. Site-of-entry infection: Infection may result with an unsterile needle or improper technique.

c. Systemic infection: An unsterile needle may result in circulatory system infection.

d. Toxicity: Materials used for the needle or for insulation my be toxic.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the needle electrode be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1350 as follows:

§ 882.1350 Needle electrode.

(a) *Identification.* A needle electrode is a device which is placed subcutaneously to stimulate or to record electrical signals.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal.

Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32868 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1011]

MEDICAL DEVICES

Classification of Electroencephalographs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electroencephalographs into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electroencephalographs:

1. Identification: An electroencephalograph is a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the electroencephalograph be classified into class II (performance standards) to ensure that the electroencephalogram is adequately reproduced and that neurological conditions are accurately diagnosed. The Panel believes that electrical safety standards are needed to prevent electrical shock. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience and familiarity with electroencephalography. Electroencephalographs have been in clinical use for many years and are standard diagnostic instruments well known to neurologists.

5. Risks to health: a. Misuse: Use of this device requires special training. Use by unqualified persons could result in improper diagnosis and treatment.

b. Misdiagnosis: Distortion of the physiological signal could cause a misdiagnosis and lead to improper treatment of a neurological condition.

c. Electrical shock: Leakage current can be especially hazardous because the device makes a low resistance contact with the patient.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the electroencephalographs be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1400 as follows:

§ 882.1400 Electroencephalograph.

(a) *Identification.* An electroencephalograph is a device used to measure and record the electrical activity of the patient's brain obtained by placing two or more electrodes on the head.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32869 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1012]

MEDICAL DEVICES

Classification of Electroencephalograph Electrode/Lead Testers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electroencephalograph electrode/lead testers into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become ef-

fective 30-days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electroencephalograph electrode/lead testers:

1. Identification: An electroencephalograph electrode/lead tester is a device used for testing the impedance (resistance to alternating current) of the electrode and lead system of an electroencephalograph to assure that an adequate contact is made between the electrode and the skin.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the electroencephalograph electrode/lead tester be classified into class II because the Panel believes that performance standards are needed to assure that the device performs the required measurement accurately and to protect the patient from electrical shock. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members are familiar with the techniques of electroencephalography. The Panel members based their recommendation on their knowledge that predictable electrical contact is necessary to obtain a satisfactory recording.

5. Risks to health: Electric shock: The patient might receive an electrical shock from the device if it is poorly designed.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the electroencephalograph electrode/lead tester be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks ot health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1410 as follows:

§ 882.1410 Electroencephalograph electrode/lead tester

(a) *Identification.* An electroencephalograph electrode/lead tester is a device used for testing the impedance (resistance to alternating current) of the electrode and lead system of an electroencephalograph to assure that an adequate contact is made between the electrode and the skin.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32870 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1013]

MEDICAL DEVICES

Classification of Electroencephalogram (EEG) Signal Spectrum Analyzers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electroencephalogram (EEG) signal spectrum analyzers into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979.

The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsehere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electroencephalogram (EEG) signal spectrum analyzers:

1. Identification: An electroencephalogram (EEG) signal spectrum analyzer is a device used to display the frequency content or power spectral density of the electroencephalogram (EEG) signal.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified in class I (general controls) because the device does not make contact with the patient and no hazards have been identified. This device is used to process data obtained from an electroencephalograph (EEG) device and to display the results. The Panel believes that the information obtained from this device is not used in a manner which involves any risks to health. The Panel believes that general controls will suffice to control this device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience in the interpretation of EEG information and their familiarity with the technique of spectral analysis.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the electroencephalogram (EEG) signal spectrum analyzer be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide a reasonable assurance of safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1420 as follows:

§ 882.1420 Electroencephalogram (EEG) signal spectrum analyzer.

(a) *Identification.* An electroencephalogram (EEG) signal spectrum analyzer is a device used to display the frequency content or power spectral density of the electroencephalogram (EEG) signal.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: Nov. 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32871 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1014]

MEDICAL DEVICES

Classification of Electroencephalograph Test Signal Generators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electroencephalograph test signal generators into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electroencephalograph test signal generators:

1. Identification: An electroencephalograph test signal generator is a device used to test or calibrate an electroencephalograph.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: This device makes no electrical contact with the patient and presents no inherent hazards. The Panel believes that the safety and effectiveness of the device can be controlled by general controls.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on extensive personal experience with electroencephalography and familiarity with these test devices.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the electroencephalograph test signal generator be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide a reasonable assurance of safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1430 as follows:

§ 882.1430 Electroencephalograph test signal generator.

(a) *Identification.* An electroencephalograph test signal generator is a device used to test or calibrate an electroencephalograph.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32872 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1015]

MEDICAL DEVICES

Classification of Nystagmographs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nystagmographs into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classsifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are

being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. the Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of nystagmographs:

1. Identification: A nystagmograph is a device used to measure, record, or visually display the involuntary movements (nystagmus) of the eyeball.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: the Panel recommends that the nystagmograph be classified into class II (performance standards) because the device may be powered by an external electrical source. Some devices of this type make low resistance electrical contact with the skin therefore, malfunction is particularly dangerous if the device is not properly designed. The Panel believes that performance standards are necessary to assure that the device measurements are accurate. The Panel also recommends that FDA require labeling which identifies the limitations of the measurement. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with this device, which is used extensively.

5. Risks to health: Electrical shock: Excessive leakage current could cause injury, or a malfunction could result in dangerous electrical shock.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the nystagmograph be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1460 as follows:

§ 882.1460 Nystagmograph.

(a) *Identification.* A nystagmograph is a device used to measure, record, or visually display the involuntary movements (nystagmus) of the eyeball.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32873 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1016]

MEDICAL DEVICES

Classification of Neurological Endoscopes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying neurological endoscopes into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of neurological endoscopes:

1. Identification: A neurological endoscope is an instrument with a light source used to view the inside of the ventricles of the brain.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the neurological endoscope be classified into class II (performance standards) because the light intensity should be controlled to avoid burns, the optical distortion should be limited so that the field of view is faithfully reproduced, and the device should be subject to an electrical safety standard because it makes contact with body fluid. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members

based their recommendation on their clinical experience with these devices.

5. Risks to health: (a) Infection: The device could introduce bacteria into cerebrospinal fluid if the device is not adequately sterilized. (b) Burns: Excessive illuminating power can cause burns. (c) Electrical shock: The patient may receive an electrical shock because a low resistance path exists between the patient and the instrument.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the neurological endoscope be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1480 as follows:

§ 882.1480 Neurological endoscope.

(a) *Identification.* A neurological endoscope is an instrument with a light source used to view the inside of the ventricles of the brain.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32874 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1017]

MEDICAL DEVICES

Classification of Esthesiometers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying esthesiometers into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of esthesiometers:

1. Identification: An esthesiometer is a mechanical device which usually consists of a single rod or fiber which is held in the fingers of the physician or other examiner and which is used to determine whether a patient has tactile sensitivity.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempted from good manufacturing practices regulations under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that the esthesiometer be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This simple device presents no risks to health, and the examiner can easily determine whether the device is effective by examining it. The Panel believes that manufacturers of the device should not be required to comply with good manufacturing practice regulations in manufacturing the device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with this device becasue it is routinely used by neurologists as an aid to physical examination.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the esthesiometer be classified into class I (general controls) because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

The Commissioner is also proposing that the esthesiometer be exempted from good manufacturing practice regulations under section 520(f) of the act and from recordkeeping and reporting requirements in good manufacturing practice regulations, because all defects related to the safety and effectiveness of the device are readily detectable prior to use. The FDA's good manufacturing practice regulations for medical devices (21 CFR Part 820) were published in the FEDERAL REGISTER of July 21, 1978 (43 FR 31508).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1500 as follows:

§ 882.1500 Esthesiometer.

(a) *Identification.* An esthesiometer is a mechanical device which usually consists of a single rod or fiber which is held in the fingers of the physician or other examiner and which is used to determine whether a patient has tactile sensitivity.

(b) *Classification.* Class I (general controls). Exempt from the good manufacturing practice regulation in Part 820 of this chapter, including recordkeeping and reporting requirements in Part 820 of this chapter.

Interested persons may, on or before January 29, 1978, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments,

and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32875 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1018]

MEDICAL DEVICES

Classification of Tuning Forks

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying tuning forks into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of tuning forks:

1. Identification: A tuning fork is a mechanical device which resonates at a given frequency and is used to diagnose hearing disorders and to test for vibratory sense.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempted from good manufacturing practice regulations under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The tuning fork is a well-known device which contains no hazards to health and which can be adequately regulated by general controls. The Panel recommends that manufacturers of the device not be required to comply with good manufacturing practice regulations in manufacturing the device because tuning forks require no special qualities for medical use.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with this device and its long history of routine use in neurological examinations.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the tuning fork be classified into class I (general controls) because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Commissioner is also proposing that the tuning fork be exempted from good manufacturing practice regulations under section 520(f) of the act and from recordkeeping and reporting requirements in good manufacturing regulations, because all defects related to safety and effectiveness of the device are readily detectable prior to use. The FDA's good manufacturing practice regulations for medical devices (21 CFR Part 820) were published in the FEDERAL REGISTER of July 21, 1978 (43 FR 31508).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1525 as follows:

§ 882.1525 Tuning fork.

(a) *Identification.* A tuning fork is a mechanical device which resonates at a given frequency and is used to diagnose hearing disorders and to test for vibratory sense.

(b) *Classification.* Class I (general controls). Exempt from the good manufacturing practice regulations in Part 820 of this chapter, including recordkeeping and reporting requirements in Part 820 of this chapter.

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32876 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1019]

MEDICAL DEVICES

Classification of Galvanic Skin Response Measurement Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying galvanic skin response measurement devices into class II (performance standards). The FDA is also publishing the recommendations of the Neurological Device Classification Panel that these devices be classified into class II and of the Physical Medicine Device Classification Panel that these devices be classified into class II if they are AC powered and into class I if they are battery powered. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and

Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8758 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel and the Physical Medicine Device Classification Panel, FDA advisory committees, made the following recommendation with respect to the classification of galvanic skin response measurement devices:

1. Identification: A galvanic skin response measurement device is a device used to determine autonomic responses as psychological indicators by measuring the electrical resistance of the skin and the tissue path between two electrodes applied to the skin.

2. Recommended classification: The Neurological Device Classification Panel recommends that these devices be classified into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Physical Medicine Device Classification Panel recommends that this device be classified into class II if it is powered by alternating current (AC) and that establishing a performance standard for this device be a low priority. The Physical Medicine Device Classification Panel recommends that if the devices are battery powered, they be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Neurological Device Classification Panel recommends that galvanic skin response measurement devices be classified into class II because the Panel believes that the characteristics of the electrical current, which is applied to measure the resistance of the skin, should be controlled to prevent injury. The Panel also believes that the measurement limitations inherent in the use of the device should be clearly specified by manufacturers in the device's labeling. The Physical Medicine Device Classification Panel recommends that AC-powered galvanic skin response measurement devices be classified into class II because they believe that a standard is needed to prevent electrical shock and burns from leakage of electrical current. The Physical Medicine Device Classification Panel recommends that battery-powered galvanic skin response measurement devices be classified into class I because they believe that the risks of electrical shock and burns are not as great with battery-powered devices as with AC-powered devices and the safety and effectiveness of the battery-powered device can be reasonably assured by general controls. Both the Neurological Device Classification Panel and the Physical Medicine Device Classification Panel believe that a standard will provide reasonable assurance of safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with this device.

5. Risks to health: a. Electrical shock: Excessive current could cause injury, or a malfunction could result in an electric shock.

b. Inaccurate measurements: An inaccurate diagnosis could result if the device does not measure skin resistance accurately.

PROPOSED CLASSIFICATION

The Commissioner does not agree with the Physical Medicine Device Classification Panel recommendation that the battery-powered galvanic skin response measurement device be classified into class I (general controls). Although it is true that there is less risk of electrical shock from a battery-powered device than from an AC-powered device, there still is enough of a risk of electrical shock from the battery-powered device to justify the application to it of a performance standard. The Commissioner therefore agrees with the Neurological Device Classification Panel and is proposing that the galvanic skin response measuring device, whether battery-powered or AC-powered, be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1540 as follows:

§ 882.1540 Galvanic skin response measurement device.

(a) *Identification.* A galvanic skin response measurement device is a device used to determine autonomic responses as psychological indicators by measuring the electrical resistance of the skin and the tissue path between two electrodes applied to the skin (including the electrode/skin interface impedance).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32877 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1020]

MEDICAL DEVICES

Classification of Nerve Conduction Velocity Measurement Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nerve conduction velocity measurement devices into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drug proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of nerve conduction velocity measurement devices:

1. Identification: A nerve conduction velocity measurement device is a device which measures nerve conduction time by applying a stimulus, usually to a patient's peripheral nerve. This device includes the stimulator and the electronic processing equipment for measuring and displaying the nerve conduction time.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that nerve conduction velocity measurement devices be classified into class II (performance standards) because the electrical properties of the device must be controlled to assure that nerve conduction velocity will be accurately measured and to prevent burns and electrical shock from the electrical stimulus that the device applies to the patient. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience with these devices.

5. Risks to health: a. Burns: The device includes an electrical stimulator which may burn the skin if the electrical current is excessive.

b. Electrical shock: Leakage current can be especially dangerous because the device makes a low resistance contact with the patient.

c. Misdiagnosis: Inaccurate measurement of the nerve conduction velocity can result in improper treatment.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the nerve conduction velocity measurement devices be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1550 as follows:

§ 882.1550 **Nerve conduction velocity measurement device.**

(a) *Identification.* A nerve conduction velocity measurement device is a device which measures nerve conduction time by applying a stimulus, usually to a patient's peripheral nerve. This device includes the stimulator and the electronic processing equipment for measureing and displaying the nerve conduction time.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32878 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1021]

MEDICAL DEVICES

Classification of Skin Potential Measurement Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation clasifying skin potential measurement devices into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, RM. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological device Classification Panel, an FDA advisory committee, made the following recommendation will respect to the classfication of skin potential measurement devices:

1. Identification: A skin potential measurement device is a general diagnostic device used to measure skin voltage by means of surface skin electrodes.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the skin potential measurement device be classified into class II (performance standards) to ensure that the device provides accurate measurements and to prevent electrical shock. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with these devices.

5. Risks to health: a. Misdiagnosis: If a device that is not calibrated and accurate is used for diagnosis of disease conditions, inappropriate treatments may be prescribed.

b. Electrical shock: Excessive leakage current can cause electrical shock.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the skin potential measurement device be classified into class II (performance standards). The Com-

missioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1560 as follows:

§ 882.1560 Skin potential measurement device.

(a) *Identification.* A skin potential measurement device is a general diagnostic device used to measure skin voltage by means of surface skin electrodes.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, RM. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: Nov. 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32879 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1022]

MEDICAL DEVICES

Classification of Powered Direct-Contact Temperature Measurement Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered direct-contact temperature measurement devices into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of powered direct-contact temperature measurement devices:

1. Identification: A powered direct-contact temperature measurement device is a device which contains a power source and is used to measure differences in temperature between two points on the body.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the powered direct-contact temperature measurement device be classified into class II (performance standards) to insure adequate sensitivity to temperature differences and to prevent accidental reversal of temperature-sensing elements. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with the device and the techniques of temperature measurement.

5. Risks to health: Misdiagnosis: Accidentally reversed sensing elements or lack of adequate sensitivity to temperature differences can result in misdiagnosis and improper treatment.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the powered direct-contact temperature measurement device be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1570 as follows:

§ 882.1570 Powered direct-contact temperature measurement device.

(a) *Identification.* A powered direct-contact temperature measurement device is a device which contains a power source and is used to measure differences in temperature between two points on the body.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32880 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1023]

MEDICAL DEVICES

Classification of Alpha Monitors

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying alpha monitors into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of alpha monitors:

1. Identifidcation: An alpha monitor is a device with electrodes that are placed on a patient's scalp to monitor that portion of the electroencephalogram which is referred to as the alpha wave.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that this device, which is a specialized version of the electroencephalograph, be classified into class II (performance standards) to assure control of electrical safety and that the device performs properly. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience with the clinical use of electroencephalography and related devices.

5. Risks to health: a. Misdiagnosis: If the phyhsiological signal is distorted or the electrical filtering process does not correctly select the alpha wave, the physician may make an erroneous assessment of the patient's neurological state.

b. Electrical shock: Excessive leakage current could cause injury, or a malfunction could result in dangerous electrical shock.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the alpha monitor be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1610 as follows:

§ 882.1610 Alpha monitor.

(a) *Identification.* An alpha monitor is a device with electrodes that are placed on a patient's scalp to monitor that portion of the electroencephalogram which is referred to as the alpha wave.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32881 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1024]

MEDICAL DEVICES

Classification of Intracranial Pressure Monitoring Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying intracranial pressure monitoring devices into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation

with respect to the classification of intracranial pressure monitoring devices:

1. Identification: An intracranial pressure monitoring device is a device used for short term monitoring and recording of intracranial pressures and pressure trends. The device includes the transducer, monitor and interconnecting hardware.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that intracranial pressure monitoring devices be classified into class II because the Panel believes that the device needs to be subject to a performance standard to assure that the pressure measurements obtained from the device are accurate, to prevent brain damage due to an excessively bulky device, and to assure that the device is designed to prevent leakage of cerebrospinal fluid. The Panel also recommends that intracranial pressure monitoring systems be required to incorporate an alarm that is triggered by sudden or abnormal increases in intracranial pressure. The Panel recommends that intracranial pressure monitoring devices be classified into class II (performance standards) but that the recommendation apply only to short-term clinical applications of intracranial pressure monitoring because sufficient clinical data are not available to evaluate long-term use and because the Panel is not aware of a commercially available product intended for long-term use. Although a variety of devices has been used to monitor intracranial pressure, they all consist essentially of a manometer (pressure indicator) inserted through a hole in the skull so that a pressure connection is made with the fluid that surrounds the brain. This procedure presents risks of brain damage and infection. However, the Panel believes that, in certain circumstances, the information obtained by monitoring intracranial pressure is sufficiently valuable to justify the risks. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: Intracranial pressure monitoring devices have been used in various forms for several years. The Panel members based their recommendation on their clinical experience with intracranial pressure monitoring devices.

5. Risks to health: a. Brain damage by pressure. An excessively bulky device could exert damaging pressure on the brain.

b. Brain damage by surgical trauma. The surgery involved in inserting this device presents inherent risks.

c. Inaccurate pressure readings. A defect in the device can result in inaccurate pressure readings.

d. Leakage of cerebrospinal fluid. The device needs to have a tight seal to prevent leakage of cerebrospinal fluid.

e. Infection. Infection may result if the device is not sterile or if contaminants enter the surgical opening.

Proposed Classification

The Commissioner agrees with the Panel recommendation to classify intracranial pressure monitoring devices into class II (performance standards). The Commissioner also agrees with the Panel's decision to distinguish between the usual short-term application of the intracranial pressure monitoring device and the possible long-term application of the device. Sufficient clinical data are not available to permit evaluation of long-term use of the device.

The FDA has reviewed literature relating to intracranial pressure monitoring devices and has found that several devices have been used which measure pressure by a direct connection with the fluid in the subdural space of the brain. (Refs. 1 through 4). Epidural devices (inserted between the cranium and the dura mater; i.e., the tough, outer membrane covering the brain) are also currently being used to monitor intracranial pressure (Refs. 5 through 7), but on an investigational basis.

In the literature reviewed, an investigation of one device in a series of 650 patients (Ref. 2) showed an average infection rate of 2.1 percent and an average device failure rate of 8 percent. Device failures were due either to faulty installation or to brain herniation. In this investigation, the monitoring device was not left in place more than 20 days, and 5 days use was typical. In another study of a different device involving 27 patients, the pressure monitoring device was left in place for longer periods of time, with 14 days being a typical period and the extreme being 41 days (Ref. 4).

Based on the Panel recommendation and the references listed below, the Commissioner is proposing that the intracranial pressure monitoring device for short-term monitoring be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

References

The following information has been placed in the office of the Hearing Clerk (HFC20), Rm. 465, 5600 Fishers Lane, Rockville, MD 20857, and may be viewed by interested persons from 9 a.m. to 4 p.m. Monday through Friday, except on Federal holidays:

1. Hanlon, K., "Description and Uses of Intracranial Pressure Monitoring," *Heart and Lung*, 5:277282, 1976.

2. Winn, H. R. et al., "Intracranial Subarachnoid Pressure Recording: Experience With 650 Patients," *Surgical Neurology*, 8:41-47, (1977).

3. Vries, J. K. et al., "A Subarachnoid Screw for Monitoring Intracranial Pressure," *Journal of Neurosurgery*, 39:416-419, 1973.

4. Tindal, G. T. et al., "Current Methods for Monitoring Patients with Head Injury," *Clinical Neurosurgery*, 19:98-120, 1972.

5. Dorsch, N. W. C. and L. Symon, "A Practical technique for Monitoring Extradural Pressure," *Journal of Neurosurgery*, 42:249-257, 1975.

6. Zervas, N. T. et al., "A Pressure-Balanced Radio-Telemetry System for the Measurement of Intracranial Pressure," *Journal of Neurosurgery*, 47:899-911, 1977.

7. Yoneda, S. et al., "Continuous Measurement of Intracranial Pressure with SFT: Clinical Experience," *Surgical Neurology*, 4:289-295, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1620 as follows:

§ 882.1620 Intracranial pressure monitoring device.

(a) *Identification.* An intracranial pressure monitoring device is a device used for short term monitoring and recording of intracranial pressures and pressure trends. The device includes the transducer, monitor, and interconnecting hardware.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32682 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1025]

MEDICAL DEVICES

Classification of Percussors

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying percussors into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of percussors:

1. Identification: A percussor is a small hammerlike device used by a physician to provide light blows to a body part. A percussor is used as a diagnostic aid during physical examinations.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempted from good manufacturing practice regulations under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for classification: A percussor is a simple nonpowered device, usually a rubber tipped hammer, used as an aid in physicial examination. Because the characteristics of the device are obvious, and its functional capability is easily determined by examination of the device, the Panel recommends that the device be classified into class I (general controls) and that the manufacturer not be required to comply with the good manufacturing practice requirements.

4. Summary of data on which the recommendation is based: The Panel members are familiar with devices of this type because they are used in routine physical examinations.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the percussor be classified into class I (general controls) because the Commissioner believes that general controls are sufficient to provide a reasonable assurance of the safety and effectiveness of the device.

The Commissioner is also proposing that the percussor be exempted from good manufacturing practice regulations under section 520(f) of the act and from recordkeeping and reporting requirements in good manufacturing practice regulations, because all defects related to the safety and effectiveness of the device are readily detectable prior to use. The FDA's good manufacturing practice regulations for medical devices (21 CFR Part 820) were published in the FEDERAL REGISTER of July 21, 1978 (43 FR 31508).

Therefore, under provisions of the Federal Food, Drug, and Cosmetic Act (sec. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360C 371(a))) and authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1700 as follows:

§ 882.1700 Percussor.

(a) *Identification.* A percussor is a small hammerlike device used by a physician to provide light blows to a body part. A percussor is used as a diagnostic aid during physical examinations.

(b) *Classification.* Class I (general controls). Exempt from the good manufacturing practice regulations in Part 820 of this chapter, including recordkeeping and reporting requirements in Part 820 of this chapter.

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32883 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1026]

MEDICAL DEVICES

Classification of Pinwheels

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pinwheels into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendations with respect to the classification of pinwheels:

1. Identification: A pinwheel is a device with sharp points on a rotating wheel used for testing pain sensation.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendations: The Panel recommends that the pinwheel be classified into class I (general controls) because it is a simple mechanical device which contains no hazards to health and which requires no special material or properties.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with this deivice.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the pinwheels be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1750 as follows:

§ 882.1750 Pinwheel.

(a) *Identification.* A pinwheel is a device with sharp points on a rotating wheel used for testing pain sensation.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32884 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1027]

MEDICAL DEVICES

Classification of Ocular Plethysmographs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ocular plethysmographs into class III (premarket approval). the FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A notice elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. the Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of ocular plethysmographs:

1. Identification: An ocular plethysmograph is a device used to measure or detect volume changes in the eye produced by pulsations of the artery, to diagnose carotid artery occlusive disease (restriction on blood flow in a carotid artery).

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reaons for recommendation: The Panel recommends that the ocular plethysmograph be classified into class III (premarket approval) because the device is used to detect the life-threatening condition that occurs when the brain does not receive adequate blood flow through a carotid artery. Also, the Panel believes that it is not possible to establish an adequate performance standard for this device. The information derived from the ocular plethysmograph may be used to screen patients for the more risky diagnostic procedure of carotid angiography (an invasive radiological technique involving injection of radiopaque material into the patient's arterial system to detect arterial disorders such as carotid artery occlusion). If the ocular plethysmograph produces a false positive result, an unnecessary carotid angiography procedure may be performed; however, a false negative result could result in the failure to detect carotid artery occlusion. the Panel believes that the reliability of ocular plethysmograph measurements in detecting the presence or absence of carotid artery occlusion has not been sufficiently demonstrated and that the device should, therefore, be subject to premarket approval to assure satisfactory performance of the device and thus to provide reasonable assurance of its safety and effectiveness.

4. Summary of data on which the recommendation is based: the Panel members based their recommendation on their clinical experience and their knowledge of the techniques used in ocular plethysmography.

5. Risks to health: a. Eye injury. Excessive pressure can damage the eye.

b. Misdiagnosis. The device may misdiagnose the presence or absence of carotid artery occclusion because of a poor relationship between pulsatile arterial blood flow changes and the degree of occlusion.

c. Infection. Eye cups that are not sterile can cause infections.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that ocular plethysmographs be classified into class III (premarket approval).

The Commissioner believes that the device presents a potential unreasonable risk of illness or injury to the patient, especially if practitioners rely upon the information derived from the device to diagnose carotid artery occclusion. Furthermore, the device is for a use (screening for carotid angiography) which is of substantial importance in preventing impairment of human health. The Commissioner believes that insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard that will provide such assurance. Therefore, the Commissioner is proposing that ocular plethysmographs be classified into class III (premarket approval).

The Commissioner has obtained additional data and information describing the application of ocular plethysmographic devices. There are two techniques used to diagnose an occlusion of the carotid artery: pulse delay detection and ophthalmic artery pressure measurement.

The pulse delay detection technique gives inaccurate diagnostic information when a patient has symmetrical bilateral occlusive disease of the carotid artery, disease of the eye globe, occlusive disease of the ophthalmic artery, or arteriosclerotic lesions that do not alter blood flow (Ref. 1). A study of 210 carotid arteries reported that this technique is 81 percent accurate when results from it are compared with those of carotid angiography (Ref.1). In another study involving 936 caparisons with results of carotid angiography, 7 percent of diagnoses were false negatives (significant occlusion that was not detected), and 8 percent of diagnoses were false positives (patients without significant occlusive disease were indicated by the technique to have occlusion) (Ref. 2).

The systolic ophthalmic artery pressure measurement technique causes a transient elevation of intraocular pressure that is 400 percent to 500 percent above normal (Refs. 3 through 5). This technique does not accurately diagnose patients with less than 70 percent occlusion of the carotid artery (Ref. 1). Greater sensitivity is reported when the carotid artery is compressed manually (Refs. 1 and 3). However, because the carotid compression technique presents risks of cardiac arrhythmia or neurologic deficit, adequate assurance of safety is not possible.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday, except on Federal Holidays:

1. Dean, R. and J. Yao, "Hemodynamic Measurements in Peripheral Vascular Disease," *Current Problems in Surgery*, 12:52-56, 1976.

2. Karchner et al., "Oculoplethysmography: An Adjunct to Arteriography in the Diagnosis of Extracranial Carotid Occlusive Disease," *American journal of Surgery*, 132:728-732, 1976.

3. Gee, W. et al., "Measurement of Collateral Cerebral Hemispheric Blood Pressure by Ocular Pneumoplethysmography," *American Journal of Surgery*, 130:121-127, 1975.

4. Gee, W. et al., "Simultaneous Bilateral Determination of the Systolic Pressure of the Ophthalmic Arteries by Ocular Pneumoplethysmography," *Investigative Ophthalmology and Visual Science*, 16:86-89, 1977.

5. Gee, W. et al., "Noninvasive Diagnosis of Carotid Occlusion by Ocular Pneumoplethysmography," *Stroke*, 7:18-21, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1790 as follows:

§ 882.1790 Ocular plethysmograph.

(a) *Identification.* An ocular plethysmograph is a device used to measure or detect volume changes in the eye produced by pulsations of the artery, to diagnose carotid artery occlusive disease (restrictions on blood flow in the carotid artery).

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32885 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1028]

MEDICAL DEVICES

Classification of Rheoencephalographs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rheoencephalographs into class III (premarket approval). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of rheoencephalographs:

1. Identification: A rheoencephalograph is a device used to estimate a patient's cerebral circulation (blood flow in the brain) by electrical impedance methods with direct electrical connections to the scalp or neck area.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the rheoencephalograph be classified into class III because satisfactory performance has never been demonstrated, and the Panel believes that it is not possible to establish an adequate performance standard for this device. Although electrical standards would be sufficient to control electric shock hazard, the device design presents an inherent risk of misdiagnosis of cerebral circulatory status. The device, therefore, should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel members are familiar with the literature on this device. Some of the panel members have witnessed its clinical application. Dr. William Jarzembski, one of the Panel members, provided some detailed information concerning his research on this device.

5. Risks to health: a. Erroneous clinical conclusions. The device may indicate that cerebral circulation is normal, when in fact it may be very abnormal.

b. Electrical shock. Excessive current could cause injury, and malfunction of the device could result in an electrical shock.

c. Skin reaction. The electrode materials and conductive media may irritate the skin.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that rheoencephalographs be classified into class III (premarket approval). The Commissioner has reviewed the Panel recommendation and has obtained additional data and information describing the application of cranial impedance techniques (rheoencephalograph) to measure cranial blood flow. Some of the literature states that this measurement is feasible but has not been sufficiently refined to be practical (Refs. 1 through 3). However, Hill et al. (Ref. 4) assert that the theoretical basis for this measurement is erroneous and that the pulsatile signal obtained from these devices is due to an unrelated phenomenon.

The Commissioner believes that the device presents a potential unreasonable risk of illness or injury to the patient if practitioners rely upon the information derived from the device to diagnose conditions which result in abnormal cerebral blood flow. The Commissioner concurs that insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and he believes that insufficient information exists to establish a performance standard that will provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, and may be viewed by interested persons from 9 a.m. to 4 p.m., Monday through Friday, except on Federal holidays:

(1) Jarzembski, W. B., "Pathological Implications of Transcranial Impedence Change," (prepublication draft).

(2) Jarzembski, W. B., "Evaluation of Specific Cerebral Impedance and Cerebral Current Density," *Annals of New York Academy of Science*, 170:476-490, 1970.

(3) Geddes, L. A. and H. E. Hoff, "The Measurement of Physiologic Events by Electrical Impedance," *American Journal of Medical Electronics*, 3:16-27, 1964.

(4) Hill, R. V. et al., "Electrical Impedance Plethysmography: A Critical Analysis," *Journal of Applied Physiology*, 22:161-68, 1967.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)) and authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1825 as follows:

§ 882.1825 Rheoencephalograph.

(a) *Identification.* A rheoencephalograph is a device used to estimate a patient's cerebral circulation (blood flow in the brain) by electrical impedance methods with direct electrical connections to the scalp or neck area.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32886 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1029]

MEDICAL DEVICES

Classification of Physiological Signal Amplifiers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying physiological signal amplifiers into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of physiological signal amplifiers:

1. Identification: A physiological signal amplifier is a general purpose device used to electrically amplify signals derived from various physiological sources (e.g., the electroencephalogram).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the physiological signal amplifier be classified into class II (performance standards) to assure that the device is electrically safe because the amplifier makes a low-resistance connection with the patient and there is a hazard of dangerous electrical shock. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience and their knowledge of these devices.

5. Risks to health: Electrical shock: Leakage of electric current can produce dangerous electrical shock.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the physiological signal amplifier be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a) 52 Stat. 1055, 90 Stat. 540546 (21 U.S.C. 360c, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1835 as follows:

§ 882.1835 Physiological signal amplifiers.

(a) *Identification.* A physiological signal amplifier is a general purpose device used to electrically amplify signals derived from various physiological sources (e.g., the electroencephalogram).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32887 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1030]

MEDICAL DEVICES

Classification of Physiological Signal Conditioners

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulaton classifying physiological signal conditioners into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of physiological signal conditioners:

1. Identification: A physiological signal conditioner is a device such as an integrator or differentiator used to modify physiological signals for recording or processing.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class II (performance standards) to assure a sufficient degree of accuracy for its intended function. Also, electrical safety standards are needed to prevent excessive leakage current when used with other electrical hospital equipment. The Panel believes that general controls will not provide sufficient control of the device characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience and indicate that these hazards are widely recognized.

5. Risks to health: a. Electrical shock: Use of this device with other hospital equipment might result in leakage current and electrical shock of the patient.

b. Inaccurate diagnosis. Inadequate accuracy or distortion of the physiological signal could result in false information.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the physiological signal conditioner be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new §882.1845 as follows:

§ 882.1845 Physiological signal conditioner.

(a) *Identification.* A physiological signal conditioner is a device such as an integrator or differentiator used to modify physiological signals for recording and processing.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hous of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32888 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1031]

MEDICAL DEVICES

Classification of Physiological Signal Telemetry Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying physiological signal telemetry systems into class II (perform-

ance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of physiological signal telemetry systems:

1. Identification: A physiological signal telemetry system consists of transmitters, receivers, and other components used for remotely monitoring or measuring physiological signals by means of radio or telephone transmission systems.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class II (performance standards) to ensure that the device performs with a sufficient degree of accuracy. The Panel believes that electrical safety standards are also needed to prevent excessive leakage current when the device is used with other electrical hospital equipment. The Panel believes that general controls will not provide sufficient control of the device characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience with this device and state that users are familiar with the identified risks to health presented by this device.

5. Risks to health: a. Electrical shock: Use of this device with other hospital equipment might cause excessive leakage current that would be hazardous to the patient.

b. Inaccurate diagnosis. Inadequate accuracy or distortion of the physiological signal could result in false information and, therefore, inaccurate diagnosis.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the physiological signal telemetry system be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1855 as follows:

§ 882.1855 **Physiological signal telemetry system.**

(a) *Identification:* A physiological signal telemetry system consists of transmitters, receivers, and other components used for remotely monitoring or measuring physiological signals by means of radio or telephone transmission systems.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32889 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1032]

MEDICAL DEVICES

Classification of Evoked Response Electrical Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying evoked response electrical stimulators into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of evoked response electrical stimulators:

1. Identification: An evoked response electrial stimulator is a device used to apply an electrical stimulus to a patient by means of skin electrodes for the purpose of measuring the evoked response.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class II (performance standards) because its electrical current may cause burns to the body if the output parameters are not controlled. The Panel believes that the device is safe when the electrical output is limited according to established parameters. The Panel believes that performance standards can be established to control the risks of this device and that the provisions of general controls are not sufficient to assure its safety and effectiveness. The Panel believes that performance standards will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which recommendation is based: The Panel members based their recommendation on their clinical experience and judgment. Electrical stimulators for evoked response measurements have been widely used.

5. Risks to health: a. Local burns. Improper electrode surface area or excessive current can cause burns.

b. Electrical shock. Leakage current can produce electrical shock.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the evoked response electrical stimulator be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1870 as follows:

§ 882.1870 Evoked respose electrical stimulators.

(a) *Identification.* An evoked response electrical stimulator is a device used to apply an electrical stimulus to be patient by means of skin electrodes for the purpose of measuring the evoked response.

(b) *Classification:* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32890 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1033]

MEDICAL DEVICES

Classification of Evoked Response Mechanical Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying evoked response mechanical stimulators into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of evoked response mechanical stimulators:

1. Identification: An evoked response mechanical stimulator is a device used to produce a mechanical stimulus or a series of mechanical stimuli for the purpose of measuring a patient's evoked response.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendations: The Panel recommends that this device be classified into class II (performance standards) to protect the patient against the possibility of electrical shock hazard from an external electrical source. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience and scientific knowledge regarding the problems posed by electrical devices.

5. Risks to health: Electrical shock: Use of this device with other hospital equipment might produce "sneak" circuits that could result in hazardous leakage current to the patient.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the evoked response mechanical stimulator be classified into class II (performance standards). However, he is aware that evoked response averaging techniques require the stimulator to be synchronized with the recording device to permit proper interpretation of the evoked response record. The Commissioner believes, therefore, that the functional characteristics of this device are important to its effectiveness and should also be addressed in a standard. The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1),

the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1880 as follows:

§ 882.1880 Evoked response mechanical stimulator.

(a) *Identification.* An evoked response mechanical stimulator is a device used to produce a mechanical stimuli or a series of mechanical stimuli for the purpose of measuring a patient's evoked response.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32891 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1034]

MEDICAL DEVICES

Classification of Evoked Response Photic Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying evoked response photic stimulators into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of evoked response photic stimulators:

1. Identification: An evoked response photic stimulator is a device used to apply a brief light stimulus to a patient's eye for use in evoked response measurements or electroencephalogram activation.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the evoked response photic stimulator be classified into class II (performance standards) because an excessively intensive light source may damage the retina, and the possibility of flashlamp implosion requires that protection be provided. Also, the Panel believes that electrical safety standards are needed to eliminate shock hazards, especially when the device is used with other electrical equipment. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectivenss of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience and state that these hazards are widely recognized.

5. Risks to health: a. Retinal damage. An intense light source could burn the retina.

b. Eye and face injury. Glass from an imploding lamp could be projected toward the face.

c. Electrical shock. Use of this device with other hospital equipment might produce "sneak" circuits that could result in hazardous leakage current to the patient.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the evoked response photic stimulator be classified into class II (performance standards). In addition to the hazards cited by the Panel, the Commissioner believes that this device has performance characteristics which should be controlled to insure that it performs its intended function. Failure of the device to perform satisfactorily can result in erroneous diagnosis of various neurological disorders. The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectivenss of the device. The Commissioner also believs that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under provisions of the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1890 as follows:

§ 882.1890 Evoked response photic stimulator.

(a) *Identification.* An evoked response photic stimulator is a device used to apply a brief light stimulus to a patient's eye for use in evoked response measurements or for electroencephalogram (EEG) activation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32892 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1035]

MEDICAL DEVICES

Classification of Evoked Response Auditory Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying evoked response auditory stimulators into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of evoked response auditory stimulators:

1. Identification: An evoked response auditory stimulator is a device that produces a sound stimulus for use during evoked response measurements or electroencephalogram activation.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Pannel recommendations that evoked response auditory stimulators be classified into class II (performance standards) because the device applies to the ear acoustic energy which should be carefully limited to prevent hearing loss and other injury, and the performance of the device should meet standards to ensure that an accurate result is obtained. Electric shock hazards are present with this device and should be controlled by standards. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: Audiometry and evoked response measurements are used clinically on a routine basis. The Panel members based their recommendation on their clinical experience and their knowledge of this technique.

5. Risks to health: a. Hearing damage: Excessive sound intensity can injure the ear.

b. Electrical shock: Use of this device with other hospital equipment might produce "sneak" circuits that could result in hazardous leakage current to the patient.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the evoked response auditory stimulator be classified into class II (performance standards). In addition to the risks to health cited by the Panel, the Commissioner believes that there are risks associated with the fact that a failure of this device to perform accurately is not necessarily apparent to the physician and may result in failure to detect hearing loss. The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissionr also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1900 as follows:

§ 882.1900 Evoked response auditory stimulator.

(a) *Identification.* An evoked response auditory stimulator is a device that produces a sound stimulus for use in evoked response measurements or electroencephalogram activation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32893 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1036]

MEDICAL DEVICES

Classification of Ultrasonic Scanner Calibration Test Blocks

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ultrasonic scanner calibration test blocks into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of ultrasonic scanner calibration test blocks:

1. Identification: An ultrasonic scanner calibration test block is a block of material with known properties used to calibrate ultrasonic scanning devices (e.g., the echoencephalograph).
2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.
3. Summary of reasons for recommendation: This device consists of a block of material of known thickness and composition that is used to calibrate ultrasonic scanning devices. Because the device makes no contact with the patient, the Panel believes that it does not present a risk to the patient and, therefore, the Panel recommended that it be classified into class I (general controls).
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on experience with ultrasonic scanning devices.
5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the ultrasonic scanner calibration test blocks be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide a reasonable assurance of safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1925 as follows:

§ 882.1925 Ultrasonic scanner calibration test block.

(a) *Identification.* An ultrasonic scanner calibration test block is a block of material with known properties used to calibrate ultrasonic scanning devices (e.g., the echoencephalograph).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32894 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1037]

MEDICAL DEVICES

Classification of Tremor Transducers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying tremor trnasducers into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of tremor transducers:

1. Identification: A tremor transducer is a device used to measure the degree of tremor caused by certain diseases.
2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.
3. Summary of reasons for recommendations: Tremor transducers are used to quantify what would otherwise be a subjective estimate. The physiological measurement which is performed does not need to be precise. However, because the device is electrically powered, the Panel recommends that it be classified into class II (performance standards) to assure electrical safety. The Panel believes that general controls will not provide sufficient control of the device's characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.
4. Summary of data on which the recommendation is based: The Panel members believe that the need to control electrical hazards is well known.
5. Risks to health: Electrical shock: Excessive leakage current could injure the patient.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the tremor transducer be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart B by adding new § 882.1950 as follows:

§ 882.1950 Tremor transducer.

(a) *Identification.* A tremor transducer is a device used to measure the degree of tremor caused by certain diseases.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug

Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32895 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1038]

MEDICAL DEVICES

Classification of Skull Plate Anvils

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying skull plate anvils into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of skull plate anvils:

1. Identification: A skull plate anvil is a device used to form alterable skull plates in the proper shape to fit the curvature of a patient's skull.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the skull plate anvil be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The device is used only as a tool to alter skull plates and does not come into contact with the patient. The Panel believes that the device is constructed with generally acceptable materials and presents no health hazards.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with this device and the conditions of its use:

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the skull plate anvil be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 by adding new Subpart E—Neurological Surgical Devices—consisting at this time of § 882.4030, to read as follows:

Subparts C and D—[Reserved]

Subpart E—Neurological Surgical Devices

§ 882.4030 Skull plate anvil.

(a) *Identification.* A skull plate anvil is a device used to form alterable skull plates in the proper shape to fit the curvature of a patient's skull.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heating of this document. Received comments may be seen in the above office between the hours 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32896 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1039]

MEDICAL DEVICES

Classification of Ventricular Cannulas

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ventricular cannulas into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification

Panel, an FDA advisory committee, made the following recommendation with respect to the classification of ventricular cannulas:

1. Identification: A ventricular cannula is a device used to puncture the ventricles of the brain for aspiration or for injection This device is frequently referred to as a ventricular needle.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the ventricular cannula be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The ventricular cannula is a simple device that is frequently used in the practice of neurosurgery. The Panel does not believe that this device requires performance standards to control the identified risks to health.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with the device, which is routinely used in neurosurgery.

5. Risks to health: (a) Tissue or blood vessel damage. Brain tissue or intracranial blood vessels may be damaged if the ventricular cannula has sharp or uneven edges or burrs. (b) Infection. Since the cannula is inserted into the brain, infection may occur if the cannula is not sterile.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the ventricular cannula be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4060 as follows:

§ 882.4060 Ventricular cannula.

(a) *Identification.* A ventricular cannula is a device used to puncture the ventricles of the brain for aspiration or for injection. This device is frequently referred to as a ventricular needle.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32897 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1040]

MEDICAL DEVICES

Classification of Ventricular Catheters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ventricular catheters into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of ventricular catheters:

1. Identification: A ventricular catheter is a device used to gain access to the cavities of the brain for injection of material into, or removal of material from, the brain.

2. Recommend classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summay of reasons for recommendation: The Panel recommends that the ventricular catheter be classified into class II (performance standards) because the Panel believes that standards are necessary to control the surface properties of the catheter to avoid injury and to insure that the catheter can be sterilized. The Panel believes that the catheter should be constructed of materials that are suitable for chronic (long term) implantation because it is often necessary for the device to remain in the patient for an extended period of time. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with the device.

5. Risks to health: (a) Tissue or blood vessel damage: Brain tissue or intracranial blood vessels may be damaged if the ventricular catheter has sharp or uneven edges or burrs. (b) Infection: Since the catheter inserted into the brain, infection may occur if the catheter is not sterile.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the ventricular catheter be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4100 as follows:

§ 882.4100 Ventricular catheter.

(a) *Identification.* A ventricular catheter is a device used to gain access to the cavities of the brain for injection of material into, or removal of material from, the brain.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32898 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1041]

MEDICAL DEVICES

Classification of Neurosurgical Chairs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying neurosurgical chairs into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of neurosurgical chairs:

1. Identification: A neurosurgical chair is an operating room chair used to position and support a patient during neurosurgery.
2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.
3. Summary of reasons for recommendation: The Panel recommends that the neurosurgical chair be classified into class I because the device is used only to position and support the patient during surgery, and therefore general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that the user can control the possible hazard of chair position instability through proper maintenance. The Panel does not believe that this device requires a performance standard to control the identified risks to health.
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience.
5. Risks to health: Chair position instability: Chair position instability may allow sudden movement of the patient during the operation.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the neurosurgical chair be classifed into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4125 as follows:

§ 882.4125 Neurosurgical chair.

(a) *Identification.* A neurosurgical chair is an operating room chair used to position and support a patient during neurosurgery.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be indentified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32899 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1042]

MEDICAL DEVICES

Classification of Scalp Clips

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying scalp clips into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of scalp clips:

1. Identification: A scalp clip is a plastic or metal clip used to stop bleeding during surgery on the scalp.
2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.
3. Summary of reasons for recommendation: The Panel recommends that the scalp clip be classified into class II (performance standards) because performance standards are necessary to control the amount of pressure applied by the clip to the point of contact. These devices are used to clip temporally tissue or blood vessels during surgery of the head. The clips are not left in the patient but are removed upon completion of the surgery. The Panel believes that general controls will not provide sufficient control over the amount of pressure applied by the clip. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with these devices.
5. Risks to health: (a) Necrosis of the scalp: Injury to the scalp tissue may occur if the clip applies excessive pressure at the point of contact. (b) Failure of hemostasis: The pressure of the clip must be sufficient to prevent bleeding in the area applied

PROPOSED CLASSIFICATION

The commissioner agrees with the Panel's recommendation and is proposing that the scalp clip be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701 (a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371 (a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4150 as follows:

§ 882.4150 Scalp clip.

(a) *Identification.* A scalp clip is a plastic or metal clip used to stop bleeding during surgery on the scalp.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32900 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1043]

MEDICAL DEVICES

Classification of Aneurysm Clip Appliers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying aneurysm clip appliers into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of aneurysm clip appliers:

1. Identification: An aneurysm clip applier is a device used by the surgeon for holding and applying intracranial aneurysm clips.
2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.
3. Summary of reasons for recommendation: The Panel recommends that the aneurysm clip applier be classified into class II (performance standards) because it is a specialized surgical tool that must be very reliable. Its design may be quite simple, but a high degree of precision is needed to minimize the risk associated with clipping intracranial aneurysms. Although various types of this device that are quite satisfactory have been marketed, the Panel believes that performance standards are needed to ensure the degree of reliability, precision, and suitability necessary for adequate safety. The Panel believes that general controls will not provide sufficient control over these characteristics. Elsewhere in this issue of the FEDERAL REGISTER, the Panel is recommending that aneurysm clips be classified into class II and that they be given a high priority for development of standards. The Panel also recommends that the development of performance standards for the aneurysm clip applier be given a high priority because of the importance of the device to safe aneurysm clip surgery. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that sufficient information is available to establish a standard to provide such assurance.
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their extensive experience with the device, which is frequently used in aneurysm surgery.
5. Risks to health: (a) Blood vessel injury: If the device has sharp edges, the edges can cut a blood vessel. Mechanical action of the clip applier can shear a blood vessel. (b) Hemorrhage: Failure of the device to properly control the clip can result in a poorly applied clip that allows the aneurysm to leak. (c) Death: Improper manipulation of the clip can result in a rupture of the aneurysm, which is likely to be fatal.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is pro-

posing that the aneurysm clip applier be classified into class II (performance standard). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4175 as follows:

§ 882.4175 Aneurysm clip applier.

(a) *Identification.* An aneurysm clip applier is a device used by the surgeon for holding and applying intracranial aneurysm clips.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32901 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1044]

MEDICAL DEVICES

Classification of Clip Forming/Cutting Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying clip forming/cutting instruments into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of clip forming/cutting instruments:

1. Identification: A clip forming/cutting instrument is a device used by the physician to make tissue clips from wire stock.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the clip forming/cutting instrument be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. A clip forming/cutting instrument is a simple device used to cut pieces of wire in order to make tissue clips for use in surgery. The Panel believes that the device presents no health hazards.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity and clinical experience.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the clip forming/cutting instrument be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4190 as follows:

§ 882.4190 Clip forming/cutting instrument.

(a) *Identification.* A clip forming/cutting instrument is a device used by the physician to make tissue clips from wire stock.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32902 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1045]

MEDICAL DEVICES

Classification of Clip Removal Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying clip removal instruments into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of clip removal instruments:

1. Identification: A clip removal instrument is a device used to remove surgical clips from the patient.
2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.
3. Summary of reasons for recommendation: The Panel recommends that the clip removal instrument be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panel believes that this simple device presents no health hazards.
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience.
5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the clip removal instrument be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4200 as follows:

§ 882.4200 **Clip removal instrument.**

(a) *Identification.* A clip removal instrument is a device used to remove surgical clips from the patient.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32903 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1046]

MEDICAL DEVICES

Classification of Clip Racks

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying clip racks into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of clip racks:

1. Identification: A clip rack is a device used to hold or store surgical clips during surgery.
2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.
3. Summary of reasons for recommendation: The Panel recommends that the clip rack be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The device is used for storing clips and does not come into direct contact with the patient.
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience.
5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the clip rack be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4215 as follows:

§ 882.4215 **Clip rack.**

(a) *Identification.* A clip rack is a device used to hold or store surgical clips during surgery.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours

of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32904 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882

[Docket No. 78N-1047]

MEDICAL DEVICES

Classification of Cryogenic Surgical Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cryogenic surgical devices into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cryogenic surgical devices:

1. Identification: A cryogenic surgical device is a device used to destroy nervous tissue or produce lesions in nervous tissue by the application of extreme cold to the selected site.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Sumary of reasons for recommendation: The Panel recommends that cryogenic surgical devices be classified into class II (performance standards) because the temperature of the device probe must be controlled assure satisfactory performance. The Cryogenic surgical device is used to destroy selectively very small parts of the brain or spinal cord. The size of the destroyed area is determined by the temperature of the tip of the device probe, and the destroyed area must be precisely controlled to minimize the risk of causing a neurologic deficit or of failing to obtain a good therapeutic result. The Panel believes that general controls will not provide sufficient control over these characteristics. The panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with these devices.

5. Risks to health: (a) Inappropriate size lesions. Inaccurate control of the temperature can result in a lesion that is either too large or too small. A lesion that is too small does not produce a good therapeutic result and a lesion that is too large may cause a neurological deficit. (b) Electrical shock. Leakage current from the thermal element or from the monitoring element can injure the patient.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cryogenic surgical device be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4250 as follows:

§ 882.4250 Cryogenic surgical device.

(a) *Identification.* A cryogenic surgical device is a device used to destroy nervous tissue or produce lesions in nervous tissue by the application of extreme cold to the selected site.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32905 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1048]

MEDICAL DEVICES

Classification of Dowel Cutting Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dowel cutting instruments into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of

Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of dowel cutting instruments:

1. Identification: A dowel cutting instrument is a device used to cut dowels of bone for bone grafting.
2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.
3. Summary of reasons for recommendation: The Panel recommends that the dowel cutting instrument be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The dowel cutting instrument is a very simple device that has no inherent hazard.
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with this device.
5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the dowel cutting instruments be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4375 as follows:

§ 882.4275 Dowel cutting instrument.

(a) *Identification.* A dowel cutting instrument is a device used to cut dowels of bone for bone grafting.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be indentified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32906 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1049]

MEDICAL DEVICES

Classification of Manual Drills, Burrs, Trephines, and Their Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying manual drills, burrs, trephines, and their accessories into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that these devices be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the devices. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of manual drills, burrs, trephines, and accessories:

1. Identification: Manual drills, burrs, trephines, and their accessories are manually operated bone cutting and drilling instruments that are used without a power source.
2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a low priority.
3. Summary of reasons for recommendation: The Panel recommends that manual drills, burrs, trephines, and their accessories be classified into class II to require guards that will prevent the device tips from plunging into the brain. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of these devices and that there is sufficient information to establish a standard to provide such assurance.
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with these devices, which are routinely used in neurosurgical procedures.
5. Risks to health: Penetration of brain tissue: The device can cause brain injury by plunging into the brain after entry through the skull.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that manual drills, burrs, trephines, and accessories be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for these devices because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4300 as follows:

§ 882.4300 Manual drills, burrs, trephines, and their accessories.

(a) *Identification.* Manual drills, burrs, trephines, and their accessories are manually operated bone cutting and drilling instruments that are used without a power source.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written

comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32907 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1050]

MEDICAL DEVICES

Classification of Powered Compound Drills, Burrs, Trephines, and Their Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered compound drills, burrs, trephines, and their accessories into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that these devices be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classfying these devices. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of powered compound drills, burrs, trephines, and their accessories:

1. Identification: Powered compound drills, burrs, trephines, and their accessories are bone cutting and drilling instruments that use a power source and employ a clutch mechanism to prevent the instrument's tip from plunging into the brain.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that powered compound drills, burrs, trephines and their accessories be classified into class II (performance standards) because standards are necessary to control the performance of the clutch used to prevent the device from accidentally plunging into the brain. Failure of the clutch mechanism could result in brain damage if the tip accidentally plunges into the brain. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of these devices and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their extensive experience with these devices; they are widely used and the hazards are well known.

5. Risks to health: Penetration of brain tissue: Accidental penetration of brain tissue can cause brain injury if the clutch fails.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that powered compound drills, burrs, trephines, and accessories be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for these devices because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4305 as follows:

§ 882.4305 Powered compound drills, burrs, trephines, and their accessories.

(a) *Identification.* Powered compound drills, burrs, trephines, and their accessories are bone cutting and drilling instruments that use a power source and employ a clutch mechanism to prevent the instrument's tip from plunging into the brain.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32908 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1051]

MEDICAL DEVICES

Classification of Powered Simple Drills, Burrs, Trephines, and Their Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered simple drills, burrs, trephines, and their accesories into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the devices be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the devices. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become ef-

fective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of powered simple drills, burrs, trephines, and their accessories:

1. Identification: Powered simple drills, burrs, trephines, and their accessories are bone cutting and drilling instruments used with a power source but without a clutch mechanism.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that powered simple drills, burrs, trephines, and their accessories be classified into class II (performance standards) because standards are necessary to assure safe design. The Panel believes that guards are needed to prevent the tool cutting tip from accidentally plunging into the brain and that general controls will not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience with these devices. The devices are widely used, and the hazards are well known.

5. Risks to health: Penetration of brain tissue: The tip of the cutting tool can accidentally plunge into the brain tissue causing brain injury if the device lacks guards to prevent plunging.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that powered simple drills, burrs, trephines, and their accessories be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4310 as follows:

§ 882.4310 Powered simple drills, burrs, trephines, and their accessories.

(a) *Identification.* Powered simple drills, burrs, trephines, and their accessories are bone cutting and drilling instruments used with a power source but without a clutch mechanism.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be indentified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32909 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1052]

MEDICAL DEVICES

Classification of Drill Handpieces (Brace)

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulations classifying drill handpiece (brace) into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A Proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of drill handpieces (brace):

1. Identification: A drill handpiece (brace) is a hand holder, which is used without a power source, for drills, burrs, trephines, or other cutting tools.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that drill handpieces (brace) be classified into class II (performance standards) because a standard is needed that requires the device to have a guard that prevents the tip of the drill from being accidentally plunged into the brain. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience with the drill handpiece. These are common surgical tools that have been used by neurosurgeons for many years.

5. Risks to health: Penetration of brain tissue: The drill tip can accidentally plunge into the brain causing brain injury.

PROPOSED CLASSIFICATION

The Commissioner ageees with the Panel's recommendation and is pro-

posing that the drill handpiece (brace) be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4325 as follows:

§ 882.4325 **Drill handpiece (brace).**

(a) *Identification.* A drill handpiece (brace) is a hand holder, which is used without a power source, for drills, burrs, trephines, or other cutting tools.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32910 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1053]

MEDICAL DEVICES

Classification of Electric Drill Motors

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulations classifying electric drill motors into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATED: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, Md 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electric drill motors:

1. Identification: An electric drill motor is an electrically operated power source used with removable rotating surgical cutting tools or drill bits.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that electric drill motors be classified into class II (performance standards) because performance standards are necessary to prevent excessive current leakage and electrical shock hazards. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience with the device. These devices have been used for many years and are very familiar to the Panel members.

5. Risks to health: (a) Electrical shock: The patient or the physician may receive an electrical shock from the device. (b) patient injury: If the device is unwieldy, poorly balanced, or too heavy, the physician may be unable to control it, and the patient may be injured.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that electric drill motors be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposed to amend Part 882 in Subpart E by adding new § 882.4360 as follows:

§ 882.4360 **Electric drill motor.**

(a) *Identification.* An electric drill motor is an electrically operated power source used with removable rotating surgical cutting tools or drill bits.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before Janurary 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32911 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1054]

MEDICAL DEVICES

Classification of Pneumatic Drill Motors

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pneumatic drill motors into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that these device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the devices. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of pneumatic drill motors:

1. Identification: A pneumatic drill motor is a pneumatically operated power source used with removable rotating surgical cutting tools or drill bits.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that pneumatic drill motors be classified into class II (performance standard) because the method of exhausting the gas used to power the device and the method of pressure regulation used with the device should be controlled to assure safety. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with these device. These devices are routinely used and have been in use for many years.

5. Risks to health: (a) Air emboli: The gas which is exhausted from the drill motor may cause emboli if directed toward the wound site: (b) Infection and contamination: The exhaust gas may carry contaminants into the wound site. (c) Patient injury: The device may explode, and the patient may be injured if the pressure regulation fails.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that pneumatic drill motors be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4370 as follows:

§ 882.4370 **Pneumatic drill motor.**

(a) *Identification.* A pneumatic drill motor is a pneumatically operated power source used with removable rotating surgical cutting tools or drill bits.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32912 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1055]

MEDICAL DEVICES

Classification of Radiofrequency Lesion Generators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying radiofrequency lesion generators into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation

with respect to the classification of radiofrequency lesion generators:

1. Identification: A radiofrequency lesion generator is a device used to produce lesions in the nervous system or other tissue by the direct application of radiofrequency currents to selected sites.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the radiofrequency lesion generator be classified into class II (performance standards) because the electrical characteristics of the lesion generator must be controlled to assure satisfactory performance. The radiofrequency lesion generator is used to selectively destroy very small parts of the brain, spinal cord, or other tissue. The size of the destroyed area must be precisely controlled to minimize the risk of causing a neurological deficit or of failing to obtain a good therapeutic result. The Panel believes that general controls will not provide sufficient controls over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience using these devices.

5. Risks to health: (a) Excessive destruction of normal tissue. Inaccurate or unreliable control of the lesioning current can produce an excessively large lesion that may produce a neurological deficit in the patient. (b) Failure to produce lesions of appropriate size. Inaccurate or unreliable control of the lesioning current can result in a lesion that is too small to produce a therapeutic result. (c) Electrical shock. Excessive leakage current can injure the patient. (d) Burns. Improper design of the return (inactive) electrode can cause burns.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the radiofrequency lesion generator be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4400 as follows:

§ 882.4400 Radiofrequency lesion generator.

(a) *Identification.* A radiofrequency lesion generator is a device used to produce lesions in the nervous system or other tissue by the direct application of radiofrequency currents to selected sites.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32913 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1057]

MEDICAL DEVICES

Classification of Neurosurgical Headrests

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying neurosurgical headrests into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of neurosurgical headrests:

1. Identification: A neurosurgical headrest is a device used to support the patient's head during a surgical procedure.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the neurosurgical headrest be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device because of the simplicity of the device design. The Panel believes that performance standards are not necessary for the neurosurgical headrest because the user can control the risks to health identified for this device by carefully positioning the patient's head.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience with this device.

5. Risks to health: Eye or ear damage. If the physician improperly positions the neurosurgical headrest, it may place excessive pressure on the patient's eye or ear.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the neurosurgical headrest be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4440 as follows:

§ 882.4440 Neurosurgical headrest.

(a) *Identification.* A neurosurgical headrest is a device used to support the patient's head during a surgical procedure.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32914 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1058]

MEDICAL DEVICES

Classification of Neurosurgical Head Holder (Skull Clamp)

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying the neurosurgical head holder (skull clamp) into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of the neurosurgical head holder (skull clamp):

1. Identification: A neurosurgical head holder (skull clamp) is a device used to clamp the patient's skull to hold the head and neck in a particular position during surgical procedures.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the neurosurgical head holder (skull clamp) be classified into class II (performance standards) to prevent penetration of the skull clamp points into the brain. The Panel believes that performance standards are necessary to ensure that the locking mechanism is suitable and to ensure that corrosion resistant materials are used. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience.

5. Risks to health: Patient injury. Excessive spring pressure or improper skull clamp pin design may allow penetration of the pin points into the brain. Premature release of pins may result in a sudden movement of the patient's head.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the neurosurgical head holder (skull clamp) be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat., 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4460 as follows:

§ 882.4460 Neurosurgical head holder (skull clamp).

(a) *Identification.* A neurosurgical head holder (skull clamp) is a device used to clamp the patient's skull to hold the head and neck in a particular position during surgical procedures.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32915 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1059]

MEDICAL DEVICES

Classification of Cranioplasty Material Forming Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cranioplasty material forming instruments into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regula-

tion based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Gerogia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of cranioplasty material forming instruments:

1. Identification: Cranioplasty material forming instruments are rollers used in the preparation and forming of cranioplasty (skull repair) materials.
2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.
3. Summary of reasons for recommendation: The Panel recommends that the cranioplasty material forming instrument be classified into class I because general controls are sufficient to provide reasonable assurance of safety and effectiveness of the device. The device is a simple roller that does not come into direct contact with the patient.
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with this device and its use.
5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cranioplasty material forming instrument be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4500 as follows:

§ 882.4500 Cranioplasty material forming instrument.

(a) *Identification.* Cranioplasty material forming instruments are rollers used in the preparation and forming of cranioplasty (skull repair) materials.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32916 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1061]

MEDICAL DEVICES

Classification of Microsurgical Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying microsurgical instruments into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of microsurgical instruments:

1. Identification: A microsurgical instrument is a nonpowered surgical instrument used in neurological microsurgery procedures.
2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.
3. Summary of reasons for recommendation: The Panel recommends that microsurgical instruments be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices. The Panel believes that the hazards associated with these devices depend primarily upon the skill of the user.
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the fact that these devices are common surgical instruments which have been in use for many years.
5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that microsurgical instruments be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.45.25 as follows:

§ 882.4525 Microsurgical instrument.

(a) *Identification.* A microsurgical instrument is a nonpowered surgical instrument used in neurological microsurgery procedures.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), and Drug Ad-

ministration, Rm 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32917 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1062]

MEDICAL DEVICES

Classification of Nonpowered Neurosurgical Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nonpowered neurosurgical instruments into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposed become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of nonpowered neurosurgical instuments:

1. Identification: A nonpowered neurosurgical instrument is a hand instrument or an accessory to a hand instrument used in neurosurgical procedures to cut, hold, or manipulate tissue. It includes specialized chisels, osteotomes, curettes, dissectors, elevators, forceps, gouges, hooks surgical knives, rasps, scissors, separators, spatulas, spoons, blades, blade holders, blade breakers, probes, etc.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that nonpowered surgical instruments be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these simple devices.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the fact that these devices are common surgical instruments which have been in routine use for many years.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the nonpowered neurosurgical instrument be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4535 as follows:

§ 882.4535 Nonpowered neurosurgical instruments.

(a) *Identification.* A nonpowered neurosurgical instrument is a hand instrument or an accessory to a hand instrument used during neurosurgical procedures to cut, hold, or manipulate tissue. It includes specialized chisels, osteotomes, curettes, dissectors, elevators, forceps, gouges, hooks, surgical knives, rasps, scissors, separators, spatulas, spoons, blades, blade holders, blade breakers, probes, etc.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be see in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32918 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR PART 882]

[Docket No. 78N-1063]

MEDICAL DEVICES

Classification of Shunt System Implantation Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying shunt system implantation instruments into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of shunt system implantation instruments:

1. Identification: A shunt system implantation instrument is an instrument used in the implantation of cerebrospinal fluid shunts, and includes tunneling instruments for passing shunt components under the skin.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that shunt system implantation instruments be classified into class I because general controls are sufficient to provide reasonable assurance of their safety and effectiveness. Although this device has a special purpose, it is a simple hand instrument that has no inherent hazards associated with it.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their own surgical experience.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that shunt system implantation instruments be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4545 as follows:

§ 882.4545 Shunt system implantation instrument.

(a) *Identification.* A shunt system implantation instrument is an instrument used in the implantation of cerebrospinal fluid shunts, and includes tunneling instruments for passing shunt components under the skin.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32919 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1064]

MEDICAL DEVICES

Classification of Stereotaxic Instruments

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying stereotaxic instruments into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Springs, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of stereotaxic instruments:

1. Identification: A stereotaxic instrument is a device consisting of a rigid frame with a calibrated guide mechanism for precisely positioning probes or other devices within a patient's brain, spinal cord, or other part of the nervous system.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that stereotaxic instruments be classified into class II (performance standards) because of the importance of ensuring the rigidity, precision, and accuracy of this instrument. In addition, the patient may be injured if the probe is not precisely positioned or if the instrument is not stable. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience with this device, which has been used by neurosurgeons for many years.

5. Risks to health: Tissue damage. Improper calibration of the device could result in surgical error and damage to brain tissues. Instability of the device or its base or inadequate rigidity could result in tissue damage if the device is moved suddenly or becomes miscalibrated. If the device does not hold the skull properly in place, the head could move and tissue damage from miscalibration could result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the panel recommendation and is proposing that the stereotaxic instrument be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (Secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4560 as follows:

§ 882.4560 Stereotaxic instrument.

(a) *Identification.* A stereotaxic instrument is a device consisting of a rigid frame with a calibrated guide mechanism for precisely positioning

probes or other devices within a patient's brain, spinal cord, or other part of the nervous system.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305) Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32920 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1065]

MEDICAL DEVICES

Classification of Leukotomes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying leukotomes into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of leukotomes:

1. Identification: A leukotome is a device used to cut sections out of the brain.
2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.
3. Summary of reasons for recommendation: The Panel recommends that the leukotome be classified into class I because general controls are sufficient to provide reasonable assurance of safety and effectiveness of the device.
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience and judgment.
5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the leukotome be classified into class I (general controls) with no exemptions because the Commissioner believes that these controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4600 as follows:

§ 882.4600 Leukotome.

(a) *Identification.* A leukotome is a device used to cut sections out of the brain.

(b) *Recommended classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32921 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1066]

MEDICAL DEVICES

Classification of Neurosurgical Suture Needles

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying neurosurgical suture needles into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of neurosurgical suture needles:

1. Identification: A neurosurgical suture needle is a needle used in suturing during

neurosurgical procedures or in the repair of nervous tissue.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: the Panel recommends that neurosurgical suture needles be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. This device is a very simple device, and the materials which have been used in the needles have all been generally acceptable.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the fact that this device is essentially equivalent to other suture needles that have been used for many years. The neurosurgeon members have had extensive experience with such suture needles.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the neurosurgical suture needle be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4650 as follows:

§ 882.4650 Neurosurgical suture needle.

(a) *Identification.* A neurosurgical suture needle is a needle used in suturing during neurosurgical procedures or in the repair of nervous tissue.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32922 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1067]

MEDICAL DEVICES

Classification of Cottonoid Paddies

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cottonoid paddies into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of cottonoid paddies:

1. Identification: A cottonoid paddie is a cotton pad used during surgery to protect nervous tissue, absorb fluids, or stop bleeding.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that cottonoid paddies be classified into class II (performance standards) because the device may fragment and leave bits of cotton or fiber within the surgical wound and the Panel believes that performance standards are needed to control this hazard. The Panel also believes that cottonoid paddies should have radiopaque markers and suture tails in case the device is accidentally left within the patient. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The panel members based their recommendation on their familiarity and experience with this device, which is used frequently in neurosurgery. One of the Panel members stated that he has seen pieces of fiber from these devices in tissue specimens taken from patients.

5. Risks to health: (a) Foreign body materials in the patient. Fragmentation of the device, leaving fibers or fragments of cotton in the patient, may result in a foreign body reaction. (b) Tissue reaction. Scarring or other adverse tissue reactions may result if the material remains in the body or is toxic.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cottonoid paddie be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4700 as follows:

§ 882.4700 Cottonoid paddies.

(a) *Identification.* A cottonoid paddie is a cotton pad used during surgery to protect nervous tissue, absorb fluids, or stop bleeding.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in

brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32923 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1068]

MEDICAL DEVICES

Classification of Radiofrequency Lesion Probes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying radiofrequency lesion probes into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of radiofrequency lesion probes:

1. Identification: A radiofrequency lesion probe is a device that is connected to a radiofrequency (RF) lesion generator to deliver the RF energy to the site within the nervous system where a lesion is desired.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class II (performance standards) to provide for a performance standard that minimizes the amount of coincidental destruction by the device of normal tissue. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with these devices.

5. Risks to health: Excessive destruction of normal tissue. A probe that does not have the correct dimensions may cause unnecessary destruction of nervous tissue.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the radiofrequency lesion probe be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4725 as follows:

§ 882.4725 Radiofrequency lesion probe.

(a) *Identification.* A radiofrequency lesion probe is a device connected to a radiofrequency (RF) lesion generator to deliver the RF energy to the site within the nervous system where a lesion is desired.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32924 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1069]

MEDICAL DEVICES

Classification of Skull Punches

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying skull punches into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides back-

ground information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of skull punches:

1. Identification: A skull punch is a device used to punch holes through a patients skull to allow fixation of cranioplasty plates or bone flaps by wire or other means.
2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.
3. Summary of reasons for recommendation: The Panel recommends that the skull punch be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with this device and their knowledge of its design and the conditions of its use.
5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the skull punch be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4750 as follows:

§ 882.4750 Skull punch.

(a) *Identification.* A skull punch is a device used to punch holes through a patient's skull to allow fixation of cranioplasty plates or bone flaps by wire or other means.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32925 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1070]

MEDICAL DEVICES

Classification of Self-Retaining Retractors

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying self-retaining retractors into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of self-retaining retractors:

1. Identification: A self-retaining retractor is a self-locking device used to hold the edges of a wound open during neurosurgery.
2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.
3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class II (performance standards) to protect against injuring the patient by sudden movement because of failure of the device's locking mechanism. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.
4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with this device, which is routinely used in neurosurgery.
5. Risks to health: Patient injury. Serious injury could result if the locking mechanism fails, allowing the retractor to collapse suddenly thereby disrupting the surgery.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the self-retaining retractor be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4800 as follows:

§ 882.4800 Self-retaining retractor.

(a) *Identification.* A self-retaining retractor a is self-locking device used to hold the edges of a wound open during neurosurgery.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours

of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32926 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR PART 882]

[Docket No. 78N-1071]

MEDICAL DEVICES

Classification of Manual Rongeurs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comments a proposed regulation classifying manual rongeurs into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of manual rongeurs:

1. Identification: A manual rongeur is a manually operated instrument used for cutting or biting bone during surgery involving the skull or spinal column.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the manual rongeur be classified into class II (performance standards) because of the need to control the variability in design and the high incidence of breakage of the rongeur jaws. Rongeurs that are represented to be of a particular design frequently vary considerably from the purported design and, in fact, may vary from year to year. The Panel believes that performance standards are needed to ensure that the thickness of the rongeur jaws and the material used in their construction are sufficient to prevent them from breaking. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with this device.

5. Risks to health: Residual foreign matter in patient. If rongeur jaws break because the metal is too thin or too brittle, pieces of metal may enter the patient's head.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the manual rongeur be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4840 as follows:

§ 882.4840 **Manual rongeur.**

(a) *Identification.* A manual rongeur is a manually operated instrument used for cutting or biting bone during surgery involving the skull or spinal column.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner Regulatory Affairs.

[FR Doc. 78-32927 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1072]

MEDICAL DEVICES

Classification of Powered Rongeurs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered rongeurs into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of powered rongeurs:

1. Identification: A powered rongeur is a powered instrument used for cutting or biting bone during surgery involving the skull or spinal column.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the powered rongeur be classified into class II (performance standards) because of the need to control the variability in design and high incidence of breakage of the rongeur jaws. Rongeurs that are represented to be of a particular design frequently vary considerably from the purported design and, in fact, may vary from year to year. The Panel believes that performance standards also are needed to ensure that the thickness of the rongeur jaws and the material used in their construction are sufficient to prevent them from breaking. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with this device.

5. Risks to health: Residual foreign matter in patient. If the rongeur jaws break because the metal is too thin or too brittle, pieces of metal may enter the patient's head.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the powered rongeur be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4845 as follows:

§ 882.4845 Powered rongeur.

(a) *Identification.* A powered rongeur is a powered instrument used for cutting or biting bone during surgery involving the skull or spinal column.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets, in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32928 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1073]

MEDICAL DEVICES

Classification of Skullplate Screwdrivers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying skullplate screwdrivers into class I (general controls). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere is this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of skullplate screwdrivers:

1. Identification: A skullplate screwdriver is a tool used by the surgeon to fasten cranioplasty plates or skullplates to a patient's skull by screws.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the skullplate screwdriver be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Summary of data on which the recommendation is based: The Panel members based their recommendation on their extensive experience with these devices.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the skullplate screwdriver be classified into class I (general controls) with no exemptions because the Commissioner believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4900 as follows:

§ 882.4900 Skullplate screwdriver.

(a) *Identification.* A skullplate screwdriver is a tool used by the surgeon to fasten cranioplasty plates or skullplates to a patients skull by screws.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hear-

ing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32929 Filed 11-27-78; 8:45]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1074]

MEDICAL DEVICES

Classification of Sponges for Internal Use

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying sponges for internal use into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of sponges for internal use:

1. Identification: A sponge for internal use is a device used for absorbing blood or other fluids inside the body during surgery. It is not left in the body cavity after surgery.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that sponges for internal use be classified into class II (performance standards) because they come into direct contact with the surgical wound and may contaminate the wound or produce a tissue reaction if the sponge materials are not suitable. The Panel believes that general controls will not provide sufficient controls over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their experience with this device, which has been used for absorption in surgical wounds for many years.

5. Risks to health: (a) Foreign body material in patients: If the sponge should fragment while in the patient, portions of the sponge may be left in the patient upon closure of the wound. (b) Tissue reaction: If not biocompatible, the sponge materials may cause adverse tissue reaction.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the sponge for internal use be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart E by adding new § 882.4925 as follows:

§ 882.4925 Sponge (internal use).

(a) *Identification.* A sponge for internal use is a device used for absorbing blood or other fluids inside the body during surgery. It is not left in the body cavity after surgery.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32930 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1075]

MEDICAL DEVICES

Classification of Methyl Methacrylate for Aneurysmorrhaphy

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying methyl methacrylate for aneurysmorrhaphy (repair of aneurysms which are balloonlike sacs formed on blood vessels) into class II (performance standards). The FDA is also publishing the recommendation of the Neurosurgical Device Classification Panel that the device be classified into class II. The effect of classifing a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug

Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issure of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of methyl methacrylate for aneurysmorrhaphy:

1. Identification: Methyl methacrylate for aneurysmorrhaphy (repair of aneurysms, which are balloonlike sacs formed on blood vessels) is a self-curing acrylic used to encase and reinforce intracranial aneurysms that are not amenable to conservative management, removal, or abliteration by aneurysm clip.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that methyl methacrylate for aneurysmorrhaphy be classified into class II (performance standards) because sufficient scientific and medical data are available to establish the safety and effectiveness of methyl methacrylate for this use. The Panel believes that premarket approval of this device is unnecessary because, although this product is implanted, methyl methacrylate has been used extensively for aneurysmorrhaphy and has been shown to be safe and effective. The hazards associated with the use of methyl methacrylate can be avoided by controlling its chemical composition and by following adequate preparation procedures. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their extensive clinical experience in repairing aneurysms, their familiarity with the large amount of literature that has been published on aneurysm repair, and testimony from Dr. Shelley Chou, Professor of Neurosurgery at the University of Minnesota Medical School. Dr. Chou presented information pertaining to several chemical substances that have been employed for aneurysmorrhaphy. He pointed out the methyl methacrylate has been successfully used since 1956 for encasing aneurysms. The Panel was also informed that the American Society for Testing and Materials (ASTM) is presently working to develop standards for the formulation of methyl methacrylate that is to be used for neurosurgery.

5. Risks to health: (a) Immediate or delayed rupture of the aneurysm. Variations in the chemical composition and formulation of the polymer can result in an unpredictable setting time. (b) Injury to surrounding normal tissue. Variation in the composition of the material or the procedures used may result in excess heat that may injure adjacent tissue. (c) Tissue toxicity. Impurities in some formulations may be toxic.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that methyl methacrylate for aneurysmorrhaphy be classified into class II (performance standards).

The Commissioner has reviewed the Panel recommendation to classify methyl methacrylate for aneurysmorrhaphy into class II and has obtained additional data and information on the safety and effectiveness of this material. Methyl methacrylate has been used generally for various medical applications for approximately 40 years and has been used extensively for cranioplasty (repair of the skull) and in dentistry. This material has been employed since 1956 for encasement of intracranial aneurysms that cannot be treated by clipping or other more conventional means (Ref. 1). Hayes and Leaver reported in 1966 on 40 patients with aneurysms that were successfully treated without major complications with this material (Ref. 2). In 1968, Hammond reported on a total of 85 patients with 102 aneurysms that were encased with polymethyl methacrylate and noted two cases of hemorrhage from aneurysms that were not completely encased by the material (Ref. 3).

Although methyl methacrylate has been shown to produce an inflammatory reaction, in rabbit brain, that gradually lessens with time (Ref. 4), the material is generally regarded as safe for implantation (Ref. 5).

A temperature of 130° F may be produced by the polymerization of the methyl methacrylate, and concern has been expressed about the effect of this heat on structures adjacent to the aneurysm, such as blood vessels or the optic nerve. Hayes and Leaver, however, reported no evidence of such injuries and stated that the heat is easily handled by irrigating the aneurysm (Ref, 2). There is also an increase risk of rupturing the aneurysm during methyl methacrylate encasement because more dissection to free the aneurysm from the surrounding tissue is required for methyl methacrylate encasement than is required for clipping (Ref. 2).

The Commissioner believes that premarket approval is unnecessary for this implanted material because there is sufficient information to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the material for use in treating intracranial aneurysms. The Commissioner also believes that general controls alone will not provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Dutton, J. E. M., "Intracranial Aneurysm: A New Method of Surgical Treatment," *British Medical Journal*, 2:585-586, 1956.

2. Hayes, G. J. and R. C. Leaver, "Methyl Methyacrylate Investment of Intracranial Aneurysms," *Journal of Neurosurgery*, 25:79-80, 1966.

3. Hammon, W. M., "Intracranial Aneurysm Encasement," *Journal of Neurology, Neurosurgery and Psychiatry*, 31:524-547, 1968.

4. Tsuchiya, G., et al., "Reactions of Rabbit Brain and Peripheral Vessels to Plastic Used in Coating Arterial Aneurysms," *Journal of Neurosurgery*, 28:409-416, 1968.

5. Lee, H. and K. Neville, "Handbook of Biomedical Plastics," Pasadena Technology Press, Pasadena, Calif., pp. 8-4 and 14-2 to 14-32.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 by adding new Subpart F, including § 882.5030, to read as follows:

Subpart F—Neurological Therapeutic Devices

§ 882.5030 Methyl methacrylate for aneurysmorrhaphy.

(a) *Identification.* Methyl methacrylate for aneurysmorrhaphy (repair of aneurysms, which are balloonlike sacs formed on blood vessels) is a self-curing acrylic used to encase and reinforce intracranial aneurysms that are not amenable to conservative management, removal, or obliteration by aneurysm clip.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32931 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR PART 882]

[Docket No. 78N-1076]

MEDICAL DEVICES

Classification of Biofeedback Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying biofeedback devices into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of biofeedback devices:

1. Identification: A biofeedback device is an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological paramenters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that biofeedback devices be classified into class II (performance standards) because they are electrically powered and are attached to patients by means of electrodes, thus exposing patients to risk of electrical shock. The Panel also believes that the device should be required to meet performance standards to assure that the device reliably measures the physiological parameter that it is intended to measure. The Panel notes that biofeedback has been reported to be useful for treating a variety of medical conditions, such as retraining muscles in paralyzed patients, treatment of stress and migraine headache, and reduction of blood pressure. The Panel recommends that the device's labeling include a warning stating that if the device is used in the diagnosis or treatment of disease, it should be used only by, or after consulting with, a physician. However, the Panel believes that use for nonmedical conditions (e.g., relaxation training) need not be under the supervision of a physician. The Panel believes that general controls will not provide sufficient control over the electrical safety and performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal knowledge of the devices and techniques used in biofeedback and on presentations made to the Panel by researchers in biofeedback. Dr. Charles Stroebel, Institute of Living, Hartford, Connecticut, and Dr. Kenneth Greenspan, New York State Psychiatric Institute, appeared before the Panel to present their opinions on biofeedback. Dr. Stroebel warned that indications and claims for biofeedback must be judged carefully because of the sensational reports in the lay press. Dr. Greenspan stressed that a patient should not be treated with biofeedback for medical conditions without an adequate medical examination because failure to diagnose some conditions may result in failure to institute appropriate treatment. Dr. Greenspan reported that stress and migraine headaches have been treated with 60 to 80 percent success after 1 year's followup. Dr. Greenspan also noted that he was concerned because of the lack of well-controlled studies for some of the investigational uses of biofeedback.

5. Risks to health: (a) Electrical shock. The patient may receive an electrical shock because the device is electrically powered and connected to the patient by means of electrodes. (b) Errors in treatment. If the device is used to treat medical conditions, the patient may become worse if the practitioner relies on the device and it does not perform properly.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that biofeedback devices be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

The Commissioner has also considered the Panel's recommendation that a warning label stating that if the device is used in the diagnosis or treatment of disease it should be used only by, or after consulting with, a physician, be affixed to the device or accompany the device. The Commissioner agrees with the Panel that biofeedback devices should be used for diagnosing or treating diseases or other medical conditions only by, or after consulting with, a physician. In the past, FDA has allowed unrestricted (over-the-counter) marketing of biofeedback devices only if no medical claims are made for the devices. The FDA does not regard a claim for use in relaxation training as a medical claim. The FDA regards a biofeedback device as misbranded if medical claims are made for the device and the device is not labeled for use only by or on the order of a physician or other licensed practitioner. The Commissioner intends to continue this policy for biofeedback devices and believes that this policy essentially satisfies the Panel's recommendation.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5050 as follows:

§ 882.5050 Biofeedback device.

(a) *Identification.* A biofeedback device is an instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters (e.g., brain alpha wave activity, muscle activity, skin temperature, etc.) so that the patient can control voluntarily these physiological parameters.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fish-

ers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32932 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1077]

MEDICAL DEVICES

Classification of Bite Blocks

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying bite blocks into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of bite blocks:

1. Identification: A bite block is a device inserted into a patient's mouth to protect the tongue and teeth while the patient is having convulsions.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that bite blocks be classified into class II (performance standards) because the design of the device and the material of which it is made must be adequate to prevent injury to the patient's teeth or gums and to prevent the patient from biting off a piece of the device and swallowing it. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with the device, which has been in use for many years.

5. Risks to health: (a) Injury to teeth and tongue. Improper design, excessively hard material, or improper application may permit injury to the patient's teeth or tongue, and the patient may aspirate or swallow teeth if the device causes them to be knocked out. (b) Aspiration of material. If the material is too weak, the patient may bite off a piece and aspirate or swallow it.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that bite blocks be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5070 as follows:

§ 882.5070 Bite Block.

(a) *Identification.* A bite block is a device inserted into a patient's mouth to protect the tongue and teeth while the patient is having convulsions.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers lane, Rockville, MD 20857, written comments regarding this proposal. Four Copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc.78-32933 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1078]

MEDICAL DEVICES

Classification of Intravascular Occluding Catheters

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying intravascular occluding catheters into class III (premarket approval). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring MD. 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of intravascular occluding catheters:

1. Identification: An intravascular occluding catheter is a catheter with an inflatable or detachable balloon tip that is used to block a blood vessel to treat malformations, e.g., aneurysms (balloonlike sacs formed on blood vessels), of intracranial blood vessels.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the intravascular occluding catheter be classified into class III (premarket approval) because the device is used to treat severe and life-threatening conditions and presents a potential unreasonable risk of illness or injury to the patient. The Panel believes that there is not sufficient information available to determine whether general controls will assure the safety and effectiveness of the device, nor is there sufficient scientific and medical data available so that performance standards can be established that will assure the safety and effectiveness of the device. Therefore, the device should be subject to premarket approval to ensure that manufacturers demonstrate satisfactorily the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the fact that there are few data available on this device. Although the Panel members are aware of the use of this device in investigational programs, they believe that there is not enough information or data to demonstrate that its safety and effectiveness can be adequately controlled by means other than premarket approval.

5. Risks to health: (a) Infarction of nervous tissue. If the catheter is not controllable or if the balloon or tip should fail or unexpectedly come loose from the catheter, use of the device may cause infarction of nervous tissue (death of nervous tissue due to stoppage of circulation) and other serious injury to the brain and other nervous tissue. (b) Hemmorhage. The catheter or improper balloon inflation may injure a blood vessel and result in bleeding. (c) Thrombogenesis. Blood coagulation and clotting may result if the material of which the catheter is constructed is not compatible with blood.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the intravascular occluding catheter be classified into class III (premarket approval). The device is used to treat severe and life-threatening conditions, and the Commissioner believes that it presents a potential unreasonable risk of illness or injury to the patient if the device should fail or if the practitioner is unable to control the ballon tip. Furthermore, the device is for a use (treatment of vascular malformations) which is of substantial importance in preventing impairment of human health. The Commissioner concurs that insufficient information exists to determine whether general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and he believes that insufficient information exists to establish a performance standard that will provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5150 as follows:

§ 882.5150 Intravascular occluding catheter.

(a) *Identification.* An intravascular occluding catheter is a catheter with an inflatable or detachable ballon tip that is used to block a blood vessel to treat malformations, e.g., aneurysms (balloonlike sacs formed on blood vessels) of intracranial blood vessels.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32934 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1079]

MEDICAL DEVICES

Classification of Carotid Artery Clamps

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying carotid artery clamps into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of carotid artery clamps:

1. Identification: A carotid artery clamp is a device that is surgically placed around a patient's carotid artery (the principal artery in the neck that supplies blood to the brain) and has a removable adjusting mechanism that protrudes through the skin of the patient's neck. The clamp is used to occlude the patient's carotid artery to treat intracranial aneurysms (balloon like sacs formed on blood vessels) or other intracranial vascular malformations that are difficult to attack directly by reducing the blood pres-

sure and blood flow to the aneurysm or other malformation.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the carotid artery clamp be classified into class II (performance standards) because the performance of the device must be controlled to assure that the blood pressure reduction can be performed smoothly and because the material used in the device must be compatible with tissue. The clamp is used for occlusion of the carotid artery in patients with aneurysms that are difficult to attack directly. The Panel believes that biocompatible materials are necessary for this device because the clamp is implanted into the patient. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal clinical experience with this device. This device has been in use for several decades to treat intracranial aneurysms.

5. Risks to health: (a) Brain injury. Poor control of the pressure reduction may result in stroke and injury to the brain. (b) Blood vessel injury. The carotid artery could be damaged if the control assembly does not easily couple with and uncouple from the clamp. (c) Tissue toxicity. The material used to construct the device may cause an adverse tissue reaction if it is not biocompatible.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that the carotid artery clamp be classified into class II (performance standards).

The Commissioner has reviewed the Panel recommendation to classify the carotid artery clamp into class II (performance standards) and has obtained additional data and information on the device to determine if reasonable assurance of the safety and effectiveness of the device can be provided by performance standards.

Carotid artery occlusion is an established technique for the treatment of intracranial aneurysms, and the carotid artery clamp is an integral part of this treatment.

According to Tindall (Ref. 1), ligation (constriction) of the carotid artery as a treatment for intracranial aneurysms has a long history dating back to 1805. It was in the 1950's, however, that adjustable clamps allowing gradual occlusion of the artery were introduced (Refs. 1 and 2). With the advent of adjustable clamps, carotid ligation became more widely practiced in neurosurgery. Tindall believes that the clamp's ability to occlude the artery gradually has contributed to a lower incidence of neurological deficits in patients treated by carotid ligation. Several clamp designs have been introduced to further refine the technique of carotid ligation (Refs. 1 and 3).

Tindall lists indications and contraindications for carotid ligation and describes the procedure in detail (Ref. 1) Tindall also discusses complications of this technique. The most severe complication is the possibility of cerebral ischemia (insufficient blood flow to the brain). Tindall states that 38 patients out of a series of 220 (11.5 percent) exhibited signs of cerebral ischemia. After the clamp was opened, 5 of the patients were left with permanent neurological deficits, 15 died, and the rest recovered normally (no data were available on two patients). Other complications listed by Tindall include erosion of the artery, infection, hemorrhage from the neck wound, and nerve injury. Tindall believes that the procedure, although characterized by rather serious complications, is nonetheless an effective treatment for some types of aneurysms because of the far greater dangers of death or neurological injury presented by the untreated aneurysm and because of the difficulties involved in a direct surgical attack on the aneurysm.

Although most clamps are constructed of stainless steel, there is at least one report of brass (a biologically unacceptable material) being used as a component in a clamp (Ref. 3). However, no reports regarding the biological compatibility of carotid artery clamps have been found.

Although it is conceivable that, if not designed properly, the mechanism used to couple the adjusting stem to the clamp could injure the blood vessel, no reports of such injury have been found in the literature. Virtually all complications that have been reported are related to the risks associated with the carotid ligation procedure rather than to any particular device. The carotid artery clamp allows more gradual occlusion than does ligation by suture.

The Commissioner believes that premarket approval is not necessary for this implanted device because there is sufficient information available to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that a performance standard is necessary for this device because general controls will not provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (HFC-20), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be viewed by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Tindall, G. T., "Management of Aneurysms of Anterior Circulation by Carotid Artery Occlusion," in *Neurological Surgery*, Vol. 2, Edited by J. R. Youmans, W. B. Sunders Co., Philadelphia, PA, pp. 768-786, 1973.

2. Mount, Lester A., "Results of Treatment of Intracranial Aneurysms Using the Selverstone Clamp," *Journal of Neurosurgery*, 16:611-618, 1959.

3. Fuster, B., et al., "An Adjustable Clamp for use in Carotid Ligation," *Acta Neurologica Latinoamericana*, 16:224-230, 1970.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5175 as follows:

§ 882.5175 Carotid artery clamp.

(a) *Identification.* A carotid artery clamp is a device that is surgically placed around a patient's carotid artery (the principal artery in the neck that supplies blood to the brain) and has a removable adjusting mechanism that protrudes through the skin of the patient's neck. The clamp is used to occlude the patient's carotid artery to treat intracranial aneurysms (balloonlike sacs formed on blood vessels) or other intracranial vascular malformations that are difficult to attack directly by reducing the blood pressure and blood flow to the aneurysm or malformation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32935 Filed 11-29-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1080]

MEDICAL DEVICES

Classification of Aneurysm Clips

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying aneurysm clips into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere is this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, on FDA advisory committee, made the following recommendation with respect to the classification of aneurysm clips:

1. Identification: An aneurysm clip is a device used to occlude an intracranial aneurysm (a balloonlike sac formed on a blood vessel) to prevent it from bleeding or bursting.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the aneurysm clip be classified into class II (performance standards) because the performance of the clip needs to be reliable and the material used to construct the clip needs to be biocompatible. The Panel believes that general controls will not provide sufficient control over these characteristics. Although the aneurysm clip is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with aneurysm surgery and with this device. J. T. McFadden, M.D., a Panel member, has personal experience in the development of spring-loaded aneurysm clips, and has written about their problems and their successful application (Refs. 1, 2, and 3). A. U. Daniels, Ph. D., of the Utah Biomedical Test Laboratory (UBTL), presented to the Panel the results of a survey that showed that aneurysm clips are marketed in a great variety of designs, but that the manufacturers seldom specify the operating characteristics of the various types. John Tew, M.D., of the Mayfield Neurological Institute, presented to the Panel a review of aneurysm clip development and discussed the steps required to develop a standard. Dr. Tew, who is also chairman of the Working Group on Aneurysm and Blood Vessel Clips under the American Society for Testing and Materials (STM), discussed the progress ASTM is making toward developing a standard.

5. Risks to health: (a) Slippage of the clip may result in hemorrhage and possible death. If the clip does not maintain sufficient pressure, or if the jaw design does not provide sufficient friction, the clip may open or slide off the aneurysm after operation and allow the aneurysm to bleed. (b) cutting of the aneurysm or its parent vessel. In some designs, the "crotch" part of a clip may cut the arterial wall, or a clip having a sharp edge may accidentally cut the artery. (c) Tissue toxicity. Clips constructed of metals that are not biocompatible may cause an adverse tissue reaction.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that aneurysm clips be classified into class II (performance standards).

The Commissioner has reviewed the Panel recommendation and has sought other data and documentation on aneurysm clips to determine if reasonable assurance of the safety and effectiveness of the device can be assured by performance standards. The Commissioner has found a considerable body of evidence to support the Panel recommendation. According to Fox, the first attempt to "clip" aneurysms probably occurred in 1911 and involved use of a soft metal device (Ref. 4). Spring clips, which were first employed in 1952 and have subsequently undergone improvements, have gained wide acceptance (Ref. 5 and 6). Since the late 1960's, the mortality rate for correction and intracranial aneurysms has decreased from approximately 25 percent to less than 5 percent due to several techniques that reduce the distance that the brain is moved during surgery (Ref. 7). Aneurysm clips have played a part in this improved mortality rate because they provide a means to repair large defects in an artery under the brain by access through a small opening (Ref. 3). Although failures of aneurysm clips are rare, they do occur (Ref. 8). Unsuccessful operations are more frequently related to incomplete occlusion of the aneurysmal sac because the clip slipped or was not applied properly (Ref. 9). Neurosurgeons have expressed a need for some means of comparing the characteristics of various clips (Ref. 10 and 11). A recent report describes a method and an instrument for testing aneurysm clips that may satisfy this need (Ref. 12).

Although the aneurysm clip is an implanted device that is of substantial importance in preventing impairment of human health, the Commissioner believes that premarket approval is not necessary because there is sufficient information to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that general controls alone will not provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be viewed by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. McFadden, J. T., "Chocked-Clip Aneurysmorrhaphy," *Surgery, Gynecology and Obstetrics*, 132:898, 1971.

2. McFadden, J. T., "Modifications of Crossed-Action Interacranial Clips," *Journal of Neurosurgery*, 32:116-118, 1970.

3. McFadden, J. T., "Metallurgical Principles in Neurosurgery," *Journal of Neurosurgery*, 31:373-385, 1969.

4. Fox, J. L., "Vascular Clips for the Microsurgical Treatment of Stroke," *Stroke*, 7:489-500, 1976.

5. Mayfield, F. H., and G. Kees, "A Brief History of the Development of the Mayfield Clip," *Journal of Neurosurgery*, 35:97-100, 1971.

6. Hiefetz, M. D., "A new Interacranial Aneurysm Clip," *Journal of Neurosurgery*, 30:763, 1969.

7. Fox, J. L., and G. R. Nugent, "Recent Advances in Intracranial Aneurysm Surgery, *West Virginia Medical Journal*, 72:104-106, 1976.

8. Servo, A., "Delayed Breaking of a Heifetz Aneurysm Clip," *Journal of Neurosurgery*, 47:463-465, 1977.

9. Drake, C. G., and J. M. Allcock, "Postoperative Angiography and the Slipped Clip," *Journal of Neurosurgery*, 39:683-689, 1973.

10. DeLong, W. B., "A Simple Method of Measuring Aneurysm Clip Tension," *Journal of Neurosurgery*, 47:788-789, 1977.

11. Sugita, K., et al, "Comparative Study of the Pressure of Various Aneurysm Clips," *Journal of Neurosurgery*, 44:723-727, 1976.

12. Aneurysm Clip Data Collection and *In Vitro* Testing, final Report TR 1603-003, Task Order No. 24 of Contract No. 223-74-5253, Utah Biomedical Test Laboratory, Salt Lake City, Utah 84108, May 10, 1978.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5200 as follows:

§ 882.5200 Aneurysm clip.

(a) *Identification.* An aneurysm clip is a device used to occlude an intracranial aneurysm (a ballonlike sac formed on a blood vessel) to prevent it from bleeding or bursting.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32936 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1081]

MEDICAL DEVICES

Classification of Implanted Malleable Clips

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying implanted malleable clips into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. the Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of implanted malleable clips:

1. Identification: A implanted malleable clip is a bent wire or staple that is forcibly closed with a special instrument to occlude a blood vessel or aneurysm (a balloonlike sac formed on a blood vessel), stop bleeding, or hold tissue or a mechanical device in place in a patient.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that implanted malleable clips be classified into class II (performance standards) because the device Must be biologically compatible with tissue and must be structurally sound so that it will hold after application. The Panel recommends that a standard prohibit construction of implanted malleable clips from sterling silver because of the toxicity of this material. The Panel believes that general controls will not provide sufficient control over these characteristics. Although the implanted malleable clip is an implanted device, the Panel believes that premarket approval is not necessary because sufficient information exists to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal clinical experience with this device. Implanted malleable clips have been used in neurosurgery since the early 1900's. Dr. J. T. McFadden, one of the Panel members, has published several journal articles on implantable metallic devices used in neurosurgery, such as the implanted malleable clip (Refs. 1, 2, 3, and 4). He has shown that clips made of sterling silver are especially reactive in tissue (Ref. 1).

5. Risks to health: (a) Local tissue reaction. An adverse tissue reaction may occur if the material used in the clip is not biocompatible. (b) Hemorrhage. Bleeding may occur if the clip is not structurally sound or fails to stay in place.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that implanted malleable clips be classified into class II (performance standards).

The Commissioner has reviewed the Panel recommendation and has obtained additional data and information on implanted malleable clips to determine if reasonable assurance of the safety and effectiveness of the device can be assured by performance standards.

According to Fox, metal clips for use in neurosurgery were first described in 1911 (Ref. 5). Fox also described the different designs for malleable clips that have been used in neurosurgery. These clips were constructed of either sterling silver or tantalum. McFadden (Refs. 1, 2, and 3) states that tantalum produces the least tissue reaction, and Fox (Ref. 5) notes that the advantages of tantalum for malleable clip construction have been known since the 1940's. Although McFadden has shown that sterling silver produces the most tissue reaction of any of the metals commonly used in neurosurgery (Refs. 1, 2, and 3) clips made of sterling silver were very popular for many years and are still being marketed today.

The Commissioner believes that the establishment of performance standards for the implanted malleable clip is feasible considering the simplicity of the device and the existence of acceptable materials for its construction. However, the Commissioner requests comments on whether a performance standard established for implanted malleable clips should exclude the use of sterling silver as a material for constructing these devices, and whether, even before such a standard is established, FDA should consider regulatory action to remove sterling silver implanted malleable clips from the market.

Although the malleable clip is an implanted device, the Commissioner believes that premarket approval is not necessary because there is sufficient information to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that general con-

trols alone will not provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be viewed by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. McFadden, J. T., "Tissue Reactions to Standard Neurosurgical Metallic Implants," *Journal of Neurosurgery*, 36:598-603, 1972.

2. McFadden, J. T., "Metallurgical Principles in Neurosurgery," *Journal of Neurosurgery*," 31:373-385, 1969.

3. McFadden, J. T., "Neurosurgical Metallic Implants," *Journal of Neurosurgical Nursing*, 3:123-130, 1971.

4. McFadden, J. T., "Chocked-clip Aneurysmorrhaphy," *Surgery, Gynecology and Obstetrics*, 132:898, 1971.

5. Fox, J. L., "Vascular Clips for the Microsurgical Treatment of Stroke," *Stroke*, 7:489-499, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5225 as follows:

§ 882.5225 **Implanted malleable clip.**

(a) *Identification.* An implanted malleable clip is a bent wire or staple that is forcibly closed with a special instrument to occlude a blood vessel or aneurysm (a balloonlike sac formed on a blood vessel), stop bleeding, or hold tisssue or a mechanical device in place in a patient.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32937 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1082]

MEDICAL DEVICES

Classification of Aversive Conditioning Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying aversive conditioning devices into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of aversive conditioning devices:

1. Identification: An aversive conditioning device is an instrument used to administer an electrical shock or other noxious stimulus to a patient to modify undersirable behavioral characteristics.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the aversive conditioning device be classified into class II (performance standards) because the device may apply an electrical current that may be hazardous to the patient. The Panel believes that general controls will not provide adequate control over this characteristic. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendaton is based: The Panel members based their recommendation on their familiarity with these techniques. As summarized below, the risks to health presented by the device are well known.

Risks to health: (a) Worsened psychological condition. The patient's mental condition may become worse if aversive conditioning is administered incorrectly or if the patient is not carefully selected for this treatment. (b) Electrical shock. Leakage current from the device may injure the patient. (c) Patient injury. An aversive shock applied to the patient may be harmful or lethal if excessive current is used or if it is applied incorrectly.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that aversive conditioning devices be classified into class II (performance standards). Electrical shocking devices frequently have been used for aversive conditioning to treat various conditions (Refs. 1, 2, and 4). A loud bell that is electrically activated by the presence of moisture on a pad in the patient's bed has been used to treat enuresis (bedwetting) (Ref. 3). The Commissioner agrees with the Panel that these devices may apply an electrical current to the patient that may be hazardous. The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Butterfield, W. H., "Electric Shock Hazards in Aversive Device Conditioning in Humans," *Behavioral Engineering*, 3:1-28, 1975

2. Logan, D. L. and J. R. Turnage, "Ethical Considerations in the Use of Faradic Aversion Therapy," *Behavioral Engineering*, 3:29-34, 1975

3. Thorne, D. E. "Instrumented Behavior Modification of Bedwetting," *Behavioral Engineering*, 2:47-52, 1975.

4. Johnson, J. B., "Electronic Aversive Conditioning," Proceedings of the 23rd Annual Conference on Engineering in Medicine and Biology, 1970, Washington, DC.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F, by adding new § 882.5235 as follows:

§ 882.5235 Aversive conditioning device.

(a) *Identification.* An aversive conditioning device is an instrument used to administer an electrical shock or other noxious stimulus to a patient to modify undersirable behaviorial characteristics.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32938 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1083]

MEDICAL DEVICES

Classification of Burr Hole Covers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying burr hole covers into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 201-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of burr hole covers:

1. Identification: A burr hole cover is a plastic or metal device used to cover or plug hole drilled into the skull during surgery and to reattach cranial bone removed during surgery.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the burr hole cover be classified into class II (performance standards) because the material used in the device must be biocompatible and must be strong enough to protect the brain. The Panel believes that general controls will not provide sufficient control over these characteristics. The device is a simple plastic or metal plug. The Panel believes that, although the burr hole cover is an implant, premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because sufficient information exists to develop a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the personal clinical experiences of the Panel members with these devices and their knowledge of the techniques, devices, and materials used in cranioplasty (repair of the skull).

5. Risks to health: (a) Local tissue reaction. The material used to construct the device may have a toxic effect if it is not biocompatible. (b) Structural failure. The material may fracture or break and expose the brain to injury if the material is not strong enough.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the burr hole cover be classified into class II (performance standards).

The Commissioner has reviewed the Panel recommendation to classify burr hole covers into class II (performance standards) and has obtained additional data and information to determine whether reasonable assurance of the safety and effectiveness of the device can be provided by performance standards. There is a limited amount of published literature that deals directly with burr hole covers (Refs. 1 and 2). However, the materials used in burr hole covers (silicone, tantalum, and acrylic) also have been used extensively in other applications, e.g., cranial repair, and have been found to elicit minimal local tissue reaction (Refs. 3 and 4). Complications from use of burr hole covers are similar to those from use of other cranioplasty devices. Erosion of the skin over the implant due to friction pressure (Ref. 4), latent infection (Ref. 5), and discomfort or headache caused by the thermal conductivity of metallic implants (Ref. 4) have been reported in the literature as complications from use of various cranial implants and probably would occur also with the use of burr hole covers. The major hazard associated with burr hole covers, as with other implants, is the potential risk of excessive tissue reaction if a material is used that is not biocompatible; however, the literature suggests that this hazard is minimal because the materials used to construct burr hole covers have been reported to have satisfactory biocompatibility (Refs. 3, 4, and 6). FDA has found no reports in the literature of structural problems with burr hole covers.

The Commissioner agrees with the Panel that general controls will not provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also agrees that premarket approval is not necessary for this implanted device because there is sufficient information to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons,

from 9 a.m. to 4 p.m., Monday through Friday.

1. Todd, E. M. and B. L. Crue, "Burr-Hole Buttons for Fixation of Craniotomy Bone," *Journal of Neurosurgery*, 20:448-449, 1963.

2. Vallfors, B. and D. Forster, "An Alternative Method for the Fixation of Bone Flaps After Craniotomy, "Journal of Neurosurgery, 37:620, 1972.

3. Lee, H. and K. Neville, "Handbook of Biomedical Plastics," Pasadena Technology Press, Pasadena, CA, pp. 8-4 and 14-2 to 14-32, 1971.

4. Timmons, R. L., "Cranial Defects and Their Repair," *Neurological Surgery*, Vol. 2, Edited by J. R. Youmans, W. B. Saunders Co., Philadelphia, PA, pp. 993-1008, 1973.

5. Mirabile, J. C., et al., "Delayed Infection Following Tantalum Cranioplasty: Case Report," *Military Medicine*, 139:398-9, 1974.

6. McFadden, J. T., "Tissue reactions to Standard Neurosurgical Metallic Implants," *Journal of Neurosurgery*, 35:593-603, 1972.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5250 to read as follows:

§ 882.5250 Burr hole cover.

(a) *Identification.* A burr hole cover is a plastic or metal device used to cover or plug holes drilled into the skull during surgery and to reattach cranial bone removed during surgery.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32939 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1084]

MEDICAL DEVICES

Classification of Nerve Cuffs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nerve cuffs into class III (premarket approval). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of nerve cuffs:

1. Identification: A nerve cuff is a tubular silicone rubber sheath used to encase a nerve for aid in repairing the nerve (e.g., to prevent ingrowth of scar tissue) and for capping the end of the nerve to prevent the formation of neuroma (tumors).

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the nerve cuff be classified into class III (premarket approval) because satisfactory performance has not been demonstrated for this implanted device and the Panel believes that there is not sufficient information available to establish a performance standard that will assure its safety and effectiveness. The Panel also believes that there is not sufficient information available on this device to show that general controls are sufficient to assure its safety and effectiveness. The Panel has changed its recommendation concerning the classification of this device. At the Panel meeting of August 20-21, 1977, the Panel members recommended that the nerve cuff be classified into class II (performance standards) because the device is simple in design and uses a material (silicone) that is widely accepted as biocompatible. However, at the Panel meeting on April 21, 1978, the Panel reassessed its previous recommendation and recommended that the nerve cuff be classified instead into class III (premarket approval) because the device is an implant and there is serious doubt that the device is safe and effective when used to repair nerves. The device, therefore, should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal experience with nerve cuffs, and familiarity with the literature on this device. A recent report (Ref. 1) states that better results are obtained by stitching the nerve together without the use of the nerve cuff.

5. Risks to health: (a) Tissue reaction: The material that is used to construct the device may have a toxic effect if it is not biocompatible: (b) Infection: Infection may result if the device is not sterile. (c) Neuroma formation: The device may act as an irritant which may cause excess growth of neural tissue. (d) Foreign body contamination: Contaminants in the material of which the device is constructed may cause it to disintegrate and contaminate the nerve site.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the nerve cuff be classified into class III (premarket approval).

The Commissioner has reviewed the Panel's recommendation and has obtained additional data and information on the safety and effectiveness of this device. The Commissioner believes that the published literature (Refs. 1, 2, and 3) supports the Panel's recommendation that the nerve cuff be classified into class III. In addition to the risks to health cited by the Panel, Szal and Milles report that swelling of the nerve after surgery may result in destruction of the repaired nerve if the diameter of the cuff is not sufficiently large (Ref. 1). Szal and Milles also report that the nerve cuff might, under some conditions, actually impede the healing of the nerve.

The Commissioner believes that this implanted device presents a potential unreasonable risk of illness or injury to the patient if it is ineffective. Furthermore, the device is for a use (aid in repairing nerves) which is of substantial importance in preventing impairment of human health. The Commissioner concurs that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effec-

tiveness of the device, and he believes that insufficient information exists to establish a performance standard that will provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Szal, G. J. and T. Milles, "Surgical Repairs of Facial Nerve Branches," *Archives of Otolaryngology*, 101:160-165, 1975.

2. Midgley, R. D. and F. M. Woolhouse, "Silicone Rubber Sheathing as an Adjunct to Neural Anastomosis," *Surgical Clinics of North America*, 48:1149-1154, 1968.

3 Bucker, T. B. and George J. Haynes, "Experimental Improvements in the Use of Silastic Cuff for Peripheral Nerve Repair," *Journal of Neurosurgery*, 28:582-587, 1968.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5257 as follows:

§ 882.5275 **Nerve cuff.**

(a) *Identification.* A nerve cuff is a tubular silicone rubber sheath used to encase a nerve for aid in repairing the nerve (e.g., to prevent ingrowth of scar tissue) and for capping the end of the nerve to prevent the information of neuroma (tumors).

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32940 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1085]

MEDICAL DEVICES

Classification of Methyl Methacrylate for Cranioplasty

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying methyl methacrylate for cranioplasty (skull repair) into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of methyl methacrylate for cranioplasty:

1. Identification: Methyl methacrylate for cranioplasty (skull repair) is self-curing acrylic that a surgeon uses to repair a skull defect in a patient. At the time of surgery, the surgeon initiates polymerization of the material and forms it into a plate or other appropriate shape to repair the defect.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that methyl methacrylate for cranioplasty be classified into class II (performance standards) because scientific and medical data are available to establish the safety and effectiveness of methyl methacrylate for this use. Although methyl methacrylate for cranioplasty is implanted in the patient's skull, the Panel believes that premarket approval of this device is not necessary because methyl methacrylate has been used extensively for cranioplasty and has been shown to be safe and effective. The hazards associated with the use of methyl methacrylate can be avoided by controlling its chemical composition and by following preparation procedures. The panel believes that general controls will not provide sufficient control over these characteristics.

The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal clinical experience with cranioplasty plates and the materials used in cranioplasty. Methyl methacrylate has been used since the 1940's for repairing skull defects and is widely used today (Ref. 1). Some Panel members have served on the subcommittee under the American Society for Testing and materials (ASTM) that is developing standards for cranioplasty materials.

5. Risks to health: (a) Heat damage of tissue: The material generates heat as it polymerizes and hardens. If the material is not cooled, adjacent tissue can be injured by the heat. (b) Loss of brain protection: If the cranioplasty plate is made from material that is not sufficiently strong, it may be easily broken and allow brain injury. (c) Tissue toxicity: Impurities in some formulations may be toxic.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the methyl methacrylate for cranioplasty be classified into class II (performance standards).

The Commissioner has reviewed the Panel recommendation to classify methyl methacrylate for cranioplasty into class II (performance standards) and has obtained additional data and information on the safety and effectiveness of this material.

The medical literature contains extensive reports on acrylic cranioplasty, including a thorough review by Timmons (Ref. 1) of the repair of cranial defects and the methods and materials that have been used for cranioplasty since the turn of the century. Timmons observes that the use of methyl methacrylate for repairing cranial defects has been common since the 1940's and has become very popular because its use avoids some of the problems of cranioplasty using metal plates. For example, acrylic is not ra-

diopaque and thus will not interfere with future x-ray diagnosis of the patient. In addition, acrylic cranioplasty plates also do not conduct heat very easily and, thus, avoid the problems of headache or patient discomfort that have been reported when metal cranioplasty plates are exposed to temperature extremes (Ref. 1). One of the advantages of acrylic is the ease with which it can be formed in place to fit precisely a skull defect.

Several reports in the medical literature show that there are, however, certain disadvantages and risks involved in using acrylic for cranioplasty. The polymerization reaction involved in forming the acrylic plate produces a great deal of heat that can damage the brain or other tissue (Refs. 1, 2, and 3). Fortunately, the surgeon can protect the brain from the heat with moist cottonoid strips, or can dissipate the heat by irrigating with a cold solution (Refs. 1 and 2). A technique was recently reported involving preparation of a plastic of paris model of the skull defect and formation and hardening of the acrylic plate to fit the model, without contact with the patient's skull (Ref. 3).

Another disadvantage of acrylic is that it is brittle and can be fractured by a relatively minor blow (Refs. 1, 4, and 6). To overcome this problem, acrylic has been reinforced using metal mesh made of stainless steel, aluminum, or tantalum (Refs. 1, 5, 6, and 7). Stainless steel and tantalum are radiopaque, however, and x-ray diagnosis may be hindered if these materials are used to reinforce acrylic.

There are also complications with acrylic cranioplasty that are common to all cranioplasty materials, including metals. Infection, erosion of the skin over the implant, and foreign body reaction to the implant have been reported (Refs. 1 and 2). Skin erosion over the implant may occur in regions where the scalp is thin if the plate has sharp or uneven edges. Some degree of foreign body reaction occurs with all implanted materials. However, methyl methacrylate acrylic is generally regarded as biologically safe for cranioplasty (Refs. 1, 2, and 8).

The Commissioner agrees with the Panel that premarket approval is not necessary for this implanted device because there is sufficient information available to establish a performance standard that will provide reasonable assurance of its safety and effectiveness. The Commissioner also agrees with the Panel that a performance standard is necessary for this device because general controls would not provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (HFA-305), Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Timmons, R. L., "Cranial Defects and Their Repair," *in* "Neurological Surgery," Vol. 2, Edited by J. R. Youmans, W. B. Saunders Co., Philadelphia, PA, pp. 993-1008, 1973.

2. Hammon, W. M. and L. G. Kempe, "Methyl Methacrylate Cranioplasty: 13 Years Experience with 417 Patients," *Acta Neurochirurgica*, 25:69-77, 1971.

3. Asimacopoulos, T. J., et al., "A New Method of Cranioplasty," *Journal of Neurosurgery*, 47:790-92, 1977.

4. Henry, H. M., et al., "Cerebrospinal Fluid Fistula from Fractured Acrylic Cranioplasty Plate," *Journal of Neurosurgery*, 45:227-8, 1976.

5. Sessions, R. B., et al., "Wire Mesh Foundation for Methyl Methacrylate Cranioplasty," *Laryngoscope*, 84:1020-30, 1974.

6. Lake, P. A., et al., "Radiolucent Prosthesis of Mesh-Reinforced Acrylic," *Journal of Neurosurgery*, 27:376-78, 1967.

7. Galicich, J. H. and K. H. Hovind, "Stainless Steel Mesh-Acrylic Cranioplasty," *Journal of Neurosurgery*, 27:376-78, 1967.

8. Lee, H. and K. Neville, "Handbook of Biomedical Plastics," Pasadena Technology Press, Pasadenia, California, pp. 8-4 to 8-5 and 14-2 to 14-32, 1971.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5300 as follows:

§ 882.5300 **Methyl methacrylate for cranioplasty.**

(a) *Identification.* Methyl methacrylate for cranioplasty (skull repair) is a self-curing acrylic that a surgeon uses to repair a skull defect in a patient. At the time of surgery, the surgeon initiates polymerization of the material and forms it into a plate or other appropriate shape to repair the defect.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32941 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1086]

MEDICAL DEVICES

Classification of Preformed Alterable Cranioplasty Plates

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying preformed alterable cranioplasty plates into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of preformed alterable cranioplasty plates:

1. Identification: A preformed alterable cranioplasty plate is a device that is implanted into a patient to repair a skull defect. It is constructed of a material, e.g., tantalum, that can be altered or reshaped at the time of surgery without changing the chemical behavior of the material.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that preformed alterable cranioplasty plates be classified into class II (performance standards) because the materials that are used in these plates must be biocompatible and strong. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes, however, that the materials that have been used for these plates have been proven acceptable through many years of use and that biological compatibility of these materials can be assured by establishment of standards for the composition of the materials. The Panel believes that premarket approval is not necessary for this implanted device because a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal clinical experience with cranioplasty plates and the materials used in those plates. Some Panel members have served on the subcommittee under the American Society for Testing and Materials (ASTM) that is developing standards for cranioplasty materials.

5. Risks to health: (a) Loss of brain protection: If the device is not sufficiently strong, it may bend or break and may cause brain injury. (b) Tissue toxicity: If the materials used to construct the device are not biocompatible, they may corrode and cause toxic reactions.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the preformed alterable cranioplasty plate be classified into class II (performace standards).

The Commissioner has reviewed the Panel's recommendation to classify preformed alterable cranioplasty plates into class II (performance standards) and has obtained additional data and information on the safety and effectiveness of the device. The Commissioner has found that surgeons have used several metals and plastics for cranioplasty plates. However, the Commissioner believes that all commercially available preformed cranioplasty plates are constructed of vitallium, tantalum, or stainless steel. Although aluminum (Ref. 3), silicone (Ref. 4), polyethylene (Refs. 2, 5, and 6), titanium (Refs. 2 and 8), and zirconium (Ref. 2) have also been used by surgeons for cranioplasty plates, the Commissioner is unaware of any commercially available preformed cranioplasty plates made of these materials. The Commissioner requests comments on whether materials other than vitallium, tantalum, or stainless steel have been used in commercially available preformed cranioplasty plates.

Several reports in the medical literature discuss corrosion of metals used for cranioplasty plates. Most metals used for cranioplasty plates are protected form corrosion by a natural oxide coating that forms on the metal (Ref. 1). If the oxide coating is disturbed by cutting, drilling, hammering, or other manipulation during surgery, the plate may corrode excessively after implantation. Tantalum has an oxide coating that is tough enough to permit the plate to be reshaped without undergoing excessive corrosion. McFadden states that tantalum can be modified by cutting, bending, hammering, drilling, or other manipulation without changing the material's chemical behavior. McFadden states that stainless steel should never be altered when used as an implant (Ref. 1).

Timmons has thoroughly reviewed the repair of cranial defects and has described the methods and materials that have been used for cranioplasty since the turn of the century (Ref. 2). According to Timmons, the metal tantalum has been used extensively for cranioplasty because of its malleability, light weight, strength, and biological inertness. McFadden has reported that tantalum produced very little tissue reaction compared with other popular metals used in neurosurgery (Refs. 10 and 11). Tantalum is, however, a radiopaque material, and useful x-rays of the skull are difficult to obtain after implantation of a tantalum plate.

Complications common to virtually all cranioplasty plates, whether metal or plastic, are infection, erosion of the skin over the implant, and foreign body reaction to the implant (Ref. 2). Infection requiring removal of the plate has been reported as long as 17 years after implantation (Ref. 9). Skin erosion over the implant may occur in regions where the scalp is thin because the plate has sharp or uneven edges (Ref. 2). Some degree of foreign body reaction occurs with all implanted materials. If handled properly, however, the plastics and metals (with the possible exception of aluminum) that have been used for cranioplasty are generally regarded as biologically safe (Refs. 1 through 11).

Because of the high thermal conductivity of the metal, metal cranioplasty plates may cause headache or patient discomfort when the plates are exposed to temperature extremes (Ref. 2). In addition, a metal plate may be deformed by a blow to the head, although this occurrence is rare (Ref. 5). Another possible drawback of metal implants is that they leave a dead space between the implant and the brain; there has been debate whether this dead space might result in brain herniation (abnormal protrusion) (Ref. 2).

Plastic or acrylic cranioplasty does not share some of the problems presented by metal cranioplasty. Plastics do not corrode and may be cut or modified to fit the particular patient. Because plastic and acrylic implants do not conduct heat as readily as metals, they do not cause temperature-induced headaches. Plastics are, however, weaker than metals and need to be made thicker to achieve sufficient strength. Acrylic plates are brittle and easily cracked (Ref. 2). Polyethylene and silicone implants, however, are flexible and are less likely to be deformed by blows than are metal plates.

The Commissioner believes that premarket approval is not necessary for this implanted device because there is sufficient information available to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that a performance standard is necessary for this device because general controls will not provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, form 9 a.m. to 4 p.m., Monday through Friday.

1. McFadden, J. T., Neurosurgical Metallic Implants," *Journal of Neurosurgical Nursing*, 3:123-130, 1971.

2. Timmons, R. L., "Cranial Defects and Their Repair," *Neurological Surgery*, Vol. 2, Edited by J. R. Youmans, W. B. Saunders Co., Philadelphia, PA, pp. 993-1008, 1973.

3. Black, S. P. W., et al., "Aluminum Cranioplasty," *Journal of Neurosurgery*, 29:562-564, 1968.

4. Courtemanche, A. D. and G. B. Thompson, "Silastic Cranioplasty Following Cranio-Facial Injuries," *Pastic and Reconstructive Surgery*, 41:165-170, 1968.

5. Karvounis, D. C., et al., "The Use of Prefabricated Polyethylene Plate for Cranioplasty," *Journal of Trauma*, 10:149-154, 1970.

6. Polisar, R. S. and A. W. Cook, "Use of Polyethylene in Cranial Implants," *Journal of Prosthetic Dentistry*, 29:310-316, 1973.

7. Simpson, D., "Titanium in Cranioplasty," *Journal of Neurosurgery*, 22:292-293, 1965.

8. Lee, H. and K. Neville, "Handbook of Biomedical Plastics," Chapter 14, Pasadena Technology Press, Pasadena, CA, 1971.

9. Merabile, J. C., et al., "Delayed Infection Following Tantalum Cranioplasty: Case Report," *Military Medicine*, 139:398-399, 1974.

10. McFadden, J. T., "Tissue Reactions to Standard Neurosurgical Metallic Implants," *Journal of Neurosurgery*, 36:595-603, 1972.

11. McFadden, J. T., "Metallurgical Principles in Neurosurgery," Journal of Neurosurgery, 31:373-385, 1968.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5320 as follows:

882.5320 **Preformed alterable cranioplasty plate.**

(a) *Identification.* A preformed alterable cranioplasty plate is a device that is implanted into a patient to repair a skull defect. It is constructed of a material, e.g., tantalum, that can be altered or reshaped at the time of surgery without changing the chemical behavior of the material.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32942 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1087]

MEDICAL DEVICES

Classification of Preformed Nonalterable Cranioplasty Plates

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying preformed nonalterable cranioplasty plates into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. the Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of preformed nonalterable cranioplasty plates:

1. Identification: A preformed nonalterable cranioplasty plate is a device that is implanted into a patient to repair a skull defect. It is constructed of a material, e.g., stainless steel or vitallium, that cannot be altered or reshaped at the time of surgery without changing the chemical behavior of the material.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that preformed nonalterable cranioplasty plates be classified into class II (performance standards) because the materials that are used in these plates must be biocompatible and strong. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes, however, that the materials that have been used for these plates have been proven acceptable through many years of use and that biological compatibility of these materials can be assured by establishment of standards for the composition of the materials. The Panel believes that premarket approval is not necessary for this implanted device because a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal clinical experience with cranioplasty plates and the materials used in those plates. Some Panel members have served on the subcommittee under the American Society for Testing and Materials (ASTM) that is developing standards for cranioplasty materials.

5. Risks to health: (a) Loss of brain protection: If the device is not sufficiently strong, it may bend or break and may cause brain injury. (b) Tissue toxicity: If the materials used to construct the device are not biocompatible, they may corrode and cause toxic reactions.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the preformed nonalterable cranioplasty plate be classified into class II (performance standards).

The Commissioner has reviewed the Panel's recommendation to classify preformed nonalterable cranioplasty plates into class II (performance standards) and has obtained additional data and information on the safety and effectiveness of the device. The Commissioner has found that several metals and plastics have been used by surgeons over the years for cranioplasty plates. However, the Commissioner believes that all commercially available preformed cranioplasty plates are constructed of vitallium, tantalum, or stainless steel. The Commissioner requests comments on whether materials other than vitallium, tantalum, or stainless steel have been used in commercially available preformed cranioplasty plates.

Several reports in the medical literature discuss corrosion of metals used for cranioplasty plates. Most metals used for cranioplasty plates are protected from corrosion by a natural oxide coating that forms on the metal (Ref. 1). If the oxide coating is disturbed by cutting, drilling, hammering, or other manipulation during surgery, the plate may corrode excessively after implantation. Some metals, e.g., tantalum, have oxide coatings that are tough enough to permit reshaping of the plate without causing excessive corrosion.

Several types of stainless steel have been used in constructing various implantable devices. Scott used Type 316 stainless steel for cranioplasty plates and reports it to be the most corrosion resistant of the stainless steels (Ref. 2). McFadden states, however, that stainless steel should never be altered by cutting, bending, drilling, or other manipulation at the time of surgery because of the tendency of stainless steel to corrode faster if its external oxide coating is disturbed (Ref. 1).

Vitallium is a very hard alloy of cobalt, chromium, and molybdenum that has been used in orthopedic implantable devices, but has received very little attention in neurosurgery because it is not malleable and is difficult to work with. McFadden (Ref. 1) rates the corrosion resistance of vitallium as better than stainless steel and worse than tantalum. Vitallium cannot be altered, and its use in neurosurgery has been confined to preformed nonalterable cranioplasty plates and the screws for such plates (Refs. 1, 2, and 4).

Complications common to virtually all cranioplasty plates are infection, erosion of the skin over the implant, and foreign body reaction to the implant (Ref. 2). Infection requiring removal of the plate has been reported as long as 17 years after implantation (Ref. 5). Skin erosion over the implant may occur in regions where the scalp is thin because the plate has sharp or uneven edges (Ref. 2). Some degree of foreign body reaction occurs with all implanted materials. If handled properly, stainless steel and vitallium are, however, generally regarded as biologically safe (Refs. 1 through 4). Because of the high thermal conductivity of the metal, metal cranioplasty plates may cause headache or patient discomfort when the plates are exposed to temperature extremes (Ref. 2). In addition, a metal plate may be deformed by a blow to the head, although this occurrence is rare. Another possible drawback of metal implants is that they leave a dead space between the implant and the brain; there has been debate whether this dead space might result in brain herniation (abnormal protrusion) (Ref. 2).

Plastic or acrylic cranioplasty does not share some of the problems presented by metal cranioplasty. Plastics do not corrode and may be cut or modified to fit the particular patient. Because plastic and acrylic implants do not conduct heat as readily as metals, they do not cause temperature-induced headaches. Plastics are, however, weaker than metals and need to be made thicker to achieve sufficient strength. Acrylic plates are brittle and easily cracked (Ref. 2). However, polyethylene and silicone implants are flexible and are less likely to be deformed by blows than are metal plates.

The Commissioner believes that premarket approval is not necessary for this implanted device because there is sufficient information available to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that a performance standard is necessary for this device because general controls will not provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. McFadden, J. T., "Neurosurgical Metallic Implants," *Journal of Neurosurgical Nursing*, 3:123-130, 1971.

2. Timmons, R. L., "Cranial Defects and Their Repair," "Neurological Surgery," Vol. 2, edited by J. R. Youmans, W. B. Saunders Co., Philadelphia, PA, pp. 993-1008, 1973.

3. McFadden, J. T., "Tissue Reactions to Standard Neurosurgical Metallic Implants," *Journal of Neurosurgery*, 36:595-603, 1972.

4. McFadden, J. T., "Metallurgical Principles in Neurosurgery," *Journal of Neurosurgery*, 31:373-385, 1968.

5. Merabile, J. C., et al., "Delayed Infection Following Tantalum Cranioplasty: Case Report," *Military Medicine*, 139:398-399, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5330 as follows:

§ 882.5330 Preformed nonalterable cranioplasty plate.

(a) *Identification.* A preformed nonalterable cranioplasty plate is a device that is implanted in a patient to repair a skull defect and is constructed of a material, e.g., stainless steel or vitallium, that cannot be altered or reshaped at the time of surgery without changing the chemical behavior of the material.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32943 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1088]

MEDICAL DEVICES

Classification of Cranioplasty Plate Fasteners

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cranioplasty plate fasteners into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cranioplasty plate fasteners:

1. Identification: A cranioplasty plate fastener is a screw, wire, or other article made of tantalum, vitallium or stainless steel used to secure a plate to the patient's skull to repair a skull defect.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that cranioplasty plate fasteners be classified into class

II (performance standards) because a standard governing the composition of materials that are used in the fasteners should require that the materials be both biocompatible and compatible with the material used in the cranioplasty plate. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that premarket approval is not necessary for this implanted device because a standard will provide reasonable assurance of the safety and effectiveness of the device and there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The panel members based their recommendation on their personal clinical experience with cranioplasty plates and the devices used to fasten those plates to the skull. Some Panel members have served on the subcommittee under the American Society for Testing and Materials (ASTM) that is developing standards for cranioplasty materials.

5. Risks to health: (a) Tissue toxicity: If the material used to construct the cranioplasty plate fastener is not biocompatible or is not compatible with the material used in the cranioplasty plate, it may corrode and cause a toxic reaction. (b) Loss of structural integrity: If the material used to construct the cranioplasty plate fastener is not compatible with the material used in the cranioplasty plate, corrosion of the fastener and plate may weaken the plate, causing the brain to be exposed to possible injury.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cranioplasty plate fastener be classified into class II (performance standards).

The Commissioner has reviewed the Panel recommendation to classify cranioplasty plate fasteners into class II (performance standards) and has obtained additional data and information on the safety and effectiveness of the device. Tantalum, vitallium, and stainless steel in the form of screws, metal wedges, and wire have been used to fasten cranioplasty plates to the skull. McFadden stresses that the chemical behavior of stainless steel wire will change if it is twisted or tied, and corrosion will ultimately occur (Refs. 1 and 2). He suggests that tantalum wire be used if the wire is to be buried in tissue. Dispite wide use of the cranioplasty plate fastener in cranioplasty, FDA has found no cases of complications directly associated with the cranioplasty plate fastener. It is, however, generally acknowledged that the fastener should be constructed of the same material as the cranioplasty plate to avoid galvanic corrosion (Refs. 1 and 2). The materials used for cranioplasty plate fasteners are generally regarded as biocompatible if handled properly (Refs. 1 through 4).

The Commissioner believes that premarket approval is not necessary for this implanted device because there is sufficient information available to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that a performance standard is necessary for this device because general controls will not provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. McFadden, J. T., "Neurosurgical Metallic Implants," *Journal of Neurosurgical Nursing*, 3:123-130, 1971.

2. McFadden, J. T., "Metallurgical Principles in Neurosurgery," *Journal of Neurosurgery*, 31:373-385, 1968.

3. McFadden, J. T., "Tissue Reactions to Standard Neurosurgical Metallic Implants," *Journal of Neurosurgery*, 36:598-603, 1972.

4. Timmons, R. L., "Cranial Defects and Their Repair," *in* "Neurological Surgery," Vol. 2, Edited by J. R. Youmans, W. B. Saunders Co., Philadelphia, PA, pp. 993-1008, 1973.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5360 as follows:

§ 882.5360 Cranioplasty plate fastener.

(a) *Identification.* A cranioplasty plate fastener is a screw, wire, or other article made of tantalum, vitallium, or stainless steel used to secure a plate to the patient's skull to repair a skull defect.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32944 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1089]

MEDICAL DEVICES

Classification of Lesion Temperature Monitors

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying lesion temperature monitors into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of lesion temperature monitors:

1. Identification: A lesion temperature monitor is a device used to monitor the tissue temperature at the site where a lesion (tissue destruction) is to be made when a surgeon uses a radiofrequency (RF) lesson generator and probe.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the lesion temperature monitor be classified into class II (performance standards) because the surgeon uses the device with a radiofrequency lesion generator to destroy selectively, for therapeutic purposes, very small parts of a patient's brain, spinal cord, or other tissue. The Panel believes that the device needs to measure the temperature accurately and reliably because the surgeon relies on the lesion temperature monitor to detect the temperature of the tissue at the lesion site so that the surgeon can control the amount of destruction. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience.

5. Risks to health: Inappropriate sized lesions. A temperature indication that is inaccurate or imprecise may lead the surgeon to form lesions that are too small or too large. Forming a lesion that is too small may not have the desired therapeutic benefit, and forming a lesion that is too large may destroy normal tissue and cause an undesired neurological deficit in the patient.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the lesion temperature monitors be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5500 as follows:

§ 882.5500 Lesion temperature monitor.

(a) *Identification.* A lesion temperature monitor is a device used to monitor the tissue temperature at the site where a lesion (tissue destruction) is to be made when a surgeon uses a radiofrequency (RF) lesion generator and probe.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32945 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1090]

MEDICAL DEVICES

Classification of Central Nervous System fluid Shunts and Components

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying central nervous system fluid shunts and components into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification central nervous system fluid shunts and components:

1. Identification: A central nervous system fluid shunt is a device or combination of devices used to divert fluid from the brain or other part of the central nervous system to an internal delivery site or an external receptacle for the purpose of relieving elevated intracranial pressure or fluid volume (e.g., due to hydrocephalus). Components of a central nervous system shunt include catheters, valved catheters, valves, connectors, and other accessory components intended to facilitate use of the shunt or evaluation of a patient with a shunt.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that central nervous system fluid shunts and their components be classified into class II (performance standards) because there is sufficient information available to establish performance standards that will assure the safety and effectiveness of these devices. Shunts have been used for many years to treat hydrocephalus. Hydrocephalus is a condition, usually in children, characterized by an accumulation of cerebrospinal fluid (CSF) in the head. The CSF causes the head to enlarge and may produce brain damage by fluid pressure. The Panel believes that the characteristics of central nervous system fluid shunts and their components are reasonably well established and that the conditions being treated are reasonably well understood. Although the Panel believes that the materials that have been used in the device are generally regarded as safe, it recommends establishment of standards to assure consistency in the composition of the materials. In addition, the panel believes it is important for the physician to know the pressure-flow characteristics of the valves used in shunts, to compare available valves, and to select the correct valve for a particular patient. Accordingly, the Panel recommends that the manufacturers of shunt valves be required to state, in standard form, the pressure-flow characteristics of their valves and to use standard test procedures to obtain measurements of those characteristics. The panel believes that general controls will not provide sufficient control over the above characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of devices in this category, which includes internal, totally implanted shunts; external temporary devices that drain CSF to an external receptacle; and components of both internal and external shunts. The Panel recommends that internal and external shunts and their components be classified in a single classification regulation because the shunts share the same characteristics that should be addressed in performance standards and because the components are used with a shunt

as a system. The Panel notes that a standard is being developed by the American Society for Testing and Materials (ASTM) and recommends that this standard, when completed, be adopted by the FDA.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with the relevant literature on these devices and on testimony and advice from Dr. Larry page, a Panel consultant. There has been extensive literature published on these devices in the 27 years of their clinical use. The published literature shows that although use of shunts is associated with death rates and mental retardation rates that may seem high, these rates are much lower than those for patients with untreated hydrocephalus. The death rate for patients with untreated hydrocephalus is 40 to 70 percent, compared with a death rate of 5 to 35 percent for patients treated with ventriculoatrial shunts (Ref. 1). The mental retardation rate among survivors with untreated hydrocephalus is 50 to 85 percent compared with a mental retardation rate of 20 to 50 percent among treated survivors (Ref. 1). The complications associated with these devices have been extensively reported in the literature and are well known to the Panel members.

5. Risks to health: (a) Abnormal intracranial pressure: Mechanical malfunctioning of the shunt or its components (e.g., blockage of the catheter or valve) may result in elevated intracranial pressure and the return of symptoms of hydrocephalus. (b) Tissue toxicity: Adverse tissue reactions may result if the shunt or component materials are not biocapatible. (c) Perforation of viscus: The tip of the catheter may puncture the bladder or other organs if the catheter material is too stiff. (d) Infection: Infection may result if the shunt or its components are not sterile or introduce contaminants into the patient.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the central nervous system fluid shunts and their components be classified into class II (performance standards).

The Commissioner has reviewed the Panel recommendation to classify central nervous system fluid shunts and their components into class II (performance standards) and has obtained additional data and information on the safety and effectiveness of these devices. Shunting devices have been used for several decades to treat hydrocephalus and other conditions that result in an increased intracranial pressure because of an abnormal accumulation of fluid in the bentricles (cavities) of the brain. If untreated, this condition usually results in death or sever mental retardation of the patient.

Several methods of shunting have been used to relieve the pressure of excess cerebrospinal fluid (CSF). All methods consist of a catheter that diverts the CSF, either to an external bag (external shunt) or to the blood stream or another part of the body (internal shunt). An external shunt uses a catheter that drains the CSF from the ventricles of the brain into a colleciton bag outside the body and is used only for short-term applications. Internal shunts are, however, totally implanted catheters intended to be used for long-term (chronic) relief of hydrocephalus. The most popular methods of internal shunting are the ventriculoatrial shunt, which diverts CSF from the ventricles of the brain to the right atrium of the heart, where the CSF is released into the blood stream; and the ventriculoperitoneal shunt, which diverts CSF from the ventricles of the brain to the peritoneal cavity, where it is reabsorbed by the body. Internal shunts have also been used, though less frequently, to divert CSF from the subarachnoid space of the spine to the peritoneal cavity (lumboperitoneal shunt) and from the ventricles of the brain to the pleural cavity (ventriculopleural shunt), the ureter (ventriculoureteral shunt), and the thoracic lymph duct (ventriculolymphatic shunt).

A study by Milhorat, described above in the panel recommendation, shows that shunting has significantly reduced the mortality and mental retardation resulting from hydrocephalus (Ref. 1). Numerous other reports have similarly verified that various forms of shunting are effective in relieving the often disastrous effects of elevated CSF pressure.

The obvious and undeniable benefits of this treatment have, however, been accompanied by a large number of complications. The complications vary depending upon the shunting technique and the anatomical site to which the CSF is delivered. Complications common to most shunting techniques include obstruction or malfunction of the shunt, infection, and tissue reaction, e.g., formation of a fibrous sheath around the catheter or erosion of tissue over the shunt (Refs. 1, 5, and 7). Ventriculoatrial shunts have been associated with unique cardiopulmonary complications because of the placement of one end of the catheter in the blood stream. Among these complications are pulmonary emboli, caused by clotting at the catheter tip or by breakage or separation and release of the catheter into the blood stream (Refs. 1, 2, and 3), and perforation of the heart wall by the catheter tip (Refs. 1 and 3). In addition, glomerulonephritis (inflammation of the kidneys) has also been reported in patients with ventriculoatrial shunts (Ref. 4). Ventriculoperitoneal shunts also have been associated with unique complications, such as perforation of the bladder or other organs by the catheter tip (Refs. 8, 9, and 10), and development of inguinal (groin) hernias (Ref. 8), intra-abdominal cysts (Refs. 6 and 8), and ascites (CSF collection in the abdominal cavity) (Ref. 6). Lumboperitoneal shunts have been associated with scoliosis (deviation in the straightness of the spine), leg pain or atrophy, and restricted back movement (Refs. 11 and 12). There have been few reports on complications associated with ventriculopleural, ventriculoureteral, and ventriculolymphatic shunts because these methods are so rarely used. However, Milhorat believes that removal of a kidney, which must precede use of a ventriculoureteral shunt, is a procedure that presents undue risk (Ref. 1).

The Commissioner believes that premarket approval is unnecessary for these devices because there is sufficient information to establish a performance standard that will provide reasonable assurance of their safety and effectiveness. Although there are many complications associated with shunts, the Commissioner recognizes that shunts are generally used when no alternatives exist and that they have reduced the death and mental retardation rates associated with hydrocephalus. Moreover, the Commissioner doubts that requirement premarket approval of these devices will improve the complication rate associated with their use.

The Neurological Device Classification Panel recommended that all central nervous system fluid shunts, both internal and external, and their components be classified into class II (performance standards). although FDA is proposing to adopt this recommendation, the agency requests comments on whether it would instead classify each shunt component (e.g., catheters, valves, connectors, collection bags, etc.) separately from the classification of shunts. The Commissioner believes that it is possible that some of these components (e.g., collection bags for external shunts) could be classified more appropriately into class I.

The Commissioner also requests comments on whether the agency should classify shunts according to the technique used (internal or external) and the anatomical site to which the CSF is delivered, instead of classifying all shunts as a single product, as proposed. The Commissioner recognizes that, depending on the type of shunt used, there may be substantial differences in the number and severity of complications. In addition, there is much more information available on the more common shunt techniques (e.g., ventriculoatrial shunts) than is available on other less frequently used shunts (e.g. ventriculolymphatic shunts).

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be viewed by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Milhorat, H.H., "Hydrocephalus and the Cerebrospinal Fluid," Williams and Wilkins Co., Baltimore, 1972, pp. 177-223.

2. Ignelzi, R. J. and W. M. Kirsch, "Follow-up analysis of Ventriculoperitioneal and Ventriculoatrial Shunts for Hydrocephalus," *Journal of Neurosurgery*, 42:679-682, 1975.

3. Hougen, T.J., et al., "Pulmonary Valvular Dysfunction in Children with Ventriculovenous Shunts for Hydrocephalus: A Previously Unreported Complication," *Pediatrics*, 55:836-841, 1975.

4. McKenzie, S.A. and K. Hyden, "Two Cases of 'Shunt Nephritis'," *Pediatrics*, 54:806-808, 1974.

5. Becker, D. P. and F. E. Nulsen, "Control of Hydrocephalus by Valve-Regulated Venous Shunt: Avoidance of Complications in Prolonged Shunt Maintenance, "*Journal of Neurosurgery*, 28:215-226, 1968.

6. Parry, S.W., et al., "Abdominal Pseudocysts and Ascites Formation after Ventriculoperitoneal Shunt Procedures," *Journal of Neurosurgery*, 43:476-479, 1975.

7. Sugar, O. and O.T. Bailey, "Subcutaneous Reaction to Silicone in Ventriculoperitoneal Shunts," *Journal of Neurosurgery*, 41:367-371, 1974.

8. Grosfield, J. L., et al., "Intraabdominal Complications Following Ventriculoperitoneal Shunt Procedures," *Pediatrics*, 54:791-796, 1974.

9. Robertson, J.S., et al., "Ventriculoperitoneal Shunting for Hydrocephalus," *British Medical Journal*, 2:289-292, 1973.

10. Hoffman, H.S., et al., "New Lumboperitoneal Shunt for Communicating Hydrocephalus," *Journal of Neurosurgery*, 44: 258-261, 1976.

11. Eisenberg, H. M., et al., "Lumboperitoneal Shunts: A Review of 34 Cases," *Journal of Neurosurgery*, 35:427-431, 1971.

12. Kushner, J., et al., "Kyphoscoliosis Following Lumbar Subarachnoid Shunts," *Journal of Neurosurgery*, 34:783-791, 1971.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5550 as follows:

§ 882.550 Central nervous system fluid shunt and components.

(a) *Identification.* A central nervous system fluid shunt is a device or combination of devices use to divert fluid from the brain or other part of the central nervous system to an internal delivery site or an external receptacle for the purpose of relieving elevated intracranial presssure or fluid volume (e.g., due to hydrocephalus). Components of a central nervous system shunt include catherters, valved catheters, valves, connectors, and other accessory components intended to facilitate use of the shunt or evaluation of a patient with a shunt.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc.78 32946 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1091]

MEDICAL DEVICES

Classification of Cranial Electrotherapy Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cranial electrotherapy stimulators into class III (premarket approval). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cranial electrotherapy stimulators:

1. Identification: A cranial electrotherapy stimulator is a device that applies electrical current to a patient's head to treat insomnia, depression, or anxiety.

2. Recommended classification: Class II (premarket approval). The Panel recommends that premarket approval for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that cranial electrotherapy stimulators be classified into class III (premarket approval) because satisfactory effectiveness has not been demonstrated. In addition, the Panel believes that it is not possible to establish an adequate performance standard for this device because the characteristics of the electrical current necessary for effectiveness are not known. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that the device present a potential unreasonable risk of illness or injury to the patient if the practitioner relies on the device, and it is ineffective in treating the patient's illness. The device, therefore, should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

At the Panel meeting of July 22-23, 1977, the Panel recommended that this device be classified into class II (performance standards) if it is used to treat situational anxiety related to alcohol and drug addiction and class III (premarket approval) if it is used to treat insomnia, depression, or other conditions. At that meeting, the Panel members stated that, although the published literature does not support the effectiveness of this device for any conditions, the evidence that the device is effective in treating situational anxiety related to alcohol or drug addiction is stronger than the evidence concerning treatment of other conditions for which the device has been prescribed. At a Panel meeting on January 13, 1978, however, the Panel reassessed its recommendation on cranial electrotherapy stimulators and recommended that the device be classified into class III (premarket approval) for all uses, including treatment of situational anxiety related to alcohol or drug addiction

because the Panel members believe that there has been no clear demonstration of the effectiveness of this device for treating any conditions.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on testimony presented to the Panel and on the results of a study performed by the National Research Council (NRC) on the safety and effectiveness of devices used for electroanesthesia and electrosleep (Ref. 1). Drs. Ray Smith and Timothy Sharma presented the results of their studies of cranial electrotherapy stimulation for detoxification of drug and alcohol addicts. These researchers stated that they believe this treatment to be more effective than other standard approaches used to treat alcohol or drug addiction. They maintained that there have been virtually no reports of hazards or injuries associated with the treatment. However, after reviewing the results of 88 published studies on cranial electrotherapy stimulation, the NRC concluded that the device has not been shown to be effective in treating any of the conditions for which it is prescribed (Ref. 1). The NRC report found, however, that the output current of the device is sufficiently low that there is little hazard to the patient from the current.

5. Risks to health: (a) Skin irritation: The electrodes or the conductive cream used with the electrodes may cause skin irritation. (b) Worsening of the condition being treated: If the device is not effective and the patient is not treated in a conventional manner, the patient's psychological condition may worsen.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the cranial electrotherapy stimulator be classified into class III (premarket appoval). The Commissioner believes that this device is for a use (treatment of insomnia, depression, or anxiety) which is of substantial importance in preventing impairment of human health. Furthermore, the device presents a potential unreasonable risk of illness or injury to the patient if the practitioner uses it instead of conventional therapy to treat severe psychological conditions. He concurs that insufficient information exists to determine that general controls are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and he believes that insufficient information exists to establish a performance standard that will provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

"An Evaluation of Electroanesthesia and Electrosleep," National Research Council, FDA Contract 70-22, Task Order No. 20 (NTIS PB 241305).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5800 as follows:

§ 882.5800 Cranial electrotherapy stimulator.

(a) *Identification.* A cranial electrotherapy stimulator is a device that applies electrical current to a patient's head to treat insomnia, depression, or anxiety.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32947 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1092]

MEDICAL DEVICES

Classification of External Functional Neuromuscular Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing for public comment a proposed regulation classifying external functional neuromuscular stimulators into class II (performance standards). The FDA is also publishing the recommendations of the Neurological Device Classification Panel and the Physical Medicine Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Administrative Proceedings Staff/Hearing Clerk's Office (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere is this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel and the Physical Medicine Device Classification Panel, FDA advisory committee, made the following recommendation with respect to the classification of external functional neuromuscular stimulators:

1. Identification: An external functional neuromuscular stimulator is an electrical stimulator that uses external electrodes for stimulating muscles in the leg and ankle of partially paralyzed patients (e.g., after stroke) to provide flexion of the foot and thus improve the patient's gait.

2. Recommended classification: Class II (performance standards). The Neurological Device Classification Panel recommends that establishing performance standards for this device be a low priority. The Physical Medicine Device Classification Panel recommends that establishing performance standards for this device be a high priority.

3. Summary of reasons for recommendation: The Physical Medicine Device Classification Panel and the Neurological Device Classification Panel recommend that external functional neuromuscular stimulators be classified into class II (performance standards) because the device applies an electrical current to the patient's body and both Panels believe that this current should be controlled to prevent injuring the patient. Both Panels also believe that the performance characteristics of the device must be controlled to assure that the device is safe and effective for its use. The Physical Medicine Device Classification Panel also recommends that the device not be used on patients with cardiac pacemakers and that caution be exercised when it is used on patients with anesthetized limbs. Both the Physical Medicine Device Classification Panel and the Neurological Device Classifi-

cation Panel believe that general controls will not provide sufficient control over the above characteristics. Both Panels also believe that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information available to provide such assurance.

4. Summary of data on which the recommendation is based: The members of the Physical Medicine Device Classification Panel and the Neurological Device Classification Panel based their recommendation on their clinical experience with this device and with other external stimulators similar to this device.

5. Risks to health: The Physical Medicine Device Classification Panel identified the following risks to health: (a) Skin reactions: The conductive gel used for the electrodes may cause skin reactions. (b) Skin burns: The patient's skin may be burned if the output current level is excessive or if the electrodes are too small. (c) Ineffectiveness of treatment: If the current level of the stimulator is not sufficient or if the electrodes are not the proper size, the stimulation may be ineffective.

The Neurological Device Classification Panel identified the following risks to health: (a) Skin burns: The patient's skin may be burned if the output current is excessive or if the electrodes are too small. (b) Skin reactions: The patient's skin may be irritated at the electrode site because of the presence of the electrodes and the conductive gel.

PROPOSED CLASSIFICATION

The Commissioner agrees with the recommendation of the Neurological Device Classification Panel and the Physical Medicine Device Classification Panel and is proposing that the external functional neuromuscular stimulator be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5810 as follows:

§ 882.5810 External functional neuromuscular stimulator.

(a) *Identification.* An external functional neuromuscular stimulator is an electrical stimulator that uses external electrodes for stimulating muscles in the leg and ankle of partially paralyzed patients (e.g., after stroke) to provide flexion of the foot and thus improve the patient's gait.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Administrative Proceedings Staff/Hearing Clerk's Office (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32948 Filed 11-27-78; 8:45]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1093]

MEDICAL DEVICES

Classification of Implanted Cerebellar Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying implanted cerebellar stimulators into class III (premarket approval). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of implanted cerebellar stimulators:

1. Identification: An implanted cerebellar stimulator is a device used to stimulate electrically a patient's cerebellar cortex for the treatment of intractable epilepsy, spasticity, and some movement disorders. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's cerebellum and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class III (premarket approval) because it is an implanted device that involves a substantial risk to the patient and there is not sufficient information available to establish a performance standard that will assure its safety and effectiveness. The Panel also believes that there is not sufficient information available on this device to show that general controls are sufficient to assure its safety and effectiveness. Therefore, the device should be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on extensive testimony and data received by the Panel from investigators and clinicians who have used the device. Because there is much disagreement among investigators as to the safety and effectiveness of the device, the Panel initially had difficulty deciding whether the device should be recommended for classification into class II or class III. The results of experimental studies on animals to determine brain damage or other adverse effects caused by electrically stimulating the cerebellar cortex were reported to the Panel. Some investigators reported finding minimal or no brain damage caused by the stimulating current, while others reported distinct changes and damage to the cerebella of test animals. Investigators also reported results of studies concerning the effectiveness of the device in reducing the frequency of epileptic seizures and the degree of spasticity in patients. The investigators reported widely varying degrees of success in treating those disorders. The Panel concluded that insufficient information exists to establish a performance stand-

ard that would assure the safety and effectiveness of this device. A summary of the testimony and data presented to the Panel by each investigator is contained in the minutes of the Panel meetings of April 8-9, 1976 and July 22-23, 1977. The minutes of those meetings may be obtained from the Hearing Clerk, Food and Drug Administration, at the address given elsewhere in this document.

5. Risks to health: (a) Injury to neural tissue. The electrical current used for stimulation and the pressure that the electrodes exert on the brain tissue may cause injury to the brain. (b) Cerebrospinal fluid leakage: The fluid that surrounds the brain may leak out where the electrode wires pass through the skull. (c) Tissue toxicity: The surface material of the implanted device, lead wires, or electrodes may contain material that is not biocompatible.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that implanted cerebellar stimulators be classified into class III (premarket approval). The Commissioner believes that the implanted cerebellar stimulator presents a potential unreasonable risk of illness or injury to the patient because of the possibility of neural damage. Furthermore, the device is for uses (reducing the severity and frequency of epileptic seizures, or reducing spasticity due to cerebral palsy) which are of substantial importance in preventing impairment of human health. The Commissioner concurs with the Panel that insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and he believes that insufficient information exists to establish a performance standard that will provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5820 as follows:

§ 882.5820 Implanted cerebellar stimulator.

(a) *Identification.* An implanted cerebellar stimulator is a device used to stimulate electrically a patient's cerebellar cortex for the treatment of intractable epilepsy, spasticity, and some movement disorders. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's cerebellum and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32949 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1094]

MEDICAL DEVICES

Classification of Implanted Diaphragmatic/Phrenic Nerve Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying implanted diaphragmatic/phrenic nerve stimulators into class III (premarket approval). The FDA is also publishing the recommendations of two FDA advisory committees concerning these devices. The Neurological Device Classification Panel and the Anesthesiology Device Classification Panel both recommend that implanted diaphragmatic/phrenic nerve stimulators be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after its publication in the FEDERAL REGISTER.

ADDRESS: Written comments (preferably four copies) to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel and the Anesthesiology Device Classification Panel, FDA Advisory Committees, made the following recommendations with respect to the classification of implanted diaphragmatic/phrenic nerve stimulators:

1. Identification: An implanted diaphragmatic/phrenic nerve stimulator is a device that provides electrical stimulation of a patient's phrenic nerve to contract the diaphragm rhythmically and produce breathing in patients who have hyperventilation (a state in which an abnormally low amount of air enters the lungs) caused by brain stem disease, high cervical spinal cord injury, or chronic lung disease. The stimulator consists of an implanted receiver with electrodes that are placed around the patient's phrenic nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

2. Recommended classification: The Anesthesiology Device Classification Panel and the Neurological Device Classification Panel recommend that this device be classified into class III (premarket approval). Both Panels recommend that premarket approval for this device be a high priority.

3. Summary of reasons for recommendation: The Anesthesiology Device Classification Panel and the Neurological Device Classification Panel recommend that the implanted diaphragmatic/phrenic nerve stimulator be classified into class III (premarket approval) because the device is a life supporting implant that has been used by only a limited number of clinical investigators and is not a well-established medical procedure. Although the reported clinical results have been favorable, this device presents a serious risk of injuring the patient's phrenic nerve and thus causing permanent injury. At the Panel meeting of August 20-21, 1977, the Neurological Device Classification Panel recommended that this device be classified into class II (performance standards because the Panel believed that the device has been shown to be safe and effective. However, at the meeting of the Neurological Device Classification Panel on April 21, 1978, the Panel reassessed its previous recommendation on this device and recommended that it be classified into class III (premarket approval) instead because the clinical results available were limited to one company's device. The Panel did not believe that the results were sufficient to establish a performance standard for the device. The Panels do not believe that there is sufficient information to establish a performance standard that will provide reasonable assur-

ance of the safety and effectiveness of the device. The Panels also believe that there is not sufficient information available on this device to show that general controls are sufficient to assure its safety and effectiveness. The device should, therefore, be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Neurological Device Classification Panel members based their recommendation on their clinical experience with this device and their knowledge of the medical literature published on the device. The Anesthesiology Device Classification Panel members based their recommendation on a lack of medical data on which to judge the safety and effectiveness of the device.

5. Risks to health: The Neurological Device Classification Panel identified the following risks to health from this device. (a) Respiratory arrest: If the device fails or if the stimulation becomes ineffective, the patient may stop breathing. (b) Tissue toxicity: The implanted stimulator, lead wires, or electrodes may contain material that is not biocompatible. (c) Injury to phrenic nerve: The patient's phrenic nerve may be injured by excessive electrical current, improper electrodes, or surgical trauma. The Anesthesiology Device Classification Panel identified the following risks to health: (a) Hypoventilation: The patient may not be able to breathe sufficiently if the device fails. (b) Hyperventilation: The patient may be forced by the device to breathe too rapidly if the rate control on the device fails.

Proposed Classification

The Commissioner agrees with the recommendations of the Anesthesiology Device Classification Panel and the Neurological Device Classification Panel and is proposing that the implanted diaphragmatic/phrenic nerve stimulator be classified into class III (premarket approval). The Commissioner believes that the device presents a potential unreasonable risk of illness or injury to the patient, because trauma to the patient's phrenic nerve due to placement of the electrode around the nerve may cause permanent injury that impairs breathing. Furthermore, the device is an implant that is for a life-supporting use (producing or aiding breathing). The act requries the Commissioner to classify an implant or a life-supporting device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. In this case, the Commissioner has determined that premarket approval is necessary. Although the reported clinical results with this device have been favorable (Ref. 1), the Commissioner concurs with the Panels that insufficient information exists on this implanted life-supporting device to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and he believes that insufficient information exists to establish a performance standard that would provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

Glenn, W. W. L., "Diaphragm Pacing: Present Status," *Pace* 1:357-370, 1978.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5830 as follows:

§ 882.5830 Implanted diaphragmatic/phrenic nerve stimulator.

(a) *Identification.* An implanted diaphragmatic/phrenic nerve stimulator is a device that provides electrical stimulation of a patient's phrenic nerves to contract the diaphragm rhythmically and produce breathing in patients who have hyperventilation (a state in which an abnormally low amount of air enters the lungs) caused by brain stem disease, high cervical spinal cord injury, or chronic lung disease. The stimulator consists of an implanted receiver with electrodes that are placed around the patient's phrenic nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32950 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1095]

MEDICAL DEVICES

Classification of Implanted Intracerebral/Subcortical Stimulators for Pain Relief

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying implanted intracerebral/subcortical stimulators for pain relief into class III (premarket approval). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of implanted intracerebral/subcortical stimulator for pain relief:

1. Identification: An implanted intracerebral/subcortical stimulators for pain relief is a device that applies electrical current to subsurface areas of a patient's brain to treat severe intractable pain. The stimulator con-

sists of an implanted receiver with electrodes that are placed within a patient's brain and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class III (premarket approval) because it is an implanted device. In addition, although the Panel considered recommending that the device be classified into class II, it concluded that there is not sufficient information available to establish that the device is safe and effective for treating pain. Although some investigators report that they have had success with this technique, the Panel members express doubt that the results could be replicated by others. The electrodes of this device must penetrate the brain, and the Panel believes that this surgery involves a substantial risk to the patient. Although the reported clinical results with these devices have been favorable, the Panel believes that sufficient information is not available to establish a performance standard for the device that will assure its safety and effectiveness. The Panel also believes that there is not sufficient information available on this device to show that general controls are sufficient to assure its safety and effectiveness. The device should, therefore, be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with this device and similar devices. In addition, the Panel members are familiar with the literature published on this device (Refs. 1, 2, and 3).

5. Risks to health: (a) Injury to neural tissue: The electrical current used for stimulation may damage the brain. (b) Hemorrhage or physical disruption of neural tissue: The insertion of the device electrodes may sever blood vessels and destroy brain tissue. (c) Tissue toxicity: The materials used in the implanted portion of this device may be toxic to brain or other tissues. (d) Cerebrospinal fluid leakage: The fluid which surrounds the brain may leak out around the connecting wires of the device that penetrate the skull.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that the implanted intracerebral/subcortical stimulator for pain relief be classified into class III (premarket approval). The Commissioner believes that this implanted device presents a potential unreasonable risk of illness or injury to the patient because of the possibility of neural damage. Furthermore, the device is for a use (treatment of severe intractable pain) which is of substantial importance in preventing impairment of human health. The Commissioner concurs with the Panel that insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and he believes that insufficient information exists to establish a performance standard that will provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Pudenz, R. H., "Adverse Effects of Electrical Energy Applied to the Nervous System," *Neurosurgery* 1:190-191, 1977.

2. Adams, J. E. and Y. Hosobuchi, "Session on Deep Brain Stimulation: Technique and Technical Problems," *Neurosurgery* 1:196-199, 1977.

3. Richardson, D. E. and H. Akil, "Long Term Results of Periventricular Gray Self-Stimulation," *Neurosurgery* 1:199-202, 1977.

Therefore, under the Federal Food, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5840 as follows:

§ 882.5840 Implanted intracerebral/subcortical stimulator for pain relief

(a) *Identification.* An implanted intracerebral/subcortical stimulator for pain relief is a device that applies electrical current to subsurface areas of a patient's brain to treat severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed within a patient's brain and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

William F. Randolph,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32951 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1096]

MEDICAL DEVICES

Classification of Implanted Spinal Cord Stimulators for Bladder Evacuation

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying implanted spinal cord stimulators for bladder evacuation into class III (premarket approval). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of implanted spinal cord stimulators for bladder evacuation:

1. Identification: An implanted spinal cord stimulator for bladder evacuation is an electrical stimulator used to empty the bladder of a paraplegic patient who has a complete transection of the spinal cord and who is

unable to empty his or her bladder by reflex means or by the intermittent use of catheters. The stimulator consists of an implanted receiver with electrodes that are placed on the conus medullaris portion of the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class III (premarket approval) because it is an implanted device, and there is not sufficient information available to establish a performance standard that will assure its safety and effectiveness. At the Panel meeting of August 20-21, 1977, the Panel recommended that this device be classified into class II (performance standards) because the device is similar in design to the implanted spinal cord stimulator for pain relief which the Panel recommended to be classified into class II. However, on April 21, 1978 the Panel reassessed its recommendation on implanted spinal cord stimulators for bladder evacuation and recommended that they be classified into class III (premarket approval) because the device has been successfully applied in only a small number of patients, and virtually all those patients were treated by one physician using a device manufactured by one company. Although the reported clinical results with those patients has been favorable, the Panel believes that there is not enough information to establish a performance standard for the device that will assure its safety and effectiveness. The Panel also believes that there is not sufficient information available on this device to show that general controls are sufficient to assure its safety and effectiveness. The device should, therefore, be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The panel members based their recommendation on information supplied by Dr. Blaine Nashold, one of the Panel members, who has been one of the primary individuals engaged in the development of the device. Dr. Nashold reported that he has implanted the device in a small group of paraplegic patients. Six of the 12 patients have been successfully emptying their bladders by this method for the past 5 years (Ref. 1).

Risks to health: (a) Injury to neural tissue: Tissue fibrosis may develop around the electrode on the spinal cord and cause a diminished response to the electrical stimulus. (b) Tissue toxicity: The implanted stimulator, lead wires, or electrodes may contain material which is not biocompatible. (c) Cerebrospinal fluid leakage: The fluid that surrounds the spinal cord might leak out around the receiver wires.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that implanted spinal cord stimulators for bladder evacuation be classified into class III (premarket approval). The Commissioner believes that the device presents a potential unreasonable risk of illness or injury, because of the possibility of neural damage. Furthermore, the Commissioner believes that this implanted device is for a use (bladder evacuation in paraplegic patients) which is of substantial importance in preventing impairment of human health. The act requires the Commissioner to classify an implant into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner concurs with the Panel that insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and he believes that insufficient information exists to establish a performance standard that will provide such assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Nashold, B. S., et al., "Operative Stimulation of the Neurogenic Bladder," Proceedings of the Symposium on the Safety and Clinical Efficacy of Implanted Neuroaugmentive Devices, *Neurosurgery*, 1:218-220, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 is Subpart F by adding New § 882.5850 as follows:

§ 882.5850 Implanted spinal cord stimulator for bladder evacuation.

(a) *Identification.* An implanted spinal cord stimulator for bladder evacuation is an electrical stimulator used to empty the bladder of a paraplegic patient who has a complete transection of the spinal cord and who is unable to empty his bladder by reflex means or by the intermittent use of catheters. The stimulator consists of an implanted receiver with electrodes that are placed on the conus medullaris portion of the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32952 filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR PART 882]

[Docket No. 78N-1097]

MEDICAL DEVICES

Classification of Implanted Neuromuscular Stimulators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying implanted neuromuscular stimulators into class III (premarket approval). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class III and the recommendation of the Orthopedic Device Classification Panel that the device be classified into class II. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel and the Orthopedic Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of implanted neuromuscular stimulators:

1. Identification: An implanted neuromuscular stimulator is a device that provides electrical stimulation to a patient's peroneal or femoral nerve to cause muscles in the leg to contract, thus improving the gait in a patient with a paralyzed leg. The stimulator consists of an implanted receiver with electrodes that are placed around a patient's nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver. The external transmitter is activated by a switch in the heel of the patient's shoe.

2. Recommended classification: The Orthopedic Device Classification Panel recommends that this device be classified into class II (performance standards) and that establishing a performance standard for this device be a high priority. The Neurological Device Classification Panel recommends that this device be classified into class III (premarket approval) and that premarket approval for the device be a high priority.

3. Summary of reasons for recommendation: The Orthopedic Device Classification Panel recommends that this device be classified into class II (performance standards) because the device uses materials that are implanted and should be controlled. This Panel believes that use of this device is contraindicated in patients with cardiac pacemakers because of the possibility that the stimulator may interfere with the operation of the pacemaker. The Orthopedic Device Classification Panel further recommends that the device be restricted to sale by or on the order of a physician. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel also believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

The Neurological Device Classification Panel recommends that the implanted neuromuscular stimulator be classified into class III (premarket approval) because the device is a surgical implant that has been used on only a limited number of patients. At the Panel meeting of August 20-21, 1977, the Neurological Device Classification Panel recommended that the device be classified into class II (performance standards) because the Panel at that time believed the device had been shown to be safe and effective. However, at the meeting of the Neurological Device Classification Panel on April 21, 1978, the Panel reassessed its previous recommendation on this device and recommended that it be classified into class III (premarket approval) instead because the clinical results available were limited to one company's device which had been used on only a few patients. The Neurological Device Classification Panel does not believe that there is sufficient information available to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Panel also believes that there is not sufficient information available on this device to show that general controls alone are sufficient to assure its safety and effectiveness. The device should, therefore, be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal knowledge of the device, the potential hazards associated with the device, the pertinent literature (Ref. 1), and their clinical experience with the device.

5. Risks to health: The Orthopedic Device Classification Panel identified the following risks to health: (a) Adverse tissue response: The materials used in the device may cause a toxic or adverse reaction in the surrounding tissue. (b) Infection: There is an increased risk of sepsis associated with the presence of a foreign object implanted in the body.

The Neurological Device Classification Panel identified the following risks to health: (a) Injury to the nerve: The presence of the electrode or the output current may injure the peroneal or femoral nerve. (b) Tissue toxicity: The implanted stimulator, lead wires, or electrodes may contain material that is not biocompatible.

PROPOSED CLASSIFICATION

The Commissioner agrees with the recommendation of the Neurological Device Classification Panel and is proposing that the implanted neuromuscular stimulator be classified into class III (premarket approval). The Commissioner does not agree with the Orthopedic Device Classification Panel that sufficient information is available on this device to establish a performance standard that will assure the safety and effectiveness of the device. The Commissioner notes that there are only limited clinical data available on this device, and most of the data are from one medical center using a device manufactured by one company. A recent publication states that only 31 patients have had the device implanted to improve their walking (Ref. 2). The Commissioner believes that the device presents a potential unreasonable risk of illness or injury to the patient, because of the possibility of nerual damage. Furthermore, the device is an implant for a use (improving the gait in a patient with a paralyzed leg) which is of substantial importance in preventing impairment of human health. The act requires the Commissioner to classify an implant into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. In this case, the Commissioner has determined that premarket approval is necessary. Therefore, the commissioner concurs with the Neurological Device Classification Panel that insufficient information exists on this implanted device to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and the Commissioner believes that insufficient information exists to establish a performance standard that would provide such assurance.

The following information has been placed in the office of the hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

REFERENCES

1. National Academy of Sciences, "Clinical Evaluation of Rancho Los Amigos/Medtronic Implanted Neuromuscular Assist Device," Committee on Prosthetic Research and Development, In Press, 1976.

2. McNeal, D. R., et al., "Experience with Implanted Electrodes, " Proceedings of the symposium on the Safety and clinical Efficacy of Implanted Neuroaugmentive Devices, *Neurosurgery*, 1:228-229, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him 21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5860 as follows:

§ 882.5860 Implanted neuromuscular stimulator.

(a) *Identification.* An implanted neuromuscular stimulator is a device that provides electrical stimulation to a patient's peroneal or femoral nerve to cause muscles in the leg to contract, thus improving the gait in a patient with a paralyzed leg. The stimulator consists of an implanted receiver with electrodes that are placed around a patient's nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver. The external transmitter is activated by a switch in the heel in the patient's shoe.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals

may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32953 Filed 11-27-78; 8:45]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1098]

MEDICAL DEVICES

Classification of Implanted Peripheral Nerve Stimulators For Pain Relief

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying implanted peripheral nerve stimulators for pain relief into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere is this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, on FDA advisory committee, made the following recommendation with respect to the classification of implanted peripheral nerve stimulators for pain relief:

1. Identification: An implanted peripheral nerve stimulator for pain relief is a device that is used to stimulate electrically a peripheral nerve in a patient to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed around a peripheral nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

2. Recommended classification: Class II (performance standards). The Panel recommends that performance standards for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class II (performance standards) because the performance of the device should be controlled to avoid injury to the nerve that is stimulated and because the implanted materials used in the device should be required to be biocompatible. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that premarket approval is not necessary for this implanted device because a standard will provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal clinical experience with these devices and their familiarity with the relevant literature.

5. Risks to health: (a) Injury to neural tissue: The nerve that is stimulated may be damaged by the presence of the electrode or by the output current from the device. (b) Tissue toxicity: The implanted stimulator, lead wires, or electrodes may contain material that is not biocompatible.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the implanted peripheral nerve stimulator for pain relief be classified into class II (performance standards).

The Commissioner has reviewed the Panel recommendation to classify implanted peripheral nerve stimulators for pain relief into class II (performance standards) and has obtained additional data and information on the safety and effectiveness of the device. Electrical stimulation of peripheral nerves has been used to relieve chronic intractable pain, produced primarily by trauma or injury to nerves. The device consists of electrodes that are placed around a peripheral nerve in a patient and connected by lead wires to a receiver that is placed in a convenient spot just under the skin. The stimulating pulses are transmitted acress the skin to the receiver by an external radiofrequency transmitter and an antenna that is placed on the skin over the receiver.

The major benefit of using this device is that patients with chronic intractable pain may be able to reduce their pain to such an extent that they can reduce or eliminate the use of analgesic drugs. Several authors have reported that peripheral nerve stimulation provides significant relief to patients with chronic intractable pain. This technique has been reported to be effective in about 55 percent of the patients on whom it was attempted (Refs. 1, 2, 3, and 4). The most common nerves that are stimulated are the sciatic, ulnar, occipital, and femoral nerves. There have been few reports of complications involving this technique. Picaza (Ref. 1) reports that the most common complication in 37 patients followed for 12 to 46 months was tenderness at the receiver implantation site or at the electrode site. He also reports two cases of formation of neuroma (a small tumor on the nerve) at the electrode site. Picaza cautions, however, that implanted stimulators should be used only in those cases where continued stimulation is necessary for long periods of time, because patients often can obtain satisfactory relief by using external transcutaneous stimulation.

The Commissioner believes that premarket approval is not necessary for this implanted device because there is sufficient information available to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that a performance standard is necessary of this device because general controls will not provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be viewed by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Picaza, J. A., et al., "Pain Suppression: Chronic Effects, " Proceedings of the symposium on the Safety and Clinical Efficacy of Implanted Neuroaugmentive Devices, *Neurosurgery*, 1:226-227, 1977.

2. Nashold, B. S. and J. L. Goldner, "Electrical Stimulation of Peripheral nerves for Relief of Intractable Chronic Pain," *Medical Instrumentation*, 9:224-225, 1975.

3. Erickson, D. and S. Chou, "Implantable Electrical Devices for pain Relief," *Minnesota Medicine*, 57:210-212, 1974.

4. Long, D. M., "Electrical Stimulation for Relief of Pain from Chronic Nerve Injury," *Journal of Neurosurgery*, 39:718-722, 1973.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546

(21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5870 as follows:

§ 882.5870 Implanted peripheral nerve stimulator for pain relief.

(a) *Identification.* An implanted peripheral nerve stimulator for pain relief is a device that is used to stimulate electrically a peripheral nerve in a patient to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed around a peripheral nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32954 Filed 11-27-78; 8:45]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1099]

MEDICAL DEVICES

Classification of Implanted Spinal Cord Stimulators for Pain Relief

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying implanted spinal cord stimulators for pain relief into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-30), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of implanted spinal cord stimulators for pain relief:

1. Identification: An implanted spinal cord stimulator for pain relief is a device that is used to stimulate electrically a patient's spinal cord to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class II (performance standards) because the performance of the device should be controlled to avoid injuring the patient's spinal cord and because the implanted materials used in the device should be required to be biocompatible. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that premarket approval is not necessary for this implanted device because a standard will provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal clinical experience with this device and their knowledge of the relevant literature.

5. Risks to health: (a) Injury to neural tissue: The patient's spinal cord may be damaged by the presence of the electrodes or by the output current from the device. (b) Tissue toxicity: The implanted stimulator, lead wires, or electrodes may contain material that is not biocompatible. (c) Cerebrospinal fluid leakage: The fluid which surrounds the spinal cord (cerebrospinal fluid) may leak out around the electrode lead wires.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the implanted spinal cord stimulator for pain relief be classified into class II (performance standards).

The Commissioner has reviewed the Panel's recommendation to classify implanted spinal cord stimulators for pain relief into class II (performance standards) and has obtained additional data and information on the safety and effectiveness of the device. Electrical stimulation of the spinal cord for relief of pain has been used by numerous clinicians since the technique was introduced in the 1960's. The stimulation apparatus consists of electrodes that are placed at the desired location on the patient's spinal cord and connected by wires to a receiver that is located in a convenient spot just under the skin. The stimulating pulses are transmitted across the skin to the receiver by an external radiofrequency transmitter and an antenna that is placed on the skin over the receiver. The major benefit of using this device is that patients with chronic intractable pain may be able to reduce their pain to such an extent that they are able to reduce or eliminate the use of analgesic drugs.

The placement of the device's electrodes on the spinal cord has been an important factor in the complication rates for this device. Electrodes are usually placed on the dorsal (back) side of the spinal cord either within the dura (the outer membrane surrounding the spinal cord), below the dura, or below the arachnoid membrane of the spinal cord (Ref. 1). These methods require major surgery to implant the electrodes. Recently, a technique has been used where the electrodes are inserted through a needle into the epidural (outside or on the dura) space, thus greatly reducing the necessary surgery (Refs. 1, 2, and 3).

The reported long-term, good-to-excellent results obtained with implanted spinal cord stimulators for treating pain has varied from about 17 percent (Ref. 4) to over 80 percent (Refs. 3 and 5). Generally, however, the device has been reported to be effective in about 40 to 60 percent of the patients treated (Refs. 1, 2, 6, 7, and 8). Nashold observed that effectiveness of the device in his group tended to decrease with time, while the level of stimulation required for effectiveness tended to in-

crease with time (Ref. 7). Virtually all authors agree, however, that the key to successful application of the device is careful selection of the patients on whom it is used.

Complications or problems with spinal cord stimulation have been reported by several investigators. Fox lists 26 problems or comments that were reported to him in his survey of 10 neurosurgeons who used these devices (Ref. 1). Others have also reported a variety of problems. The complications reported include spinal cord compression or injury by the electrode, resulting in transient paralysis (Refs. 1, 2, 6, 8, and 9); leakage of cerebrospinal fluid around the lead wires (Refs. 1, 7, and 8); thickening of the arachnoid membrane of the spinal cord (Refs. 1 and 7); rejection of the implant or tissue reaction (Refs. 2 and 8); and infection (Ref. 1). Grillo, et al. reported one case where the patient was temporarily paralyzed when bleeding occurred beneath a subarachnoid electrode 18 months after it was implanted (Ref. 9).

The Commissioner believes that premarket approval is not necessary for this implanted device because there is sufficient information available to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that a performance standard is necessary for this device because general controls will not provide such assurance.

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

REFERENCES

1. Fox, J. L., "Problems Encountered with Implanted Electrodes for Dorsal Column Stimulation for Pain," *in* "Functional Electrical Stimulation," Edited by F. T. Hambrecht and J. R. Reswick, Marcel Dekker, Inc., New York, pp. 459-463, 1977.

2. Burton, C. V., "Safety and Clinical Efficacy," Proceedings of the Symposium on the Safety and Clinical Efficacy of Implanted Neuroaugmentive devices, *Neurosurgery*, 1:214-215.

3. North, R. B., et al., "Chronic Stimulation via Percutaneously Inserted Epidural Electrodes," Proceeding of the Symposium on the Safety and Clinical Efficacy of Implanted Neuroaugmentive Devices, *Neurosurgery, 1:215—218.*

4. Long, D. M. and D. E. Erickson, "Stimulation of the Posterior Columns of the Spinal Cord for relief of Intractable Pain," *Surgical Neurology*, 4:134-141, 1975.

5. Nielson, K. D., et al., "Phantom Limb Pain: Treatment with Dorsal Column Stimulation," *Journal of Neurosurgery*, 42:301-307, 1975.

6. Nashold, B. S. and H. Friedman, "Dorsal Column Stimulation for Control of Pain: Preliminary Report on 30 Patients," *Journal of Neurosurgery*, 36:590-597, 1972.

7. Nashold, B. S., "Dorsal Column Stimulation for Control of Pain: A Three-Year Follow-up," *Surgical Neurology*, 4:146-147, 1975.

8. Sweet, W. H. and J. G. Wepsic, "Stimulation of the Posterior Columns of the Spinal Cord for Pain Control: Indications, Technique and Results," *Clinical Neurosurgery*, 21:278-310, 1974.

9. Grillo, P. J., et al., "Delayed Intraspinal Hemorrhage after Dorsal Column Stimulation For Pain," *Archives of Neurology*, 30:105-106, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5880 as follows:

§ 882.5880 Implanted spinal cord stimulator for pain relief.

(a) *Identification.* An implanted spinal cord stimulator for pain relief is a device that is used to stimulate electrically a patient's spinal cord to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32955 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1100]

MEDICAL DEVICES

Classification of Transcutaneous Electrical Nerve Stimulators for Pain Relief

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying transcutaneous electrical nerve stimulators for pain relief into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of transcutaneous electrical nerve stimulators for pain relief:

1. Identification: A transcutaneous electrical nerve stimulator for pain relief is a device used to apply an electrical current to electrodes on a patient's skin to treat pain.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that transcutaneous electrical nerve stimulators for pain relief be classified into class II (performance standards) because the patient may be injured if the device is used incorrectly or if the output current is excessive. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their extensive personal clinical experience with this device, data presented by experts in the use of the device, and a review of the relevant literature on the device. A summary of the literature reviewed was prepared by the Panel (Ref. 1). Users of transcutaneous electrical nerve stimulator devices have reported that long-term (1 year or more) effectiveness of this device in treating pain is about 25 to 30 percent for selected patients who have intractable chronic pain. The best results were obtained on patients who had chronic low back pain, phantom limb pain, and pain of osteoarthritis. The literature contains no reports of mortalities caused by this device.

5. Risks to health: (a) Burns. The patient's skin may be burned if the output current levels are excessive or if the electrodes are too small. (b) Skin reactions. The conductive cream or gel used with the electrodes or the presence of the electrodes on the skin may cause adverse skin reactions.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the transcutaneous electrical nerve stimulator for pain relief be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "Report on the Findings and Recommendations on Transcutaneous Electrical Nerve Stimulation for Pain Relief," prepared by the Panel on Review of Neurological Devices, Food and Drug Administration, February 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5890 as follows:

§ 882.5890 Transcutaneous electrical nerve stimulator for pain relief.

(a) *Identification.* A transcutaneous electrical nerve stimulator for pain relief is a device used to apply an electrical current to electrodes on a patient's skin to treat pain.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32956 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1101]

MEDICAL DEVICES

Classification of Preformed Craniosynostosis Strips

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying preformed craniosynostosis strips into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of preformed craniosynostosis strips:

1. Identification: A preformed craniosynostosis strip is a plastic strip used to cover bone edges of craniectomy sites (sites where the skull has been cut) to prevent the bone from regrowing in patients whose skull sutures are abnormally fused together.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class II (performance standards) to assure that the material used in craniosynostosis strips is biocompatible and performs properly. The Panel believes that general controls will not provide sufficient control over these characteristics. Although preformed craniosynostosis strips are implanted devices, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information availabe to establish a standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their familiarity with this device and the literature related to biocompatibility.

5. Risks to health: (a) Risk of ineffective treatment: If the material does not maintain its structural integrity, it will fail to prevent the bone from growing back together. (b) Tissue toxicity: The material used in the device may cause adverse tissue reaction if it is not biocompatible.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that preformed craniosynostosis strips be classified into class II (performance standards).

The Commissioner has reviewed the Panel's recommendation to classify preformed craniosynostosis strips into class II (performance standard) and has obtained additional data and information on the safety and effectiveness of the device. Shillito provides a detailed explanation of the procedure and reports improvement in 74 percent of 519 infants (Ref. 1) He reported two deaths and an overall complication

rate of 14 percent in that group. The more serious complications included wound sepsis, hematoma, tears in the dura, erosion through the scalp of the clips holding the plastic strip in place, septicemia, and permanent scarring of the forehead caused by the pressure of the surgical head rest. Polyethylene film and silicone rubber strips have been used in the treatment of craniosynostosis and are generally regarded as biologically compatible (Ref. 2).

The Commissioner agrees with the Panel that premarket approval is not necessary for this implanted device because there is sufficient information available to establish a performance standard that will provide reasonable assurance of its safety and effectiveness. The Commissioner also agrees with the Panel that a performance standard is necessary for this device because general controls would not provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Shillito, J., Jr., "Craniosynostosis," *in* "Neurological Surgery," Vol. 1, Edited by J. R. Youmans, W. B. Saunders Co., Philadelphia, PA, pp. 608-627, 1973.

2. Lee, H. and K. Neville, "Handbook of Biomedical Plastics," Pasadena Technology Press, Pasadena, Calif., pp. 14-2 to 14-32.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5900 as follows:

§ 882.5900 Preformed craniosynostosis strips.

(a) *Identification.* A preformed craniosynostosis strip is a plastic strip used to cover bone edges of craniectomy sites (sites where the skull has been cut) to prevent the bone from regrowing in patients whose skull sutures are abnormally fused together.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32957 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1102]

MEDICAL DEVICES

Classification of Dura Substitutes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dura substitutes into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological and Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of dura substitutes:

1. Identification: A dura substitute is a sheet of material that is used to repair the dura mater (the membrane surrounding the brain).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that this device be classified into class II performance standards) because the material should be required to be biocompatible and to be able to maintain a seal to prevent cerebrospinal fluid (CSF) leakage. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that premarket approval is not necessary for this implanted device because a standard will provide reasonable assurance of the safety and effectiveness of the device and there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with these devices.

5. Risks to health: (a) Tissue reaction: The material used in the device may be toxic to surrounding tissue, or may adhere to neural tissue. (b) CSF leakage: If the material does not maintain a seal with the dura, or if defects in the material occur, the CSF may leak out.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the dura substitute be classified into class II (performance standards).

The Commissioner has reviewed the Panel's recommendation and has obtained additional data and information on the safety and effectiveness of this implanted device. Since the turn of the century, a wide variety of both natural and synthetic materials has been used to seal holes in the dura mater (Ref. 1). The natural materials have included both processed and unprocessed tissues. Numerous synthetic materials have been used. According to several authors, dura substitutes must have three basic qualities: biocompatibility; the ability to prevent tissue adhesions between the cerebral cortex and overlying soft tissue; and the ability to prevent cerebrospinal fluid (CSF) leakage (Refs. 1 through 3). CSF leakage has been reported to be a problem, especially with woven materials (Ref. 4). Tantalum foil has the disadvantages of being radiopaque and of being easily torn (Ref. 4). Silicone film dura replacement has been reported to have been associated with two cases of intracranial bleeding (Ref. 4). Infection also is an inherent risk with any operative procedure involving an implant such as the dura substitute.

The Commissioner believes that premarket approval is not necessary for this implanted device because there is sufficient information available to es-

tablish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that a performance standard is necessary for this device because general controls will not provide such assurance.

REFERENCES

The following information has been placed in the Office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Keener, E. B., "Regeneration of Dural Defects," *Journal of Neurosurgery*, 16:415-423, 1957.

2. Lee, J. F., et al., "Experimental Evaluation of Silicone Coated Dacron and Collagen Fabric Film Laminate as Dural Substitute," *Journal of Neurosurgery*, 27:558-564, 1967.

3. Abin, S. M., et al., "Nonsuture Sealing of a Dural Substitute Utilizing a Plastic Adhesive Methyl 2-Cyanoacrylate," *Journal of Neurosurgery*, 19:545-550, 1962.

4. Banerjee, T., et al., "Unusual Complications with Use of Silastic Dural Substitute," *American Surgeon*, 40:434-437, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5910 as follows:

§ 882.5910 **Dura substitute.**

(a) *Identification.* A dura substitute is a sheet of material that is used to repair the dura mater (the membrane surrounding the brain).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32958 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1103]

MEDICAL DEVICES

Classification of Electroconvulsive Therapy Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electroconvulsive therapy devices into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electroconvulsive therapy devices:

1. Identification: An electroconvulsive therapy device is a device used for treating severe psychiatric disturbances, e.g., severe depression, by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient's head.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that electroconvulsive therapy (ECT) devices be classified into class II (performance standards) because the devices must be capable of providing the correct amount of current to the patient to induce a seizure without unnecessarily injuring the patient. The Panel believes that general controls will not provide sufficient control over these characteristics. Although the use of this device involves a substantial risk to the patient, the Panel believes that the benefit of the treatment outweighs the risks involved if the patients are selected carefully and the devices are designed and used properly. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their personal familiarity with the use of this device and on information provided by Dr. Allen R. Grahn of the Utah Biomedical Test Laboratory. Dr. Grahn conducted a study under contract to the FDA on ECT devices and presented the results of his study to the panel (Ref. 1). Dr. Grahn's study was based on a review of the scientific literature, information supplied by ECT device manufacturers, and a survey of ECT users. He pointed out that the optimum electrical characteristics of ECT devices have not been determined but that a reliable therapeutic result may be achieved using a variety of device electrical designs. Dr. Grahn also stated that no controlled study has been performed that determines precisely the mortality associated with ECT treatments. However, estimates predict a mortality frequency that ranges from one death per 10,000 treatments to one death per 28,000 treatments (Ref. 1).

5. Risks to health: (a) Burns: Excessive electrical current or improperly designed electrodes may cause the patient's skin under the electrodes to be burned. (b) Pain: The patient is subjected to pain if the device fails to administer sufficient current to achieve a convulsive seizure. (c) Brain damage: Excessive or improper control of the applied electrical current may produce injury to the patient's brain. (d) Self-injury during seizure: Inadequate supportive drug treatment may allow the patient to be injured from unconscious violent movements during convulsions. (e) Aspiration: The patient may inhale foreign material, such as regurgitated stomach contents, if preventive procedures are not employed. (f) Adverse drug effects: The muscle relaxing and tranquilizing drugs that are a part of the procedure may hamper the patient's ability to breathe spontaneously. (g) Cardiac arrhythmia: The therapeutic convulsions may be accompanied by irregular heartbeat or cardiac arrest. (h) Memory loss: The patient may suffer amnesia after the treatment.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the electroconvulsive therapy devices be classified into class II (performance standards). The Commissioner believes that a performance

standard is necessary for this device because general controls by themselves are insufficient to control the risks to health described above. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

Grahn, Allen R., "Summary of Presentation to FDA Neurology Panel—Study of Electroconvulsive Therapy Device Safety and Efficacy," (Contract 223-74-5753, Task 22), October 15, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 is Subpart F by adding new § 882.5940 as follows:

§ 882.5940 Electroconvulsive therapy devices.

(a) *Identification.* An electroconvulsive therapy device is a device used for treating severe psychiatric disturbances (e.g., severe depression) by inducing in the patient a major motor seizure by applying a brief intense electrical current to the patient's head.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32959 filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1104]

MEDICAL DEVICES

Classification of Artificial Embolization Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying artificial embolization devices into class III (premarket approval). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each application includes information concerning safety and effectiveness tests of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of artificial embolization devices:

1. Identification: Artificial embolization devices are objects that are placed in a blood vessel to permanently obstruct blood flow to an aneurysm or other vascular malformation.

2. Recommendd classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that artificial embolization devices be classified into class III (premarket approval) because the devices are permanent implants and the patient may be seriously injured if the physician is not able to ensure that the devices go to the selected target site after release into the blood stream. The Panel believes that there is not sufficient information to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device, nor is there enough information to show that general controls will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the belief that there is insufficient clinical information which shows that artificial embolization devices are safe and effective for treating vascular malformations.

5. Risks to health: (a) Infarction of nervous tissue: The embolism can lodge in an unintended site after release into the blood stream. The embolism may then prevent blood from reaching healthy tissue and cause permanent damage to the nervous system. (b) Tissue toxicity: The material used in the device may produce a toxic reaction if it is not compatible with tissue or blood.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the artificial embolization device be classified into class III (premarket approval). The Commissioner believes that the device presents a potential risk of death or serious injury to the patient if the physician is unable to control the emboli or thrombus-forming material. Furthermore, the device is for a use (treatment of vascular malformations) which is of substantial importance in preventing impairment of human health. Finally, the device is an implant, which the act requires to be classified into class III unless the Commissioner determines that premarket approval is necessary to provide reasonable assurance of the safety and effectiveness of the device. In this case, the Commissioner has determined that premarket approval is necessary.

The Commissioner has reviewed the Panel's recommendation and has obtained additional data and information on the safety and effectiveness of artificial embolization devices. Artificial embolization has been used to treat various patient conditions involving malformations of blood vessels or tumors in the brain or spinal cord. The most frequent method reported has been the use of radiopaque silicone spheres that are directed to the site where embolization is desired and released into the blood stream by means of a special catheter (Refs. 1 through 5). Various sizes and quantities of spheres are used depending on the size of the blood vessel to be

blocked. Investigators have also used gelfoam (Ref. 1), polyurethane foam (Ref. 6), liquid silicone (Ref. 1), and small bits of muscle (Ref. 7) to serve as artificial emboli. Alksne has developed and used a technique for treating intracranial aneurysms where iron particles are injected into the aneurysm and held in place by a magnetic field until the blood clots and closes the aneurysm (Refs. 8 through 10).

The Commissioner concurs with the Panel that insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and he believes that insufficient information exists to establish a performance standard that will provide such assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (address above), Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Hilal, S. K., and J. W. Michelsen, "Therapeutic Percutaneous Embolization for Extra-Axial Vascular Lesions of the Head, Neck, and Spine," *Journal of Neurosurgery*, 43:275-287, 1975.

2. Luessenhop, A. J., and J. H. Presper, "Surgical Embolization of Cerebral Arteriovenous Malformations Through Internal Carotid and Vertebral Arteries," *Journal of Neurosurgery*, 42:443-451, 1975.

3. Pugatch, R. D., and S. M. Wolpert, "Transfemoral Embolization of an External Carotid-Cavernous Fistula," *Journal of Neurosurgery*, 42:94-97, 1975.

4. Kricheff, I. I., et al., "Transfemoral Catheter Embolization of Cerebral and Posterior Fossa Arteriovenous Malformations," *Neuroradiology*, 103:107-111. 1972.

5. Boulos, R., et al., "Value of Cerebral Angiography in the Embolization Treatment of Cerebral Arteriovenous Malformations," *Radiology*, 97:65-70, 1970.

6. Ohta, T., et al., "Closure of Carotid-Cavernous Fistula with Polyethylene Foam Embolus," *Journal of Neurosurgery*, 38:107-112, 1973.

7. Black, R., et al., "Carotid-Cavernous Fistula: A Controlled Embolus Technique for Occlusion of Fistula with Preservation of Carotid Blood Flow," *Journal of Neurosurgery*, 38:113-118, 1973.

8. Alksne, J. F., and R. W. Smith, "Iron-Acrylic Compound for Stereotaxic Aneurysm Thrombosis," *Journal of Neurosurgery*, 47:137-141, 1977.

9. Alksne, J. F., "Stereotactic Thrombosis of Intracranial Aneurysms," *New England Journal of Medicine*, 284:171-174, 1971.

10. Alksne, J. F., "Current Status of Metallic Thrombosis of Intracranial Aneurysms," *Progress in Neurological Surgery*, 3:212-229, 1969.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5950 as follows:

§ 882.5950 Artificial embolization device.

(a) *Identification.* Artificial embolization devices are objects that are placed in a blood vessel to permanently obstruct blood flow to an aneurysm or other vascular malformation.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32960 Filed 11-27-78; 8:45 am]

[4110-03-M]

[21 CFR Part 882]

[Docket No. 78N-1105]

MEDICAL DEVICES

Classification of Skull Tongs for Traction

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying skull tongs for traction into class II (performance standards). The FDA is also publishing the recommendation of the Neurological Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 29, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Neurological Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of skull tongs for traction:

1. Identification: Skull tongs for traction is an instrument used to immobilize a patient with a cervical spine injury (e.g., fracture or dislocation). The device is caliper shaped with tips that penetrate the skin. It is anchored to the skull and has a heavy weight attached to it that maintains, by traction, the patient's position.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that skull tongs for traction be classified into class II (performance standards) because the pressure that the tong tips exert on the skull may injure the patient if the tong tips are not designed properly. The Panel believes that the design of these devices is particularly important because of the possible serious consequences to the patient should the device slip out or penetrate the skull. The Panel believes that general controls will not provide sufficient control of these characteristics. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on their clinical experience with this device. Skull tongs for traction have been used clinically for several decades.

5. Risks to health: (a) Infection: Because the tips of the skull tongs penetrate the skin and must be left in place for a long period of time, infection is an inherent risk. (b) Necrosis: The pressure of the tong tips may kill skull or scalp tissue. (c) Neurological injury or death: If the device collapses or pulls out of the skull a significant injury to the spinal cord or death may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that skull tongs for traction be classified into class II (performance standards). The Commissioner believes that a performance standard is neces-

sary for this device because general controls by themselves are not sufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 882 in Subpart F by adding new § 882.5960 as follows:

§ 882.5960 Skull tongs for traction.

(a) *Identification.* Skull tongs for traction is an instrument used to immobilize a patient with a cervical spine injury (e.g., fracture or dislocation). The device is caliper shaped with tips that penetrate the skin. It is anchored to the skull and has a heavy weight attached to it that maintains, by traction, the patient's position.

(b) *Classification.* Class II (performance standards). Interested persons may, on or before January 29, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated November 15, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-32961 Filed 11-27-78; 8:45 am]

federal register

TUESDAY, NOVEMBER 28, 1978
PART IV



DEPARTMENT OF ENERGY

Economic Regulatory Administration

■

CANADIAN ALLOCATION PROGRAM

Proposed Rulemaking and Public Hearing

[6450-01-M]

DEPARTMENT OF ENERGY

Economic Regulatory Administration

[10 CFR Part 214]

[Docket No. ERA-R-78-23]

CANADIAN ALLOCATION PROGRAM

Proposed Rulemaking and Public Hearing

AGENCY: Economic Regulatory Administration, Department of Energy.

ACTION: Notice of proposed rulemaking and public hearing.

SUMMARY: The Economic Regulatory Administration ("ERA") of the Department of Energy ("DOE") is proposing to amend the Canadian Allocation Program ("CAP") to reflect current conditions in the Northern Tier Petroleum supply situation and to simplify the administration of the program. Since the inception of the CAP in 1976, the export level of Canadian crude oil has declined from 510,000 barrels per day (B/D) in 1976 to approximately 180,300 B/D for the present allocation period, resulting in a reduction in the number of refineries receiving allocations from 59 in 1976 to 10 in the present period. In addition, a number of priority refineries have been successful in decreasing their dependence on Canadian crude oil. In view of these changes, we have tentatively determined that the CAP should be revised to provide us with greater flexibility to ensure that the declining export level of Canadian crude oil is allocated equitably among northern tier refineries that are least able to replace their Canadian feedstocks. The proposed amendments also would eliminate the reporting requirements for those refineries that are no longer receiving allocations under the program.

DATES:

COMMENTS BY: January 26, 1979.

HEARING: 9:30 a.m.; January 25, 1979.

REQUESTS TO SPEAK BY: January 8, 1979.

ADDRESSES:

COMMENTS TO:

Public Hearing Management, Docket No. ERA-R-78-23, Economic Regulatory Administration, 2000 M Street, N.W., Room 2313, Washington, D.C. 20461.

HEARING:

John C. Kluczynski Building, Room 3619, 230 S. Dearborn Street, Chicago, Illinois 60604.

REQUESTS TO SPEAK TO:

Public Hearing Management, Docket No. ERA-R-78-23, Economic Regulatory Administration, 2000 M Street, N.W., Room 2313, Washington, D.C. 20461.

FOR FURTHER INFORMATION CONTACT:

Robert G. Gillette (Comment Procedures), Department of Energy, 2000 M Street, N.W., Room 2214B, Washington, D.C. 20461, (202) 254-3345.

William Webb (Office of Public Information, Department of Energy, 2000 M Street, N.W. Room B-110, Washington, D.C. 20461, (202) 634-2170.

Robert G. Bidwell, Jr. (Office of Fuels Regulation), Economic Regulatory Administration, 2000 M Street, N.W., Room 6128-P Washington, D.C. 20461, (202) 254-9707.

Robert J. Kane (Regulations and Emergency Planning), Economic Regulatory Administration, 2000 M Street, NW., Room 2304, Washington, D.C. 20461, 202-254-7200.

Samuel M. Bradley (Office of General Counsel), Department of Energy, 12th and Pennsylvania Avenue, NW., Room 5138, Washington, D.C. 20461, 202-566-9565.

SUPPLEMENTARY INFORMATION:

I. Background:
A. Description of the Canadian Allocation Program.
B. Reasons for Reevaluation of the Program.
II. Proposed Amendments:
A. Definition of First Priority Refinery.
B. Adjustments to Base Period Volumes.
C. Allocation of Canadian Heavy Crude Oil.
D. Changes in Priority Designations.
E. Alternative Proposal to Establish Separate Classes of Priority Refineries for Canadian Light and Heavy Crude Oil.
F. Reporting Requirements.
III. Additional Comments Requested.
IV. Proposed Effective Date.
V. Comment Procedures.

I. BACKGROUND

A. DESCRIPTION OF CANADIAN ALLOCATION PROGRAM

The Mandatory Canadian Crude Oil Allocation Regulations (10 CFR Part 214) were adopted by the Federal Energy Administration ("FEA") in response to the Canadian National Energy Board's ("NEB's") decision in 1974 gradually to phase out exports of crude oil to the United States. The program was intended to give the refiners that are most dependent on Canadian crude oil additional time to arrange for alternative crude oil delivery systems. The current CAP regulations provide for the allocation of Canadian light and heavy crude oil separately to priority classes of refineries and other facilities for calendar quarter allocation periods.

The classes of firms dependent upon Canadian crude oil sources and thereby eligible for allocations are distinguished by their current capability to replace Canadian crude oil with crude oil from other sources. First priority refineries are those which processed Canadian crude oil that constituted at least 25 percent of their base period crude oil runs to stills and that possess no current capability of replacing that Canadian crude oil due to a demonstrated lack of access to domestic pipelines or port facilities with adequate marine docking and storage facilities. The first priority category also includes all industrial facilities or utilities with no replacement capability, without regard to the 25 percent test. Second priority refineries are those industrial facilities, utilities and refineries that used Canadian crude oil during the base period but were not designated first priority.

For each allocation period, the ERA issues a number of Canadian crude oil rights for light and heavy crude oil, respectively, based on the volume of such crude oils included in a refiner's runs to stills or otherwise used by the particular firm during the base period of November 1, 1974 through October 31, 1975. The ERA first allocates the Canadian light crude oil to first and second priority refineries according to their use of light crude oil in the base period, with the base period volumes of first priority refineries being satisfied before any light crude oil is allocated to second priority refineries.

Canadian heavy crude oil is allocated according to a six-step procedure. In the first two steps, the ERA allocates Canadian heavy crude oil on a pro-rata basis to first priority refineries up to their total base period volumes of Canadian crude oil, less allocations of Canadian light crude oil. In the third step, heavy crude oil is allocated on a pro-rata basis to second priority refineries which processed heavy crude oil in the base period up to their base period use of such crude oil. In the fourth step, additional heavy crude oil is allocated on a pro-rata basis to first priority refineries with reference to their nominations for such crude oil. Any remaining heavy crude oil is allocated among second priority refineries with reference to their total base period volumes of Canadian crude oil, less any Canadian light and/or heavy crude oil allocated in the prior steps.[1]

[1] As originally adopted on January 30, 1976, the CAP regulations did not distinguish between Canadian light and heavy crude oil (41 FR 4716, January 30, 1976). The regulations were amended in response to Canada's decision to license the light and heavy crude oil streams separately for export and to increase the export volume for the heavy crude oils and were intended to facilitate the importation into the U.S. of

Footnotes continued on next page

The regulations as originally adopted prohibited the disposition by first priority refineries of Canadian crude oil except pursuant to barrel-for-barrel exchanges for other Canadian crude oil. In early 1978, the exchange provision was amended to permit first priority refineries dependent upon the diminishing supply of Canadian light crude oil to develop alternate supply sources through exchanges of Canadian heavy crude oil for non-Canadian crude oil (43 FR 6206, February 14, 1978). Second priority refineries are not prohibited from exchanging Canadian crude oil for non-Canadian crude oil.

B. REASONS FOR REEVALUATION OF THE PROGRAM

We commenced our reevaluation of the CAP primarily because of the significant reductions in the export level of Canadian crude oil and the changes which have occurred in the crude oil supply situation of some priority refineries. Since the inception of the program in 1976, the export level of Canadian crude oil has declined from 510,000 B/D to approximately 180,300 B/D (comprised of 55,000 B/D of Canadian light crude oil and about 125,315 B/D of Canadian heavy crude oil) for the allocation period which began October 1, 1978.[2] As a result of the reduction in the export level of Canadian crude oil, especially Canadian light crude oil, and because a number of second priority refineries have been successful in replacing their Canadian feedstocks, the number of first and second priority refineries receiving allocations has declined from 59 in 1976 to 10 in the present allocation period. In this regard, in the last allocation period only one second priority refinery received an allocation, and that was due to an operational constraint. Similarly, the present allocation period has only three second priority refineries receiving allocations, and one of these was due to an operational constraint. First priority refineries also are receiving substantially smaller allocations of Canadian crude oil, particularly those refineries which historically processed Canadian light crude oil. Although two first priority refineries, Koch Refining Company's (Koch's) refinery at Pine Bend, Minnesota, and Ashland Oil, Inc.'s (Ashland's) refinery at St. Paul Park, Minnesota, now have greater access to non-Canadian crude oil than they did when the CAP was begun,[3] other first priority refineries remain substantially dependent upon Canadian crude oil.[4]

These changes in the petroleum supply situation in the Northern Tier have created several problems in the operation of the CAP. First, it appears that the definition of first priority refinery is no longer an accurate description of refineries that should be in that class, in that some refineries in the class, for example, the Koch and Ashland Minnesota refineries, now have considerable greater access to non-Canadian crude oil than other refineries in the class, in part for reasons not recognized in the definition. However, there may be uncertainty as to whether such refineries currently have the capability, especially at certain times of the year, to replace a sufficient percentage of their base period volume of Canadian crude oil to warrant changing their designation entirely to second priority refineries as defined in the current regulations.

The present provision governing adjustments to base period volumes does not provide sufficient flexibility to reduce allocations for priority refineries whose dependence on Canadian crude oil has decreased since the base period but who still qualify for first priority designation. Thus, although the regulations permit adjustments to a refinery's total base period volume of Canadian crude oil, they do not explicitly permit us to make separate adjustments to a refinery's base period volume of light or heavy crude oil, or to provide for automatic adjustments in a refinery's base period volume at certain times of the year to reflect seasonal changes in the refinery's access to non-Canadian crude oil. Nor do the regulations provide for automatic changes in a refinery's priority status to reflect seasonal changes in its access to non-Canadian crude oil. Such flexibility would be particularly appropriate with respect to the Koch and Ashland Minnesota refineries, which have the capability of receiving substantial shipments of non-Canadian crude oil by barge during the period April through October. In this regard, we have tentatively concluded that the present definition of first priority refinery should be revised to make clear that barging of crude oil on inland waterways is to be considered in determining a refinery's access to alternate sources of crude oil.

A second problem in the operation of the CAP is the reporting requirement in Subpart D of Part 214, which requires the large number of second priority refineries that no longer receive allocations of Canadian crude oil to continue reporting to us information regarding their crude oil supply situation. Third, as a result of the sharply declining export level of Canadian crude oil, a number of firms have urged us to restrict exchanges of Canadian crude oil to ensure that it is actually processed by those refineries which need it most. Finally, it appears that the present allocation procedures for Canadian heavy crude oil accord an undue preference to first priority refineries. As noted above, the first four steps of these procedures provide that Canadian heavy crude oil will be allocated to first priority refineries up to their nominations for such crude oil before any heavy crude oil is allocated to second priority refineries in excess of their base period use of Canadian heavy crude oil. Given the present export level for heavy crude oil, these procedures effectively ensure that no second priority refinery will receive an allocation in excess of its base period use of Canadian heavy crude oil.

II. PROPOSED AMENDMENTS

Set forth in this section is the substance of various proposals to amend the CAP regulations. We are requesting comments on whether these measures should be adopted, in light of current conditions in the Northern Tier. We may adopt one or more of these proposals, or any reasonable variation thereof that might be suggested by the comments or otherwise, which may be determined to be appropriate to accomplish the general objectives discussed above. In general, you are encouraged to provide your own analyses of the need for any revision to the CAP and the DOE proposals, and to support your views with appropriate data. you also are encouraged to recommend alternative approaches that would achieve the objectives of this rulemaking.

Footnotes continued from last page

the entire export level of Canadian heavy crude oil (42 FR 29295, June 8, 1977). When the export level of Canadian heavy crude oil began to decline, the allocation scheme for Canadian heavy crude oil was amended to accord a preference in the allocation of Canadian heavy crude oil to priority refineries that historically processed such crude oil. (43 FR 6206, February 14, 1978)

[2] This represents an increase over the 138,000 B/D for the July through September 1978 allocation period. In its *Crude Oil Supply and Requirements Report* released in September 1978 the NEB projected that light crude oil exports likely would remain at the 55,000 B/D level through 1981, while the export level for heavy crude oil would range about 107,000 to 117,000 B/D in 1979.

[3] In a notice of request for public comment (43 FR 13388, March 30, 1978) and at a public conference held May 31, 1978 (43 FR 20956, May 15, 1978), we announced that we were considering changing the priority designation of these refineries from first to second priority status. After consideration of all the comments, we determined that the evidence did not warrant reclassification of the Koch and Ashland refineries at that time.

[4] Consumers Power's Marysville, Michigan SNG facility; Continental Oil Company's Billings, Montana and Wrenshall, Minnesota refineries; Farmers Union's Laurel, Montana refinery; Exxon Company's Billings, Montana refinery; and Murphy Oil Corporation's Superior, Wisconsin refinery.

A. DEFINITION OF FIRST PRIORITY REFINERY

The first action proposed in this notice is an amendment to the definition of "first priority refinery" in § 214.21 to make clear that deliveries of non-Canadian crude oil by barge on inland waterways are to be considered in determining a refinery's access to alternative sources of crude oil. Although the access test in § 214.21 does not make express reference to such barge deliveries, we interpret the provision to require their consideration, since the underlying intent of the CAP regulations is to take account of all alternate sources of crude oil. However, in connection with the proceeding which we conducted concerning the reclassification of the Koch and Ashland Minnesota refineries to second priority status, Koch and Ashland contended that the definition of first priority refinery precludes consideration of barged crude oil. The proposed amendment would remove any ambiguity on this point.

B. ADJUSTMENTS TO BASE PERIOD VOLUMES

We are proposing to amend § 214.31(d) governing adjustments to base period volumes in several respects. First, for the reasons noted above, we are proposing to amend § 214.31(d) to permit us to adjust separately a refinery's base period volume of either Canadian light or heavy crude oil, as well as its total base period volume of Canadian crude oil as currently provided, to reflect changes in access to non-Canadian crude oil. In addition, § 214.31(d) would be modified to give us the flexibility to provide for automatic adjustments to a refinery's base period volume at certain times of the year to reflect seasonal variations in that refinery's access to non-Canadian crude oil. Although we do not propose specific regulatory language, we also invite comments on whether § 214.31(d) should be modified further to permit us to convert all or part of a refinery's base period volume of Canadian light crude oil to heavy crude oil in the event the refinery has converted light crude oil capacity existing in the base period to capacity for processing heavy crude oil.

We are also proposing to amend § 214.31(d) to provide that, in the event we reduced any first priority refinery's base period volume of Canadian light or heavy crude oil to reflect its access to non-Canadian crude oil, that refinery would be eligible for an allocation not only as a first priority refinery, to the extent of its adjusted base period volume, but also as a second priority refinery to the extent of the reduction in its based period volume. This proposal recognizes that although some first priority refineries, notably the Koch and Ashland Minnesota refineries, have the capability to replace a portion of their Canadian feedstocks with non-Canadian crude oil, some uncertainty exists as to whether such refineries currently have the capability to replace a sufficient volume of their base period use of Canadian crude oil to warrant changing their designation to second priority refineries.

The adjustments to base period volumes discussed above would be set forth in an allocation notice or in an appropriate order issued pursuant to Subpart G of 10 CFR Part 205 [Administrative Procedures and Sanctions]. The adjustments, which would be based on data reported to us pursuant to Subpart D of the CAP regulations and other information available to us, could be made effective at the beginning of or during an allocation period.

C. ALLOCATION OF CANADIAN HEAVY CRUDE OIL

For the reasons discussed above, we are proposing to amend the present procedures for allocating Canadian heavy crude oil to make the procedures more equitable for second priority refineries. Under the amendment, we would first issue rights for Canadian heavy crude oil on a pro rata basis to first priority refineries with reference to one-fourth of their respective base period volumes of such crude oil. In the second step, we would issue rights for Canadian heavy crude oil on a pro rata basis to all first priority refineries with reference to one-fourth of their respective total base period volumes of Canadian crude oil, less any rights issued in the prior steps for Canadian light and heavy crude oil. In the third and fourth steps, we would allocate Canadian heavy crude oil to second priority refineries in the same manner as in the first two steps for first priority refineries. We would allocate any remaining Canadian heavy crude oil on a pro rata basis to all first and second priority refineries with reference to their nominations. As is the case under the present procedures, in the event that the allocable supply of Canadian heavy crude oil exceeds the needs of first and second priority refineries, we would treat the surplus as outside the scope of the CAP.

D. CHANGES IN PRIORITY DESIGNATIONS

We are also proposing to amend § 214.34 to provide for automatic changes in the priority designation of any refinery to reflect seasonal changes in the refinery's access to non-Canadian crude oil. As in the case of base period volume adjustments, changes in priority designation would be based on data reported to us or other information available to the agency. Priority designation changes would be announced either in an allocation notice or an appropriate order and could be made effective at the beginning of or during an allocation period.

E. ALTERNATIVE PROPOSAL TO ESTABLISH SEPARATE CLASSES OF PRIORITY REFINERIES FOR CANADIAN LIGHT AND HEAVY CRUDE OIL

As an alternative to the proposed amendment to § 214.31(d) presented above providing for dual treatment of first priority refineries whose base period volumes are reduced, we are also soliciting comments on whether we should establish separate classes of priority refineries for the allocation of Canadian light and heavy crude oil, respectively. Under this alternative, for which we are not at this time proposing specific regulatory language but nevertheless could adopt as part of this rulemaking, a "first priority refinery" for the allocation of Canadian light crude oil would be defined as any refinery which (1) satisfies the present definition of first priority refinery, (2) processed Canadian light crude oil in the base period, and (3) is not capable of currently replacing 25 percent or more of the Canadian light crude oil that it processed in the base period with non-Canadian crude oil (other than through exchanges for Canadian crude oil) due to lack of access to non-Canadian crude oil delivered through a pipeline or over water by tanker or barge. Note that this 25 percent test is different from the 25 percent test in the present regulation, which provides that a first priority refinery is one whose crude oil runs to stills during the base period were constituted by at least 25 percent Canadian crude oil. "Second priority refinery" would be defined as any priority refinery other than a first priority refinery which processed Canadian light crude oil in the base period and which received an allocation of Canadian light crude oil in the period January 1, 1978 through December 31, 1978.

With respect to Canadian heavy crude oil, "first priority refinery" would be defined as any refinery which (1) satisfies the present definition of first priority refinery, (2) processed Canadian heavy crude oil in the base period, and (3) is not capable of currently replacing 25 percent of the volume of Canadian heavy crude oil that it processed in the base period. "Second priority refinery" would be defined as any refinery other than a first priority refinery which processed Canadian heavy crude oil in the base period and which received an allocation of Canadian heavy crude oil in the period January 1, 1978 through December 31, 1978.

This alternative proposal would retain the current allocation plan for Canadian light crude oil. However, Canadian heavy crude oil would be allocated in accordance with the proposed procedures set forth above.

The rationale for the 25 percent test in the alternative proposal is based on our conclusion that a current first priority refinery which can replace the specified percentage of either light or heavy crude oil is not sufficiently dependent upon the type of Canadian crude oil involved to require first priority status in order to avoid serious economic harm. The alternative proposal would effectively change the priority designation of the Koch and Ashland Minnesota refineries from first to second priority status in recognition of the fact that these refineries apparently have the capability to replace a significant volume of their Canadian feedstocks with non-Canadian crude oil delivered through the Williams Pipe Line Company pipeline and, from April through October each year, by barge on the Mississippi River. On the other hand, the alternative proposal recognizes that the remaining first priority refineries continue to be severely limited in their ability to replace their Canadian feedstocks. Further, this alternative would eliminate from the CAP the large number of second priority refineries that are no longer receiving allocations.

F. REPORTING REQUIREMENTS

The final action proposed in this notice is an amendment to Subpart D of the CAP regulations to eliminate the reporting requirements for second priority refineries which no longer receive allocations of Canadian crude oil. Apart from simplifying the administration of the CAP, this proposal will benefit a large number of second priority refineries which have not received allocations for some time.

II. Additional Comments Requested

On February 8, 1978 (43 FR 6206, February 14, 1978), we adopted an amendment to § 214.31(g) governing exchanges and sales of Canadian crude oil to permit first priority refineries dependent upon the diminishing supply of Canadian light crude oil to develop alternate supply sources of non-Canadian crude oil through exchanges of Canadian heavy crude oil. Inasmuch as none of the first priority refineries have used this provision, and given the recent decline in the export level of Canadian heavy crude oil, it is not clear whether the regulations should continue to permit such exchanges. In addition, given the overall decline in the export level of both Canadian light and heavy crude oil, it also is not clear whether the other types of exchanges permitted by § 214.31(g) continue to be of value. Accordingly, we are requesting specific comment on the following possible revisions to § 214.31(g):

a. Prohibit exchanges so that Canadian crude oil would be required to be processed in the refinery to which it is allocated.

b. Prohibit exchanges of Canadian for non-Canadian crude oil.

c. Permit first priority refineries to make exchanges of Canadian crude oil for other Canadian crude oil only, and prohibit exchanges by second priority refineries.

d. Permit first priority refineries to make exchanges as presently provided in the regulations and restrict second priority refineries to exchanges of Canadian crude oil for other Canadian crude oil only.

We also request comments on whether we should amend the procedures for allocating Canadian heavy crude oil to provide that such crude oil would be allocated only to priority refineries which have the capability of receiving and processing it. Such an amendment may be appropriate in the event we determine, on the basis of the comments in this proceeding, to amend § 214.31(g) to prohibit exchanges of Canadian crude oil for non-Canadian crude oil. In addition, a number of refiners have commented to us that it is inconsistent with the CAP's underlying rationale of allocating "wet barrels"—crude oil which can be processed in the recipient refinery—to allocate Canadian heavy crude oil to refineries which do not have the capability to process or receive it.

IV. Proposed Effective Date

We intend to issue final regulations with respect to any amendments adopted in this rulemaking in February and make them effective April 1, 1979.

V. Comment Procedures

A. WRITTEN COMMENTS

You are invited to participate in this proceeding by submitting data, views, or arguments with respect to the issues set forth in this Notice. Comments should be submitted to the address indicated at the beginning of this Notice and should be identified on the outside envelope with the designation "Revision of Canadian Allocation Program." Fifteen copies should be submitted. All comments that we receive will be available for public inspection in the DOE Freedom of Information Office, Room GA-152, Forrestal Building, 1000 Independence Avenue SW., between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday.

You should identify separately any information or data you consider to be confidential and submit it in writing, one copy only. We reserve the right to determine the confidential status of the information or data and to treat it according to our determination.

B. PUBLIC HEARING

1. *Procedure to request participation.* The time and place for the public hearing are indicated in the "HEARING" section of this Notice. If necessary to present all testimony, the public hearing will be continued to 9:30 a.m. of the first business day following the hearing date shown above.

You may make a written request for an opportunity to make an oral presentation at the hearing. The request should contain a phone number where you may be contacted through the day before the hearing. Since it may be necessary to limit the number of persons making such presentations, you should be prepared to describe your interest in this Proceeding, and why you are a proper representative of a group or class of persons that has such an interest, and to give a concise summary of your proposed oral presentation.

We will notify each person selected to be heard before 4:30 p.m., January 10, 1979. Persons scheduled to speak at the hearing must bring 50 copies of their statement to the location of the hearing on the day testimony is presented.

2. *Conduct of the hearing.* We reserve the right to limit the number of persons to be heard at the hearing if necessary in the interests of time, to schedule their respective presentations, and to establish the procedures governing the conduct of the hearing. The length of each presentation may be limited, based on the number of persons requesting to be heard.

An ERA official will be designated to preside at the hearing, which will not be a judicial or evidentiary-type hearing. Questions may be asked only by those officials conducting the hearing, and there will be no cross-examination of persons presenting statement. Each person who has made an oral statement will be given the opportunity, if he or she so desires, to make a rebuttal statement. The rebuttal statements will be given in the order in which the initial statements were made and will be subject to time limitations.

You may submit questions to be asked of any person making a statement at the hearing. Such questions must be submitted to the same address indicated above for requests to speak, three days before the hearing. In addition, if you decide at a hearing to ask a question, you may submit the question, in writing, to the presiding officer. We will determine whether the question is relevant and whether time limitations permit it to be presented for answer.

Any further procedural rules needed for the proper conduct of the hearing

will be announced by the presiding officer.

A transcript of the hearing will be made, and we will retain the entire record of the hearing, including the transcript, which will be made available for inspection at the DOE Freedom of Information Office, Room GA-152, Forrestal Building, 1000 Independence Avenue SW., Washington, D.C., between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday. You may purchase a copy of the transcript of the hearing from the reporter.

In the event that it becomes necessary for us to cancel the hearing, we will make every effort to publish advance notice in the FEDERAL REGISTER of such cancellation. Moreover, we will notify all persons scheduled to testify at the hearing. However, it is not possible to give actual notice of cancellations or schedule changes to persons not identified to us as participants. Accordingly, persons desiring to attend the hearing are advised to contact us on the last working day preceding the date of the hearing to confirm that it will be held as scheduled.

As required by section 7(a)(1) of the Federal Energy Administration Act of 1974, as amended, as copy of this Notice was submitted to the Administrator of the Environmental Protection Agency for his comments concerning the impact of this proposal on the quality of the environment. The Administrator had no comments.

Pursuant to the requirement of Section 404 of the Department of Energy Organization Act, upon issuance a copy of this proposed rule will be forwarded to the Federal Energy Regulatory Commission for a determination by it, in its discretion, whether this proposed rule may significantly affect any function within the Commission's jurisdiction pursuant to section 402 (a)(1), (b) and (c)(1) of that Act. The Commission will have until January 26, 1979, the date the public comment period closes, to make this determination.

Executive Order 12044 (43 FR 12661, March 24, 1978) requires that a regulatory analysis be prepared for all significant regulations which will result in "an annual effect on the economy of $100 million or more" or will result in "a major increase in costs or prices for individual industries, levels of government or geographic regions." On the basis of our analysis of the impact of the regulations proposed in this notice on the refineries in the CAP and the market areas they serve, we have determined that the proposed regulations could potentially result in the redistribution of only a small volume of Canadian crude oil among participants in the CAP and, accordingly, will not result in an annual effect on the economy of $100 million and will not result in a major increase in costs or prices for any such refinery or the market areas they serve. Accordingly, a regulatory analysis is not required for this proposed rulemaking.

(Emergency Petroleum Allocation Act of 1973, Pub. L. 93-159, as amended, Pub. L. 93-511, Pub. L. 94-99, Pub. L. 94-133, Pub. L. 94-163, and Pub. L. 94-385; Federal Energy Administration Act of 1974, Pub. L. 93-275, as amended, Pub. L. 94-332, Pub. L. 94-385, Pub. L. 95-70, and Pub. L. 95-91; Energy Policy and Conservation Act, Pub. L. 94-163, as amended, Pub. L. 94-385, and Pub. L. 95-70; Department of Energy Organization Act, Pub. L. 95-91; E.O. 1170, 39 FR 23185; E.O. 12009, 42 FR 46267.)

In consideration of the foregoing, Part 214 of Chapter II, Title 10 of the Code of Federal Regulations, is proposed to be amended as set forth below.

Issued in Washington, D.C., November 17, 1978.

HAZEL R. ROLLINS,
Deputy Administrator, Economic Regulatory Administration.

1. Section 214.1 is amended by revising paragraph (b) to read as follows:

§ 214.1 Scope.

* * * * *

(b) *Applicability.* This part applies to all Canadian crude oil imported after April 1, 1979, except for (1) crude oil authorized for export by the Canadian National Energy Board for the period ending March 31, 1979, that was not actually imported into the United States by that date, (2) Canadian crude oil the export of which is not a factor in the calculations for the maximum export levels fixed by Canada, and (3) Canadian crude oil which ERA determines pursuant to § 214.31(b) is not subject to this part.

2. Section 214.21 is amended by revising the definition of "First priority refinery" to read as follows:

§ 214.21 Definitions.

* * * * *

"First priority refinery" means (i) a refinery (A) of which the crude oil runs to stills in the base period includes at least a 25 percent volume of Canadian crude oil, and (B) of which the volume of Canadian crude oil constituting at least 25 percent by volume of that refinery's crude oil runs to stills in the base period is not capable of currently being replaced with crude oil from sources other than Canada, by reason of a lack of access to crude oil (other than Canadian crude oil) delivered either by means of pipelines with adequate current surplus capacity or through port or barge facilities with adequate docking and storage facilities; or (ii) a facility other than a refinery that consumed or otherwise utilized Canadian crude oil in the base period and where the volume of Canadian crude oil is not capable of currently being replaced with crude oil from sources other than Canada or with alternative fuels by reason of a lack of access to crude oil (other than Canadian crude oil) or alternative fuels delivered either by means of pipelines with adequate current surplus capacity or through port or barge facilities with adequate docking and storage facilities.

3. Section 214.31 is amended by revising subparagraph (3) of paragraph (a) and paragraph (d) to read as follows:

§ 214.31 Allocation of Canadian light and heavy crude oil.

(a) *Basis for issuance of Canadian crude oil rights.* * * *

(3) *Canadian crude oil rights for heavy crude oil.* (i) ERA shall first issue a number of rights for Canadian heavy crude oil for first priority refineries on a pro rata basis with reference to (but not to exceed) one-fourth of their respective base period volumes of Canadian heavy crude oil (as adjusted under the provisions of paragraphs (c) and (d) of this section).

(ii) In the event that the allocable supply of Canadian heavy crude oil for a particular allocation period is greater than the total number of rights calculated under subparagraph (3)(i) of this paragraph, ERA shall issue a number of rights for Canadian heavy crude oil for first priority refineries on a pro rata basis with reference to (but not to exceed) one-fourth of their respective total base period volumes of Canadian crude oil (as adjusted under the provisions of paragraphs (c) and (d) of this section), less the number of rights for Canadian light and/or heavy crude oil issued under subparagraphs (2) and (3)(i) of this paragraph.

(iii) In the event that the allocable supply of Canadian heavy crude oil for a particular allocation period is greater than the total number of rights calculated under subparagraphs (3) (i) and (ii) of this paragraph, ERA shall issue a number of rights for Canadian heavy crude oil for second priority refineries on a pro rata basis with reference to (but not to exceed) one-fourth of their respective base period volumes of Canadian heavy crude oil (as adjusted under the provisions of paragraphs (c) and (d) of this section).

(iv) In the event that the allocable supply of Canadian heavy crude oil for a particular allocation period is greater than the total number of rights calculated under subparagraphs (3) (i) through (iii) of this paragraph, ERA shall issue a number of rights for Canadian heavy crude oil for second pri-

ority refineries on a pro rata basis with reference to (but not to exceed) one-fourth of their respective total base period volumes of Canadian crude oil (as adjusted under the provisions of paragraphs (c) and (d) of this section), less the number of rights issued for Canadian light and/or heavy crude oil issued under subparagraphs (2) and (3)(iii) of this paragraph.

(v) In the event that the allocable supply of Canadian heavy crude oil for a particular allocation period is greater than the total number of rights calculated under subparagraph (3)(i) through (3)(iv) of this paragraph, ERA shall issue a number of additional rights for Canadian heavy crude oil for first and second priority refineries on a pro rata basis with reference to their respective nominations for Canadian heavy crude oil to ERA for that allocation period pursuant to paragraph (h) of this section.

* * * * *

(d) *Adjustments to base period volumes.* (1) Upon application filed with the ERA at least 45 days prior to the beginning of an allocation period, by a refiner or other firm that owns or controls a priority refinery, for purposes of issuances of Canadian crude oil rights under this subpart, the ERA may adjust that priority refinery's reported volume of Canadian light or heavy crude oil, or total volume of Canadian crude oil, included in its crude oil runs to stills or its volume of Canadian light or heavy crude oil, or total volume of Canadian crude oil, consumed or otherwise utilized in the base period to compensate for reductions in volume due to unusual or nonrecurring operating conditions (which shall not include routine shutdowns or turnarounds for normal maintenance or repairs).

(2) The ERA may at any time, for purposes of issuances of Canadian crude oil rights under this subpart and without application by the refiner or other firm concerned, adjust any base period volume referred to in subparagraph (1) of this paragraph if it determines that such volume is inaccurate or not representative of that refiner's or other firm's base period or current operating conditions, or to reflect any change in such priority refinery's access to crude oil from sources other than Canada. The ERA may provide that such adjustments to base period volumes shall become effective at specified times of the year to reflect seasonal changes in such priority refinery's access to crude oil from sources other than Canada.

(3) In the event that the ERA reduces any base period volume referred to in subparagraph (1) of this paragraph of any first priority refinery to reflect any change in such refinery's access to crude oil from sources other than Canada, such refinery will be eligible for an allocation under this section as a first priority refinery to the extent of its based period volume as so adjusted and as a second priority refinery to the extent of the reduction in its base period volume.

* * * * *

§ 214.34 [Amended]

4. Section 214.34 is amended by revising paragraph (a) to read as follows:

* * * * *

(a) *Supplemental affidavits and changes in initial designation.* Refiners and other firms that own or control priority refineries shall correct any errors contained in affidavits filed pursuant to Subpart D of this part by filing a supplemental affidavit pursuant to § 214.41(b). Affidavits shall be so supplemented to reflect any changes in the access of the refiner or other firm to alternative sources of crude oil. Based on information set forth in any such supplemental affidavit or in any affidavit filed after February 10, 1976, the ERA may change its initial priority designation as to a refinery or other facility, may provide for changes in the priority designation as to a refinery or other facility at specified times of the year to reflect seasonal changes in such refinery's or facility's access to alternative sources of crude oil, may determine that a particular refinery or other facility is no longer eligible to receive Canadian crude oil rights under this part, or may make an initial priority designation as to that refinery or other facility. Any such action taken by the ERA under this paragraph (a) may be based, in whole or in part, on information available to the ERA from sources other than the affidavits filed pursuant to Subpart D of this part.

§ 214.41 [Amended]

5. Section 214.41 is amended by revising paragraph (d) to read as follows:

* * * * *

(d) *Periodic reports.* (1) On or prior to the thirtieth day preceding each allocation period commencing after March 31, 1979, each refiner or other firm that owns or controls a refinery or other facility that is classified as a priority refinery and which received and allocation under this part for the preceding allocation period shall file with the ERA a report certifying, as to each such refinery or other facility, the estimated volume of Canadian crude oil not subject to this program and crude oil from sources other than Canada to be obtained by or for that refinery or other facility for that allocation period, with a specification as to the type of transaction or transactions involved in obtaining that crude oil.

(2) Within 30 days following the close of each allocation period, each refiner or other firm that owns or controls a priority refinery that received an allocation under this part for that allocation period shall file with the ERA a report certifying, as to each such refinery or other facility: (i) The actual volumes of Canadian crude oil and Canadian plant condensate included in the crude oil runs to stills of or consumed or otherwise utilized by each such priority refinery or other facility for the immediately preceding allocation period (specifying the portion thereof that was obtained through allocations under this program), and (ii) the actual volumes of crude oil from sources other than Canada included in the crude oil runs to stills of or consumed or otherwise utilized by each such priority refinery or other facility for the immediately preceding allocation period.

[FR Doc. 78-33194 Filed 11-22-78; 10:05 am]

Public Papers of the Presidents of the United States

Annual volumes containing the public messages and statements, news conferences, and other selected papers released by the White House.

Volumes for the following years are now available:

HERBERT HOOVER

1929	$13.30	1931	$14.00
1930	$16.60	1932–33	$17.25

HARRY S. TRUMAN

1945	$11.75	1949	$11.80
1946	$10.80	1950	$13.85
1947	$11.15	1951	$12.65
1948	$15.95	1952–53	$18.45

DWIGHT D. EISENHOWER

1953	$14.60	1957	$14.50
1954	$17.20	1958	$14.70
1955	$14.50	1959	$14.95
1956	$17.30	1960–61	$16.85

JOHN F. KENNEDY

1961	$14.35	1962	$15.55
		1963	$15.35

LYNDON B. JOHNSON

1963–64 (Book I)	$15.00	1966 (Book II)	$14.35
1963–64 (Book II)	$15.25	1967 (Book I)	$12.85
1965 (Book I)	$12.25	1967 (Book II)	$11.60
1965 (Book II)	$12.35	1968–69 (Book I)	$14.05
1966 (Book I)	$13.30	1968–69 (Book II)	$12.80

RICHARD NIXON

1969	$17.15	1972	$18.55
1970	$18.30	1973	$16.50
1971	$18.85	1974	$12.30

GERALD R. FORD

1974	$16.00	1975 (Book I)	$13.50
		1975 (Book II)	$13.75

JIMMY CARTER

1977 (Book I)	$16.00	1977 (Book II)	$15.25

Published by Office of the Federal Register, National Archives and Records Service, General Services Administration

Order from Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402