highlights

MOTOR GASOLINE ALLOCATION
DOE/ERA changes hearing dates and location on base rate period; location changed in Washington, D.C., for 3-27-79; rescheduled to 3-21, 3-22, and 3-23-79, requests to speak by 3-16-79, written comments by 3-30-79

CRUDE OIL ALLOCATION
DOE/ERA issues a supplemental buy/sell list for period 10-1-78 through 3-31-79

MEDICAL DEVICES
HEW/FDA establishes administrative detention procedures; effective 4-9-79 (Part IV of this issue)
HEW/FDA solicits comments regarding proposed rules on various devices; comments by 5-6-79 (144 documents) (Part IX of this Issue)

NEW DRUG APPLICATIONS
HEW/FDA withdraws approval of 43 applications; effective 3-20-79

ANIMAL DRUGS
HEW/FDA amends rules to provide for safe and effective use of anthelmintic tablets in certain treatments; effective 3-9-79
HEW/FDA revises nomenclature; effective 3-9-79
HEW/FDA revises labeling for certain anthelmintic capsules for dogs and cats; effective 3-9-79

HUMAN DRUGS
HEW/FDA reopens record on proposed over-the-counter antimicrobial drugs; comments by 6-7-79, reply comments by 7-9-79

GRAS SUBSTANCES
HEW/FDA announces opportunity for hearing on safety of certain ascorbates and copper salts; requests for hearing by 4-9-79

PIPERIDINE
Justice/DEA establishes interim reporting and purchaser identification requirements; effective 4-9-79

CHILD-RESISTANT PACKAGING
EPA reissues rule on special packaging in toxic pesticide containers; effective 3-9-79
CPSC amends rules to exempt certain amounts of methandrene; effective 3-9-79

EDUCATION CONTRACTS
Interior/BIA proposes to determine a formula for distribution of funds; comments by 5-7-79

ENVIRONMENTAL EDUCATION
HEW/OE proposes rules governing grants; comments by 4-23-79
**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.)

<table>
<thead>
<tr>
<th>Monday</th>
<th>Tuesday</th>
<th>Wednesday</th>
<th>Thursday</th>
<th>Friday</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOT/COAST GUARD</td>
<td>USDA/ASCS</td>
<td></td>
<td>DOT/COAST GUARD</td>
<td>USDA/ASCS</td>
</tr>
<tr>
<td>DOT/NHTSA</td>
<td>USDA/APHIS</td>
<td></td>
<td>DOT/NHTSA</td>
<td>USDA/APHIS</td>
</tr>
<tr>
<td>DOT/FAA</td>
<td>USDA/FNS</td>
<td></td>
<td>DOT/FAA</td>
<td>USDA/FNS</td>
</tr>
<tr>
<td>DOT/OHMO</td>
<td>USDA/FSQS</td>
<td></td>
<td>DOT/OHMO</td>
<td>USDA/FSQS</td>
</tr>
<tr>
<td>DOT/OPSO</td>
<td>USDA/REA</td>
<td></td>
<td>DOT/OPSO</td>
<td>USDA/REA</td>
</tr>
<tr>
<td>CSA</td>
<td>MSPB*/OPM*</td>
<td></td>
<td>CSA</td>
<td>MSPB*/OPM*</td>
</tr>
<tr>
<td></td>
<td>LABOR</td>
<td></td>
<td></td>
<td>LABOR</td>
</tr>
<tr>
<td></td>
<td>HEW/FDA</td>
<td></td>
<td></td>
<td>HEW/FDA</td>
</tr>
</tbody>
</table>

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 January 1, 1979, the Merit Systems Protection Board (MSPB) and the Office of Personnel Management (OPM) will publish on the Tuesday/Friday schedule. (MSPB and OPM are successor agencies to the Civil Service Commission.)

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. 600, as amended; 41 U.S.C., Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. 1). 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.*

**FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979**
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) ...................................................... 202-275-3054.  
"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.  
Photo copies of documents appearing in the Federal Register.  
Corrections .......................................................... 523-5237  
Public Inspection Desk ............. 523-5215  
Finding Aids .......................... 523-5227  
Public Briefings: "How To Use the Federal Register."  
Code of Federal Regulations (CFR)  
523-3419  
523-3517  
Finding Aids .......................... 523-5227

HIGHLIGHTS—Continued

DESEGREGATION OF PUBLIC EDUCATION  
HEW/OE announces closing date for applications for FY 1979; applications by 4-23-79 ......................................................... 13083

SEX DISCRIMINATION  
EEOC adopts interim interpretive guidelines; effective 3-9-79  
(Part VIII of this issue) ......................................................... 13278

VETERANS PREFERENCE  
Labor/ETA establishes FY 1979 levels for indicators of compliance; effective 4-4-79 (Part V of this issue) ......................................................... 13244

COMPREHENSIVE EMPLOYMENT AND TRAINING  
Labor/ETA proposes new rules and solicits comments regarding the Youth Program; comments by 4-9-79 (Part II of this issue) ......................................................... 13188

GENERATION-SKIPPING TRANSFER TAX  
Treasury/IRS announces hearing on proposed application of effective date provisions; hearing 4-10-79, outlines of oral comments by 3-27-79 ......................................................... 13043

LOANS BY CORRESPONDENT BANKS  
FRS, Treasury, and FDIC propose to prohibit corresponding account relationships, and require certain members of insured banks to file certain reports; comments by 4-20-79 ......................................................... 13035

BANK SERVICE ARRANGEMENTS  
FRS revokes Regulation S and revises Interpretations of Bank Service Corporation Act; effective 3-10-79 ......................................................... 12968

PRESIDENTIAL PAPERS:  
Executive Orders and Proclama- 
tions. .......................................................... 523-5233

Weekly Compilation of Presidential Documents.  
Public Papers of the Presidents ......... 523-5235

Index .......................................................... 523-5235

PUBLIC LAWS:  
Public Law numbers and dates ...... 523-5266

Slip Law orders (GPO) .................. 523-5282

U.S. Statutes at Large ................. 275-3030

Index .......................................................... 523-5282

U.S. Government Manual .......... 523-5282

Automation ........................................ 523-3408

Special Projects ........................ 523-4534

BANKS LOANS  
FRS amends rules governing loans to executive officers, directors or principal shareholders of the member bank; effective 3-10-79; comments by 5-9-79 ......................................................... 13035

RELOCATION BENEFITS  
Navajo and Hopi Indian Relocation Commission revises rules regarding eligibility requirements; effective 3-9-79 ......................................................... 13007

VOLUNTARY FEDERAL MEAT GRADING SERVICES  
USDA/FSQS changes rules to reflect decrease in hourly fees; effective 3-25-79 ......................................................... 12953

MINIATURE CHRISTMAS TREE LIGHTS  
CPSC extends time when it must publish final safety standards ......................................................... 13040

CHARTER PACKAGES  
CAB establishes consumer protection for charter participants, and simplifies filing procedures ......................................................... 12971

LABORATORY ACCREDITATION  
Commerce announces optional procedures for Federal agencies to utilize the National Voluntary Laboratory Accreditation Program; effective 3-9-79 ......................................................... 12982

HEALTH RESEARCH  
HEW/PHS eliminates conflicts in administrative policies and extends applicability to certain projects; effective 4-9-79 ......................................................... 13025
CHILD ABUSE AND NEGLECT
HEW/HDSO solicits comments on proposed fiscal year 1979/80 Research, Demonstration and Service Improvement priorities; comments by 5-8-79 (Part VI of this issue) ........................................ 13254

FEDERAL ACQUISITION REGULATION PROJECT
OMB/FFPO makes available segments of draft rules and requests comment; comments by 5-3-79 ......................................................... 13053

UNIFORM SYSTEM OF ACCOUNTS FOR TELEPHONE COMPANIES
FCC establishes a service list to be used in future rounds of comment in proceedings ............................................................... 13051

PUBLIC TELECOMMUNICATIONS FINANCING
Commerce/NTIA seeks comments on proposals governing administration of grants; comments by 4-12-79 (Part VII of this issue) .................................................. 13262

MEETINGS
Commerce/ITA: Exporters’ Textile Advisory Committee, 4-18-79 ............................................................ 13058
NOAA: Gulf of Mexico and South Atlantic Fishery Management Councils, Advisory Subpanels on corals, 3-29-79 ................................................................. 13059
Mid-Atlantic Fishery Management Council, 4-11 through 4-13-79 .................................................................................. 13059
New England Fishery Management Council, 3-23-79 ........................................................... 13059
CPSC: Product Safety Advisory Council, 3-26 and 3-27-79 ........................................................................... 13061
CRC: Indiana Advisory Committee (SAC), 4-2-79 .......................................................... 13058
Nebraska Advisory Committee (SAC), 3-31-79 .............................................................................. 13058
New Jersey Advisory Committee (SAC), 4-23-79 ........................................................................ 13058
Vermont Advisory Committee (SAC), 4-5-79 .............................................................................. 13058
Wisconsin Advisory Committee (SAC), 4-2-79 .............................................................................. 13058
DOE: National Petroleum Council, Committee on Materials and Manpower Requirements, one subcommittee and two task groups, March 1979 ........................................ 13062

HEW/CE: Advisory Council on Developing Institutions, 3-26 and 3-27-79 .............................................................................. 13083
Justice: Bureau of Prisons, National Institute of Corrections Advisory Board, 3-25-79 ............................................................ 13088
Labor/OSHA: National Advisory Committee on Occupational Safety and Health, 4-2-79, and a Subgroup on 3-15 and 3-16-79 .............................................................................. 13091
NSF: Advisory Committee for Environmental Biology, Executive Committee, 3-26 and 3-27-79 .................................................. 13096
VA: Structural Safety of Veterans Administration Facilities Advisory Committee, 4-6-79 ............................................................... 13098

CHANGED MEETINGS
HEW/NIE: Panel for the Review of Laboratory and Center Operations, 3-17 and 3-18-79 .............................................................................. 13082
NSF: Advisory Committee for Engineering, Subcommittee on Engineering Chemistry and Energetics, 3-19 and 3-20-79, room change ........................................ 13096

CANCELLED MEETING
HEW/FDA: Fertility and Maternal Health Drugs Advisory Committee, 3-16-79 .............................................................................. 13079

POSTPONED HEARING
Office of the Special Representative for Trade Negotiations: Tanner’s Council of America 301 Committee, 3-13 and 3-14-79, indefinitely postponed ........................................ 13097

SUNSHINE ACT MEETINGS .................................................................. 13123

SEPARATE PARTS OF THIS ISSUE
Part II, Labor/ETA .............................................................................. 13188
Part III, Labor/ESA .............................................................................. 13205
Part IV, HSW/FDA .............................................................................. 13234
Part V, Labor/ETA .............................................................................. 13244
Part VI, HEW/HDSO .............................................................................. 13254
Part VII, Commerce/NTIA ........................................................................ 13262
Part VIII, EEOC .............................................................................. 13278
Part IX, HEW/FDA .............................................................................. 13284
CONTENTS

HEALTH, EDUCATION, AND WELFARE DEPARTMENT

See also Education Office; Food and Drug Administration; Human Development Services Office; National Institutes of Health; Public Health Service.

Rules

Heating examiners; Supplemental Security Income; CPP part removed  13028

HEARING AND APPEALS OFFICE, ENERGY DEPARTMENT

Hearings

Puerto Rico; refining and petrochemical industry report; hearing  13068

HOUSING AND URBAN DEVELOPMENT DEPARTMENT

See Federal Insurance Administration.

HUMAN DEVELOPMENT SERVICES OFFICE

See also.

CHILD WELFARE

Meetings;

Advisory committees review; inquiry  13054

INDIAN AFFAIRS BUREAU

Proposed Rules

Indian self-determination and education assistance programs;

Funds; Supplemental; distribution formula  13042

Rules

Financial assistance or social services;

Near reservation locations; designations  13084

INDUSTRY AND TRADE ADMINISTRATION

See also.

COMMISSION ON INDUSTRY AND TRADE

Meetings;

Exporters’ Textile Advisory Committee  13058

INTERIOR DEPARTMENT

See Fish and Wildlife Service; Indian Affairs Bureau; Land Management Bureau; National Park Service.

INTERNAL REVENUE SERVICE

Proposed Rules

Estate and gift taxes;

Generation-skipping transfer tax; hearing  13043

INTERSTATE COMMERCE COMMISSION

Rules

Freedom of information  13029

Practice Rules;

Rail service continuation subsidies standards; denial of request to reopen rulemaking  13030

LAND MANAGEMENT BUREAU

Rules

Alaska native selections; applications, etc.; Ekwok Natives Ltd  13085

APPLICATIONS, etc.

New Mexico  13087

Motor vehicles, off-road, etc.; area closures; Oregon  13084

MANAGEMENT AND BUDGET OFFICE

See Federal Procurement Policy Office.

MINE SAFETY AND HEALTH ADMINISTRATION

Notices

Petitions for mandatory safety standard modification;

CLIMAX MOLYBDENUM CO  13091

Kanawha Coal Co  13091

NATIONAL INSTITUTE OF EDUCATION

Meetings;

Panel for the Review of Laboratory and Center Operations; correction  13082

NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION

Rules

Marine mammal permit applications, etc.;

Norris, Dr. Kenneth S.  13059

Northwest Fisheries Center  13060

Meetings;

Gulf of Mexico and South Atlantic Fishery Management Councils  13059

Mid-Atlantic Fishery Management Council  13059

New England Fishery Management Council  13059

NATIONAL PARK SERVICE

Rules

Snowmobile; management policy; inquiry; extension of time  13084

NATIONAL SCIENCE FOUNDATION

Rules

Advisory committees review; inquiry  13097

Meetings;

Engineering Advisory Committee  13096

Environmental Biology Advisory Committee  13096

NATIONAL TELECOMMUNICATIONS AND INFORMATION ADMINISTRATION

Rules

Public telecommunications facilities program; construction and planning grants  13282

NAVAJO AND HOPI INDIAN RELOCATION COMMISSION

Rules

Commission operations and relocation procedures; eligibility for benefits  13007

NUCLEAR REGULATORY COMMISSION

Rules

Advisory committee review; inquiry  13097

Meetings; Sunshine Act (2 documents)  13124

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979

vii
Occupational Safety and Health Administration

Rules
State plans for enforcement of standards:
South Carolina ........................................ 13013

Notices
Meetings:
Occupational Safety and Health National Advisory Committee ........................................ 13091
State plans; development, enforcement, etc.:
Utah .......................................................... 13092

Patent and Trademark Office

Notices
Closure of office on February 20, 1979, due to heavy snow; definition as “holiday” .......... 13060

Postal Rate Commission

Notices
Meetings; Sunshine Act ......................... 13125

Postal Service

Rules
Practice rules and procedures:
Small claims—optional; expedited and accelerated procedures and rules for subpoe-

nae ..................................................... 13013

Prisons Bureau

Notices
Meetings:
Corrections Advisory Board National Institute .................................................. 13088

Public Health Service

Rules
Grants:
Research projects; applicability, etc .......................................................... 13025

Securities and Exchange Commission

Notices
Meetings; Sunshine Act ......................... 13125

Soil Conservation Service

Notices
Environmental statements; availability, etc.:
Crooked Lake Bayou Watershed, Ark ................................................... 13056
Garrett Bridge Watershed, Ark .......................................................... 13056
Rameur Public Watershed-Based Recreation RC&D Measure, N.C ...................... 13057
Richland Creek Watershed Project, S. Dak .............................................. 13056
Tri-County Turkey Creek Watershed, Okla .................................................. 13057
Upper Little Minnesota River Watershed Project, S. Dak ................................ 13057

Southwestern Power Administration

Notices
Power rates order; increase; con-
formation and approval on inter-
term basis .................................................. 13088

Trade Negotiations, Office of Special Representative

Notices
Unfair trade practices, petitions:
Japan; quotas and increased duties of products; hearings postponement .............. 13097

Transportation Department

See Federal Highway Administration; Federal Railroad Administration.

Treasury Department

See Internal Revenue Service.

Uniformed Services University of the Health Sciences

Notices
Meetings; Sunshine Act ......................... 13125

Veterans Administration

Notices
Meetings:
Structural Safety of Veterans Administration Facilities Advisory Committee ........ 13098

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

EPA—Regulations for the enforcement of the Federal Insecticide, Fungicide and Ro- donecide Act; Registration, re-registration and classification procedures .... 7958; 2-7-79
State implementation plans: California (2 documents) .................... 7711; 7713; 2-7-79
FCC—New or revised classes of interstate and foreign message toll telephone service (MTS) and wide area telephone service (WATS); specifying standards, plugs, and jacks for the connection of telephone equipment to the Nationwide Telephone Network; specifying standards for and means of connection of telephone equipment to lamp and/or annunciator functions of systems ........................................ 7955; 2-6-79
SEC—Micrographic conversion program; filing of documents; formal requirements .... 4685; 1-23-79

Rules Going Into Effect March 10, 1979

DOT/CG—Sheboygan River, Wis., drawbridge operation regulations ........................................ 7951; 2-8-79
FDIC—Change in bank control and delegations of authority; filing of advance notice and compliance with procedures ........................................ 7122; 2-6-79
DOT/CG—Wappinger Creek, N.Y., drawbridge operation regulations ........................................ 7850; 2-8-79
FHLLB—Amendments relating to the change in Savings and Loan Control Act of 1978 .................................................. 10500; 2-21-79
ERS—Change in bank control; filing of advance notice and compliance with procedures ........................................ 7120; 2-6-79
Treasury/Comptroller—Change in bank control; filing of advance notice and compliance with procedures ........................................ 7118; 2-6-79

List of Public Laws

This is a continuing listing of public bills from the current session of Congress which have become Federal laws. The text of laws is not published in the Federal Register but may be ordered in individual pamphlet form (referred to as “slip laws”) from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 (telephone 202-375-3030).

(Last Listing Jan. 24, 1979)

H.R. 1902 ......................... Pub. L. 96-2

S. 37 .............................. Pub. L. 96-3
To repeal a section of Public Law 95-630. (Mar. 7, 1979; 93 Stat. 5) Price $60.
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.

<table>
<thead>
<tr>
<th>CFR</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 CFR</td>
<td>1062              13033</td>
</tr>
<tr>
<td>9 CFR</td>
<td>82               12957</td>
</tr>
<tr>
<td>10 CFR</td>
<td>211              12959</td>
</tr>
<tr>
<td>12 CFR</td>
<td>215              12959</td>
</tr>
<tr>
<td>14 CFR</td>
<td>360              12971</td>
</tr>
<tr>
<td>15 CFR</td>
<td>2001             13262</td>
</tr>
<tr>
<td>16 CFR</td>
<td>1700             12990</td>
</tr>
<tr>
<td>20 CFR</td>
<td>1200             13040</td>
</tr>
<tr>
<td>653</td>
<td>660              13244</td>
</tr>
<tr>
<td></td>
<td>Proposed Rules: 13188</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>21 CFR</th>
<th>Proposed Rules: 13234</th>
</tr>
</thead>
<tbody>
<tr>
<td>16</td>
<td>13234</td>
</tr>
<tr>
<td>184</td>
<td>12991</td>
</tr>
<tr>
<td>520</td>
<td>12991, 12992</td>
</tr>
<tr>
<td>522</td>
<td>12992</td>
</tr>
<tr>
<td>1224</td>
<td>12993</td>
</tr>
<tr>
<td>870</td>
<td>13041</td>
</tr>
<tr>
<td>771</td>
<td>12995</td>
</tr>
<tr>
<td>23</td>
<td>12995</td>
</tr>
<tr>
<td>24</td>
<td>12995</td>
</tr>
<tr>
<td>1915</td>
<td>12995</td>
</tr>
<tr>
<td>1917</td>
<td>12995</td>
</tr>
<tr>
<td>25</td>
<td>12996-13006</td>
</tr>
<tr>
<td>26</td>
<td>13007</td>
</tr>
<tr>
<td>278</td>
<td>13042</td>
</tr>
<tr>
<td>26</td>
<td>13043</td>
</tr>
<tr>
<td>29</td>
<td>13008</td>
</tr>
<tr>
<td>1404</td>
<td>13008</td>
</tr>
<tr>
<td>1604</td>
<td>13278</td>
</tr>
<tr>
<td>1652</td>
<td>13013</td>
</tr>
<tr>
<td>39</td>
<td>13013</td>
</tr>
<tr>
<td>955</td>
<td>13013</td>
</tr>
<tr>
<td>40</td>
<td>13019</td>
</tr>
<tr>
<td>65</td>
<td>13015-13018</td>
</tr>
<tr>
<td></td>
<td>162                 13019</td>
</tr>
</tbody>
</table>

40 CFR—Continued

<table>
<thead>
<tr>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>56              13043</td>
</tr>
<tr>
<td>41 CFR</td>
</tr>
<tr>
<td>Ch. 101         13024</td>
</tr>
<tr>
<td>42 CFR</td>
</tr>
<tr>
<td>52              13025</td>
</tr>
<tr>
<td>45 CFR</td>
</tr>
<tr>
<td>25              13028</td>
</tr>
<tr>
<td>47 CFR</td>
</tr>
<tr>
<td>Proposed Rules:</td>
</tr>
<tr>
<td>161h            13048</td>
</tr>
</tbody>
</table>

48 CFR

<table>
<thead>
<tr>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>31              13051</td>
</tr>
<tr>
<td>43              13051</td>
</tr>
<tr>
<td>49 CFR</td>
</tr>
<tr>
<td>211             13028</td>
</tr>
<tr>
<td>1001            13029</td>
</tr>
<tr>
<td>1013            13030</td>
</tr>
<tr>
<td>1125            13030</td>
</tr>
<tr>
<td>50 CFR</td>
</tr>
<tr>
<td>26              13031</td>
</tr>
</tbody>
</table>

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
CUMULATIVE LIST OF CFR PARTS AFFECTED DURING MARCH

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 March.

<table>
<thead>
<tr>
<th>CFR</th>
<th>Proposed Rules:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ch. I: 38, 475, 928, 937, 2123, 2129, 600, 1022</td>
</tr>
<tr>
<td>2</td>
<td>Ch. II: 11517, 12155, 12198</td>
</tr>
<tr>
<td>3</td>
<td>Ch. III: 11517, 12155, 12198</td>
</tr>
<tr>
<td>4</td>
<td>Ch. IV: 35, 205, 210, 211, 212, 475, 500, 501, 502, 503, 505</td>
</tr>
<tr>
<td>5</td>
<td>Ch. V: 215, 219, 225, 228, 250, 252, 701</td>
</tr>
<tr>
<td>6</td>
<td>Ch. VI: 11517, 12155, 12198</td>
</tr>
<tr>
<td>7</td>
<td>Ch. VII: 215, 304, 349, 701, 720</td>
</tr>
<tr>
<td>8</td>
<td>Ch. VIII: 11517, 12155, 12198</td>
</tr>
<tr>
<td>9</td>
<td>Ch. IX: 210, 108, 121</td>
</tr>
<tr>
<td>10</td>
<td>Ch. X: 39, 11528-12024, 12026-12034, 12635-12637</td>
</tr>
<tr>
<td>11</td>
<td>Ch. XI: 71, 11530-11534, 12026-12034, 12635-12637</td>
</tr>
<tr>
<td>12</td>
<td>Ch. XII: 73, 11536, 12640</td>
</tr>
<tr>
<td>13</td>
<td>Ch. XIII: 97, 11536, 12640</td>
</tr>
<tr>
<td>14</td>
<td>Ch. XIV: 380, 12971</td>
</tr>
<tr>
<td>15</td>
<td>Ch. XV: 1, 210, 12042, 12044, 12045, 12855, 12859, 12861, 12865, 12866, 12868, 12869</td>
</tr>
<tr>
<td>16</td>
<td>Ch. XVI: 6, 11555, 12042, 12044, 12045, 12855, 12859, 12861, 12865, 12866, 12868, 12869</td>
</tr>
<tr>
<td>17</td>
<td>Ch. XVII: 73, 11555, 12042, 12044, 12045, 12855, 12859, 12861, 12865, 12866, 12868, 12869</td>
</tr>
<tr>
<td>18</td>
<td>Ch. XVIII: 73, 11555, 12042, 12044, 12045, 12855, 12859, 12861, 12865, 12866, 12868, 12869</td>
</tr>
<tr>
<td>19</td>
<td>Ch. XIX: 73, 11555, 12042, 12044, 12045, 12855, 12859, 12861, 12865, 12866, 12868, 12869</td>
</tr>
<tr>
<td>20</td>
<td>Ch. XX: 73, 11555, 12042, 12044, 12045, 12855, 12859, 12861, 12865, 12866, 12868, 12869</td>
</tr>
</tbody>
</table>

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
### FEDERAL REGISTER

#### 47 CFR—Continued

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ch. I.</td>
<td>12466</td>
<td>211</td>
</tr>
<tr>
<td>31</td>
<td>13051</td>
<td>230</td>
</tr>
<tr>
<td>33</td>
<td>13051</td>
<td>531</td>
</tr>
<tr>
<td>42</td>
<td>13051</td>
<td>571</td>
</tr>
<tr>
<td>43</td>
<td>13051</td>
<td>573</td>
</tr>
<tr>
<td>94</td>
<td>12220, 12221</td>
<td>1001</td>
</tr>
<tr>
<td>97</td>
<td>12273</td>
<td>1011</td>
</tr>
<tr>
<td>73</td>
<td>11568</td>
<td>1033</td>
</tr>
</tbody>
</table>

#### 48 CFR

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ch. I.</td>
<td>12225</td>
<td>177</td>
</tr>
<tr>
<td>3</td>
<td>13053</td>
<td>178</td>
</tr>
<tr>
<td>4</td>
<td>13053</td>
<td>179</td>
</tr>
<tr>
<td>5</td>
<td>13053</td>
<td>191</td>
</tr>
<tr>
<td>20</td>
<td>13053</td>
<td>395</td>
</tr>
<tr>
<td>25</td>
<td>13053</td>
<td>571</td>
</tr>
<tr>
<td>28</td>
<td>13053</td>
<td>581</td>
</tr>
<tr>
<td>33</td>
<td>13053</td>
<td>1082</td>
</tr>
<tr>
<td>34</td>
<td>13053</td>
<td>1351</td>
</tr>
</tbody>
</table>

#### 50 CFR

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>26</td>
<td>13031</td>
<td>13801-12063</td>
</tr>
<tr>
<td>33</td>
<td>12031</td>
<td>12826</td>
</tr>
<tr>
<td>Ch. II</td>
<td>12562</td>
<td>12562</td>
</tr>
<tr>
<td>Ch. VI</td>
<td>12562</td>
<td>12562</td>
</tr>
<tr>
<td>17</td>
<td>12382, 12386, 12390</td>
<td>12382</td>
</tr>
<tr>
<td>651</td>
<td>11571</td>
<td>11571</td>
</tr>
</tbody>
</table>

### FEDERAL REGISTER PAGES AND DATES—MARCH

<table>
<thead>
<tr>
<th>Pages</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>11517-11727</td>
<td>Mar. 1</td>
</tr>
<tr>
<td>11729-12015</td>
<td>2</td>
</tr>
<tr>
<td>12017-12149</td>
<td>5</td>
</tr>
<tr>
<td>12151-12397</td>
<td>6</td>
</tr>
<tr>
<td>12399-12599</td>
<td>7</td>
</tr>
<tr>
<td>12601-12951</td>
<td>8</td>
</tr>
<tr>
<td>12953-13494</td>
<td>9</td>
</tr>
</tbody>
</table>
Arizona lemons that may be shipped under the
provided, will tend to effectuate the
tive Committee, and upon other infor-
U.S.C. 601-674),
in California and Arizona, effective
ulating th6 handling of lemons grown
910,
Findings.
CONTACT:
FOR FURTHER INFORMATION
EFFECTIVE
industry.
marketing situation confronting the lemon
lemons for this period due to the mar-
SUMMARY: This regulation estab-
handling during the period March
1979, to consider supply and market
3-17, 1979. Such action is needed to pro-
ordinate marketing of fresh
chapter IX—AGRICULTURAL MARKETING SERVICE (MARKETING AGREEMENTS AND ORDERS; FRUITS, VEGETABLES, NUTS), DEPARTMENT OF AGRICULTURE
PART 910—LEMONS GROWN IN CALIFORNIA AND ARIZONA
Limitation of Handling
AGENCY: Agricultural Marketing Service, USDA.
ACTION: Final rule.
SUMMARY: This regulation establishes the quantity of fresh California-Arizona lemons that may be shipped to market during the period March 11-17, 1979. Such action is needed to provide for orderly marketing of fresh lemons for this period due to the marketing situation confronting the lemon industry.
EFFECTIVE DATE: March 11, 1979.
FOR FURTHER INFORMATION CONTACT:
SUPPLEMENTARY INFORMATION: Findings. Pursuant to the marketing agreement, as amended, and Order No. 910, as amended (7 CFR Part 910), regulating the handling of lemons grown in California and Arizona, effective under the Agricultural Marketing Agreement-Act of 1937, as amended (7 U.S.C. 601-874), and upon the basis of the recommendations and information submitted by the Lemon Administrative Committee, and upon other information, it is found that the limitation of handling of lemons, as hereafter provided, will tend to effectuate the declared policy of the act. This regulation has not been determined significant under the USDA criteria for implementing Executive Order 12044.
The committee met on March 6, 1979, to consider supply and market conditions and other factors affecting the need for regulation and recommended a quantity of lemons deemed advisable to be handled during the
specified week. The committee reports the demand for lemons has improved. It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 30 days after publication in the Federal Register (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this regulation is based and the effective date necessary to effectuate the declared policy of the act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting. It is necessary to effectuate the declared purposes of the act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.
§ 910.489 Lemon Regulation 189.
Order. (a) The quantity of lemons grown in California and Arizona which may be handled during the period March 11, 1979, through March 17, 1979, is established at 240,000 cartons.
(b) As used in this section, “handled” and “carton(s)” mean the same as defined in the marketing order.
(See 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-874.)

CHARLES R. BRADER,
Acting Director, Fruit and Vegetable Division, Agricultural Marketing Service.
(202) 447-6393

SUPPLEMENTARY INFORMATION: In June 1977, the base hourly fee rate was increased from $17 to $19 primarily due to projected costs associated with travel time provisions of the Fair Labor Standards Act. The $2 per hour increase was an interim measure to cover projected grader travel costs for transportation of meat grading equipment from residence to worksite and return until alternate procedures could be implemented to minimize or eliminate these costs. Since that increase, procedures have been implemented which permit in-plant storage of equipment in most grading locations, thereby substantially reducing FLSA travel costs. Consequently, a large portion of that fee increase is no longer required.

A second major factor is the planned substantial increase in the number of technical employees. This increase is necessitated by the transfer of responsibility to the USDA for the certification of all meat and meat items procured by the Department of Defense. This expansion will result in an increase in the estimated number of revenue hours over those of FY 1978. The relationship between the projected increase in the number of revenue hours and the average salary of employees further contributes to the reduction in the hourly fee rate. In recent years, the average grade level of meat grading employees has been approximately GS-9/6 with a current annual salary.

CHAPTER XXVII—FOOD SAFETY AND QUALITY SERVICE, DEPARTMENT OF AGRICULTURE
SUBCHAPTER C—REGULATIONS AND STANDARDS UNDER THE AGRICULTURAL MARKETING ACT OF 1946.
PART 2853—MEATS, PREPARED MEATS AND MEAT PRODUCTS (GRADING, CERTIFICATION AND STANDARDS)
Subpart A—Regulations, Fees and Charges
AGENCY: Food Safety and Quality Service, USDA.
ACTION: Final rule.
SUMMARY: These regulations are being changed to reflect a decrease in the hourly fees charged for voluntary Federal meat grading services. Even though provisional Pub. L. 97-210 has resulted in a 5.5 percent pay increase for Federal employees for FY 1978, this pay increase is more than offset by the combined effects of (1) reduced travel costs and (2) lower ratio of salary cost per hour of revenue.
EFFECTIVE DATE: March 25, 1979.
FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION: In June 1977, the base hourly fee rate was increased from $17 to $19 primarily due to projected costs associated with travel time provisions of the Fair Labor Standards Act. The $2 per hour increase was an interim measure to cover projected grader travel costs for transportation of meat grading equipment from residence to worksite and return until alternate procedures could be implemented to minimize or eliminate these costs. Since that increase, procedures have been implemented which permit in-plant storage of equipment in most grading locations, thereby substantially reducing FLSA travel costs. Consequently, a large portion of that fee increase is no longer required.

A second major factor is the planned substantial increase in the number of technical employees. This increase is necessitated by the transfer of responsibility to the USDA for the certification of all meat and meat items procured by the Department of Defense. This expansion will result in an increase in the estimated number of revenue hours over those of FY 1978. The relationship between the projected increase in the number of revenue hours and the average salary of employees further contributes to the reduction in the hourly fee rate. In recent years, the average grade level of meat grading employees has been approximately GS-9/6 with a current annual salary.
of $18,575. With an increase in staff planned for FY 1979—primarily trainee and nonjourneymen level graders at the GS-5 and GS-7 levels—the average grade level will be reduced. This reduction in the average grade level has the effect of slightly lowering that portion of the hourly fee required to recover grader salary costs, thereby resulting in lower costs per hour of revenue earned.

Accordingly, 7 CFR 2853.27(a) prescribing fees for Federal meat grading service is hereby amended by changing the phrases “$20.00 per hour,” “$24.00 per hour,” and “$40.00 per hour” to “$18.20 per hour,” “$22.20 per hour,” and “$36.40 per hour” respectively.

Since these amendments reflect a decrease in the hourly fees charged for voluntary Federal meat grading service, Donald L. Houston, Acting Administrator, has determined that the benefits to be derived therefrom should be effected immediately.

Further, these amendments have not been designated “significant” and this final rulemaking is being published under emergency procedures as authorized by Executive Order 12044 and Secretary's Memorandum 1955. It has been determined by Donald L. Houston that the emergency nature of these amendments, warrants publication without waiting for public comment and preparation of an Impact statement. These amendments, as well as the complete regulation, will be scheduled for review under provisions of Executive Order 12044 and Secretary's Memorandum 1955.

Therefore, pursuant to the authority in 5 U.S.C. 555, it is found upon good cause that notice and other public procedure with respect to these amendments is impracticable and contrary to the public interest and good cause is found for making these amendments effective less than 30 days after publication in the Federal Register.


DONALD L. HOUSTON,
Acting Administrator,
Food Safety and Quality Service.

(Rule Doc. 79-6918 Filed 3-8-79; 8:45 am)

[RULES AND REGULATIONS 3410-13-M]

SUBCHAPTER E—EXPORT AND DOMESTIC CONSUMPTION PROGRAMS

PART 2880—FRESH IRISH POTATOES

Support—Fresh Round White and Red Potatoes—Livestock Feed Diversion Program

AGENCY: Food Safety and Quality Service, USDA.

ACTION: Final rule.

SUMMARY: The purpose of this rule is to set forth the terms and conditions of a potato diversion program for the 1978 crop of Round White and Red potatoes produced in the Red River Valley of Minnesota and North Dakota. This rule sets out the provisions of eligibility for payments, the need for approval of diversion by USDA, the rate of payment to producers, and other conditions of participation. This rule is necessary to inform eligible producers of this new program's requirements.

EFFECTIVE DATE: March 12, 1979.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION: Following unusually good weather during the growing and harvesting season, a surplus crop of potatoes for fall harvest was produced in 1978. Although the surplus consists principally of Russet potatoes, which are produced primarily in the Pacific Northwest, other types of potatoes consisting of Round White and Red varieties are at extremely low prices in the Red River Valley of Minnesota and North Dakota. This rule sets out the provisions of eligibility for payments, the need for approval of diversion by USDA, the rate of payment to producers, and other conditions of participation. This rule is necessary to inform eligible producers of this new program's requirements.

EFFECTIVE DATE: March 12, 1979.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION: Following unusually good weather during the growing and harvesting season, a surplus crop of potatoes for fall harvest was produced in 1978. Although the surplus consists principally of Russet potatoes, which are produced primarily in the Pacific Northwest, other types of potatoes consisting of Round White and Red varieties are at extremely low prices in the Red River Valley of Minnesota and North Dakota. This rule sets out the provisions of eligibility for payments, the need for approval of diversion by USDA, the rate of payment to producers, and other conditions of participation. This rule is necessary to inform eligible producers of this new program's requirements.

EFFECTIVE DATE: March 12, 1979.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION: Following unusually good weather during the growing and harvesting season, a surplus crop of potatoes for fall harvest was produced in 1978. Although the surplus consists principally of Russet potatoes, which are produced primarily in the Pacific Northwest, other types of potatoes consisting of Round White and Red varieties are at extremely low prices in the Red River Valley of Minnesota and North Dakota. This rule sets out the provisions of eligibility for payments, the need for approval of diversion by USDA, the rate of payment to producers, and other conditions of participation. This rule is necessary to inform eligible producers of this new program's requirements.
agency making a claim against any
amount due under the program.
However, the diverter has the right to
test the justness of the indebtedness
involved either by administrative
appeal or legal action.
The payment will be $2.00 per hundred
weight for potatoes diverted. Due to
the small volume to be diverted and
the limited time available this season
to achieve successful dehydration by
alternate freezing and thawing, the
program period will be limited to 30
days.

Immediate action is necessary to re-
move the commercial potato markets
from the price-depressing impact
which persistently exists when potato
supplies are in surplus. Accordingly,
Dr. Donald L. Houston, Acting Admin-
istrator, FSQS, has determined that
an emergency situation exists requir-
ing immediate program action without
notice and comment period, that
compliance with the notice and public
procedure provisions of 5 U.S.C. 553 is
impracticable and contrary to the
public interest, and in accordance with
the provisions of Executive Order
12044 (43 FR 15861, March 24, 1978)
that it is not possible to publish these
regulations in proposed form and
allow 60 days for public comment.
However, the public is invited to
submit written comments concerning
this program to: Executive Secretariat,
Attention: Annie Johnson, Food
Safety and Quality Service, Room
3167, South Agriculture Building, U.S.
Department of Agriculture, Washing-
ton, D.C. 20250, in order to be sure of
consideration, comments must be re-
ceived by March 21, 1979. The pro-
gram will be reevaluated on the basis
of comments submitted. All comments
submitted pursuant to this notice will
be made available for public inspection
in the office of the Executive Secretar-
iat during regular hours of business.

Accordingly, 7 CFR Chapter XXVIII
is amended by adding a new subpart to
read as follows:

PART 2880—FRESH IRISH POTATOES
Subpart—Fresh Round White and Red
Potatoes—Livestock Feed Diversion Programs

Sec. 2880.50 General statement.

2880.51 Administration.

2880.52 Area.

2880.53 Period of program.

2880.54 Rate of payment.

2880.55 Eligibility for payment.

2880.56 Application and approval for par-
ticipation.

2880.57 Performance bond.

2880.58 Period of diversion.

2880.59 Definition of diversion.

2880.60 Inspection and certificate of diver-
sion.

2880.61 Methods of utilization.

2880.62 Claim for payment.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979

§ 2880.50 General statement.

The program provided for in this
subpart will be administered under
the general direction and supervision of
the Director, Food and Vegetable
Quality Division, Food Safety and Qual-
ity Service, United States Department of
Agriculture, Washington, D.C. 20250.

State Agricultural Stabilization and
Conservation Committees in the
States of Minnesota and North
Dakota.

County Agricultural Stabilization
and Conservation Committees in the
respective counties.

§ 2880.51 Administration.

The program provided for in this
subpart will be administered under
the general direction and supervision of
the Director, Food and Vegetable
Quality Division, Food Safety and Qual-
ity Service, and in the field will
be carried out by the Agricultural Sta-
bilization and Conservation Service
through Agricultural Stabilization
and Conservation County Committees,
hereinafter referred to as the State
and County Committees. Each State
Committee will authorize one or more
employees to act as representatives
of the United States Department of Agri-
culture, hereinafter referred to as
USDA, to approve applications for
participation. The State and County
Committees or their authorized repre-
sentatives do not have authority to
modify any or any part of the provisions
of this subpart or any amendments or
supplements to this subpart.

§ 2880.52 Area.

This program will be effective in the
States of Minnesota and North Dakota.

§ 2880.53 Period of program.

This program will be effective for a
thirty day period beginning March 12,
1979.

§ 2880.54 Rate of payment.

The rate of payment per 100 pounds
of potatoes in each lot which meet the
requirements of Specification A as de-
dined in § 2880.60 will be two dollars
per hundredweight for potatoes di-
verted from the inception of the pro-
gram through a period of 30 days. No
payment will be made for any frac-
tional part of 100 pounds and such
quantities shall be disregarded.

§ 2880.55 Eligibility for payment.

Payments will be made under this
program to any individual, partner-
ship, association, or corporation pro-
ducing Round White and Red potatoes
in the States of Minnesota and North
Dakota, (a) who executes and files an
application for participation on the
prescribed form, (b) who files a per-
formance bond as provided in §
2880.57, (c) whose application is ap-
proved, (d) who diverts his fresh
Round White and Red potatoes within
the States specified in the approved
application, directly or through any
other person or persons, (e) who files a
claim as provided in § 2880.63, and (f)
who complies with all other terms and
conditions contained in this subpart.

§ 2880.56 Application and approval for
participation.

Producers desiring to participate in
this program must submit a written
application on Form ASCS-117 "Appli-
cation for Participation in Fresh Irish
Potato Livestock Feed Diversion Pro-
grame. Each applicant must submit a
performance bond as provided in
§ 2880.57. Applications and bonds
should be submitted to the County
ASCS Office for the county within
which the potatoes are to be diverted.
Applications will be considered in the
order received and in accordance with
the availability of funds. Applicants
will be notified of the approval, in
whole or in part, or nonapproval of
their application. Approved applica-
tions may be modified or amended
with the consent of the applicant and
the duly authorized representative of
the State Committee: Provided, that
such modification or amendment shall
not be in conflict with the provisions
of this subpart or any amendment or
supplements hereto. An approved ap-
plicant is hereinafter referred to as
"the diverter".

§ 2880.57 Performance bond.

In order to protect the Govern-
ment's interest, each applicant shall
submit with his first application for
participation a performance bond as
further assurance that the potatoes di-
Rule 2880.61 Inspection and certificate of diversion.

Prior to diversion, the potatoes shall be inspected by an inspector authorized or licensed by the Secretary of Agriculture to inspect and certify the class, quality, and condition of fresh Irish potatoes. The diverter shall be responsible for requesting and arranging for inspection so that the inspector can present to determine the proportion of potatoes in each lot which meet the quality requirements of Specification A. The inspector shall also verify the quantity of potatoes being diverted and that such potatoes have been diverted as defined in §2880.59. The diverter shall furnish such scale tickets, weighing facilities, or other suitable measuring instruments determined by the inspector to be necessary for ascertaining the net weight of the potatoes being diverted. The cost of inspecting, verifying the quantity, certifying that diversion has been performed, and issuing certificates thereof shall be borne by the diverter. Certificates shall be prepared on Form ASCS-118, "Invoice and Certificates of Inspection and Diversion."

§2880.62 Methods of utilization.

Following the initial processing as specified in §2880.59, the potatoes must be fed to livestock by one or more of the following methods:

(a) Feeding in barn or feed lots directly from troughs, bunkers, bins, or other suitable feeding receptacle;
(b) Spreading on pasture land where livestock are grazing, but the rate of spreading during any seven-day period shall not exceed 500 pounds of potatoes per head of cattle or horses or 250 pounds per head of sheep or swine; or
(c) Utilizing the potatoes for livestock feed after dehydration through a process of alternating freezing and thawing. In addition to other program requirements, the following special terms and conditions will be applicable to such method:
   (1) The potatoes must be spread on pasture consisting of sod or other grassland. The potatoes may not be spread on land set aside under the Feed Grain Program, the Wheat Program, or under a Water Bank Program agreement. The land on which the potatoes are spread may not be plowed or otherwise cultivated until it is determined by USDA that adequate pasturing by livestock has taken place.
   (2) The potatoes may be spread no deeper than 4 inches at any point.
   (3) Diversion payments will be computed at the rate of $2.00 per hundredweight, but fifty percent of the payment to diverters by USDA will not be made until it is determined by USDA that adequate pasturing by livestock has taken place. Adequate pasturing will be considered to have occurred when potatoes have been grazed or consumed to the extent little or no feed value remains.

(i) Consideration shall be given to evidence that reasonable numbers of livestock had ample time to consume the feedable potatoes as determined through actual counts of livestock or visual remains thereof—tracks, droppings, pasture growth, etc.
(ii) In the event potatoes remain after pasturing, evidence must exist that most of such potatoes are no longer edible because of normal spoilage due to weather conditions, spreading, damage, trappings, droppings, etc. The range of losses from such causes may be expected to be from 25 percent to 50 percent of the potatoes originally spread. In case of greater loss, documentation satisfactory to ASCS must be provided to establish the cause of such loss.

§2880.63 Claim for payment.

In order to obtain payment, the diverter must submit to the State ASCS Office which approved his application a properly executed "Invoice and Certificates of Inspection and Diversion", Form ASCS-118, and (except where the diverter is the feeder) a certification of receipt by the ultimate feeder. All such claims shall be filed not later than one calendar month after the termination date specified in the applicable approved application.

§2880.64 Compliance with program provisions.

If USDA determines that any quantity of potatoes diverted under this program was not used exclusively for livestock feed purposes, whether such failure was caused directly by the diverter or by any other person or persons, the diverter shall not be entitled to diversion payments made in connection with such potatoes, shall refund to USDA for any other damages incurred as a result of such failure to use the potatoes exclusively for livestock feed purposes. USDA may deny any diverter the right to participate in this program or the right to receive payments in connection with any diversion previously made under this program, or both. If USDA determines that: (a) The diverter has failed to use or caused, to be used any quantity of potatoes diverted under this program exclusively for livestock feed, whether such failure was caused directly by the diverter or by any other person or persons, (b) the diverter has not acted in good faith in connection with any transaction under this program, or (c) the diverter has failed to discharge fully any obligation assumed by him under this program. Persons making any misrepresentation of facts in connection with this program for the purpose of defrauding USDA will be sub-

---

Cellar Run potatoes are hereby defined as storage potatoes which have not been sorted.
flect to the applicable civil and criminal provisions of the United States Code.

§ 2880.65 Inspection of premises.

The diverter shall permit authorized representatives of USDA at any reasonable time to have access to his premises or other premises on which diversion for livestock feeding is to take place, to inspect and examine potatoes which are being diverted, used, or stored for diversion or use, and to inspect and examine the facilities for or relating to the diversion and disposition of such potatoes. The diverter shall permit authorized representatives of USDA and the General Accounting Office at any reasonable time to inspect, examine, and make copies of such records and accounts showing the details relative to the diversion and disposition of such potatoes. The diverter shall permit authorized representatives of USDA and the General Accounting Office at any reasonable time to inspect, examine, and make copies of such records and accounts in order to determine to what extent there is or has been compliance with the provisions of this program.

§ 2880.66 Records and accounts.

If the diverter sells or otherwise disposes of potatoes diverted pursuant to this program to any other person or persons for use as livestock feed or starch manufacture, the diverter shall keep accurate records and accounts showing the details relative to the diversion and disposition of such potatoes. The diverter shall permit authorized representatives of USDA and the General Accounting Office at any reasonable time to inspect, examine, and make copies of such records and accounts in order to determine to what extent there is or has been compliance with the provisions of this program. Such records and accounts shall be retained by the diverter for three years after date of last payment to him under the program or for two years after date of audit of records by USDA as provided herein, whichever is the later.

§ 2880.67 Set-off.

If the diverter is indebted to USDA or to any other agency of the United States, set-off may be made against any amount due the diverter hereunder. Setting off shall not deprive the diverter of the right to contest the justness of the indebtedness involved, either by administrative appeal or by legal action.

§ 2880.68 Joint payment or assignment.

The diverter may name a joint payee on the claim for payment or may assign, in accordance with the provisions of the Assignment of Claims Act of 1940, Public Law 811, 76th Congress, as amended (31 U.S.C. 203, 41 U.S.C. 15), the proceeds of any claim to a bank, trust company, Federal lending agency, or other recognized financing institution: Provided, that such assignment shall be recognized only if and when the assignee thereof files written notice of the assignment with the authorized representative of USDA who approved the application, together with a true copy of the instrument of assignment, in accordance with the instructions on Form CSS-65 or ASCS-66 "Notice of Assignment", which form must be used in giving notice of assignment to USDA. The "Instrument of Assignment" may be executed on Form CSS-347 or ASCS-36, or the assignee may use his own form of assignment. The forms may be obtained from the State ASCS Office or the Washington office shown in § 2880.50.

§ 2880.69 Officials not to benefit.

No member of or delegate to Congress or Resident Commissioner shall be entitled to any share or part of any contract resulting from this program or to any benefits that may arise therefrom, but this provision shall not be considered to extend to such a contract if made with a corporation for its general benefit or to any such person acting in his capacity as a farmer.

§ 2880.70 Amendment and termination.

This subpart may be amended or terminated at any time, but the amendment or termination shall not be effective earlier than the date of filing with the Office of the Federal Register. No amendment or termination shall be applicable to any potatoes diverted before the effective time of such amendment or termination.

An impact analysis has been prepared and is available from: D. A. Thibeault, Chief, Commodity Procurement Branch, Fruit and Vegetable Quality Division, FSQS, U.S. Department of Agriculture, Washington, D.C. 20250, Telephone: 202-447-2781.

NOTE—The reporting and recordkeeping requirements contained herein have been approved by the Office of Management and Budget in accordance with the Federal Register Act of 1942.

Dated: March 5, 1979.

DONALD L. HOUSTON,
Acting Administrator,
Food Safety and Quality Service.

[FR Doc. 79-7110 Filed 3-8-79; 8:45 am]

PART 82—EXOTIC NEWCASTLE DISEASE; AND PSITTACOSIS OR ORNITHOSIS IN POULTRY

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final Rule.

SUMMARY: The purpose of this amendment is to quarantine an additional portion of Orange County, California, and additional portions of Los Angeles County, California, because of the existence of exotic Newcastle disease. Exotic Newcastle disease was confirmed in Orange County, California on February 26, 1979, and in Los Angeles County, California, on March 1, 1979. Therefore, in order to prevent the dissemination of contaminated poultry, it is necessary to quarantine additional portions of such counties.

EFFECTIVE DATE: March 5, 1979.

FOR FURTHER INFORMATION CONTACT:

Dr. M. A. Milson, USDA, APHIS, VS, Federal Building, Room 748, Hyattsville, Maryland 20782. 301-447-8073.

SUPPLEMENTARY INFORMATION: This amendment quarantines an additional portion of Orange County, California, and additional portions of Los Angeles County, California, because of the existence of exotic Newcastle disease in such areas.

Therefore, the restrictions pertaining to the interstate movement of poultry, mynah, and psittacine birds, and birds of all other species, under any form of confinement, and their carcasses and parts thereof, and certain other articles, from quarantined areas, as contained in 9 CFR Part 82, as amended, will apply to the quarantined areas.

Accordingly, Part 82, Title 9, Code of Federal Regulations, is hereby amended in the following respects:

In § 82.3(a)(1), relating to the State of California, a new paragraph (v) relating to Orange County, and new paragraphs (vi) and (vii) relating to Los Angeles County, are added to read:

§ 82.3 Areas quarantined.

(a) ... 

(1) California. 

... 

(v) The premises of Parrot World, Inc., 1251 Harbor Boulevard, Garden Grove, Orange County.
RULES AND REGULATIONS

[3410-34-M]

SUBCHAPTER D—EXPORTATION AND IMPORTATION OF ANIMALS (INCLUDING POULTRY AND ANIMAL PRODUCTS)

PART 92—IMPORTATION OF CERTAIN ANIMALS AND POULTRY AND CERTAIN ANIMAL AND POULTRY PRODUCTS; INSPECTION AND OTHER REQUIREMENTS FOR CERTAIN MEANS OF CONVEYANCE AND SHIPPING CONTAINERS THEREON

Harry S. Truman Animal Import Center

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final Rule.

SUMMARY: This document revises the provisions of the cooperative agreement to be used for the importation of cattle into the Harry S. Truman Animal Import Center. The changes are minor in nature and are being made merely to clarify the provisions of the cooperative agreement.

EFFECTIVE DATE: March 5, 1979.

FOR FURTHER INFORMATION CONTACT:

Dr. D. E. Herrick, USDA, APHIS, VS, Federal Building, Room 815, Hyattsville, MD 20782 (301) 436-8170.

SUPPLEMENTARY INFORMATION: On Friday, February 16, 1979, there was published in the Federal Register (44 FR 10052-10056) the fees and method of collection of the fees from importers of cattle to be imported through the Harry S. Truman Animal Import Center (HSTAIC).

The docket further explained that in order to provide sound financial management both for the prospective importers and the Department, it is essential that the importers, prior to issuance of the special permits, assume fiscal responsibility for the expenses to be incurred. Due to the unusual nature of the service and the need to have adequate funds on a fee basis available to the Department for the cost of the significant services which will be performed in connection with the importation of animals into the HSTAIC in accordance with the provisions of section 1 of the Act of May 6, 1970 (21 U.S.C. 135), the Department is requiring either advance payment or a payment bond meeting the requirements specified in the cooperative agreement.

The Department has determined that there is a need to amend the cooperative agreement in order for the importer to secure the necessary financing and to enter into the cooperative agreement, and to enable the Department to continue with the procedures necessary to qualify the cattle for importation into the facility.

The Department is unable to furnish specific effective dates, in advance, for those importers wishing to use the provisions of paragraph A(1)(b) (payment bond) in the cooperative agreement. Therefore, the cooperative agreement is being amended to delete provisions for such specific dates and to provide that the bond shall be in effect from the date of issuance of the import permit to the date the cattle are released from quarantine, otherwise disposed of. The date for the termination of the bond has been changed from “the date the cattle are scheduled to be released from quarantine” to “the date the cattle are released from quarantine” in case some reason arises which precludes their release from quarantine on the scheduled date. The life of the payment bond is estimated to be 8 months. (Five months in U.S. quarantine and 3 months to complete foreign qualifying procedures.)

Additionally, the first sentences of paragraphs A(1)(a) and A(1)(b) of the cooperative agreement are amended by revising the language concerning the computation of the amount to be deposited with the Department. Under the present agreement, the amount to be deposited with the Department is equal to the established fee multiplied by the number of cattle on the cooperative’s import permit. Since an import permit will not be issued until the cooperative agreement has been signed, the language in the agreement has been amended to reflect this fact. The amount to be deposited will be equal to the established fee multiplied by the number of cattle for which an import permit is to be issued to the cooperative.

It is expected that approval of the cooperative agreement and the deposit of the necessary funds or payment bond will be made no later than April 9, 1979, in order to expedite the first importation.

The aforementioned changes are minor and have been made for the purpose of clarifying the cooperative agreement.

Accordingly, Part 92, Title 9, Code of Federal Regulations, is amended in the following respects:

In §92.41, paragraph (c) Parts A (13a) and A(13b) are amended to read:

§92.41 Requirements for the importation of animals into the United States through the Harry S. Truman Animal Import Center.

(c) Cooperative Agreement.
RULES AND REGULATIONS

[6450-01-M]

Title 10—Energy

CHAPTER II—ECONOMIC REGULATORY ADMINISTRATION, DEPARTMENT OF ENERGY

PART 211—MANDATORY PETROLEUM ALLOCATION REGULATIONS

Standby Petroleum Product Allocation Regulations—Activation Order To Update the Motor Gasoline Allocation Base Period: Change of Hearing Dates and Location; Standby Regulation Activation Order No. 1

AGENCY: Economic Regulatory Administration.

ACTION: Notice of Change of Hearing Dates and Location.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) hereby gives notice of a change in the date and location for the public hearing on its activation order to update the motor gasoline base period previously set forth in the notice of the activation order issued on February 22, 1979 (44 FR 11202, February 28, 1979). The change is being made to allow ERA to receive public comments as quickly as possible to resolve many of the issues raised since issuance of the activation order.

DATES: The hearing in Washington, D.C., previously scheduled for March 27, 1979, is now scheduled for March 21, 1979, 9:30 a.m., and will be continued, if necessary, at 9:30 a.m. on March 22 and March 23. Written comments to be submitted by 4:30 p.m., e.s.t., March 30, 1979, to: Public Hearing Management, Room 2313, 2000 M Street, N.W., Washington, D.C. 20461.


Michael Paige or Joel M. Yudson (Office of General Counsel), Department of Energy, 1600 Independence Avenue, S.W., Room 6A-127, Washington, D.C. 20585 (202) 252-6739.

Issued in Washington, D.C., March 6, 1979.

DOUGLAS G. ROBINSON, Assistant Administrator, Regulations and Emergency Planning, Economic Regulatory Administration.

[FR Doc. 79-7222 Filed 3-7-79; 8:45 am]

[6210-01-M]

Title 12—Banks and Banking

CHAPTER II—FEDERAL RESERVE SYSTEM

SUBCHAPTER A—BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

[Reg. O; Docket No. R-0194]

PART 215—LOANS TO EXECUTIVE OFFICERS, DIRECTORS, AND PRINCIPAL SHAREHOLDERS OF MEMBER BANKS

Rules to Implement New Law

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final regulation.

SUMMARY: The Board of Governors of the Federal Reserve System has amended its Regulation O (12 CFR Part 215), formerly entitled "Loans to Executive Officers of Member Banks." Amended Regulation O implements section 22(b) of the Federal Reserve Act, recently enacted by Congress as section 104 of the Financial Institutions Regulatory and Interest Rate Control Act of 1978 ("FIRREA") (Pub. L. 95-630). The requirements of section 22(b) relate to loans by a member bank (1) to an executive officer, director or principal shareholder of the member bank or of any of its bank holding company affiliates or (2) to a company or political or campaign committee controlled by any of these persons.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
The amendments to the regulation were adopted after a review of the extensive public comment on the proposals. The amendments will become effective on March 10, 1979, but not before the effective date of section 22(h). However, the Board has invited additional public comment on the final rules for a further 60 day period. The Board will consider and adopt any appropriate amendments to the regulation as soon as practicable.

DATES: The regulation is effective March 10, 1979. Comments must be received by May 9, 1979.

ADDRESS: Comments should be in writing and should refer to Docket No. R-0194. They should be sent to Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551. The comments will be made available for inspection and copying as provided in the Board's Rules Regarding Availability of Information (12 CFR Part 261).

FOR FURTHER INFORMATION CONTACT:

James V. Mattingly or Michael E. Bleier, Senior Attorneys, Legal Division (202-452-3430 or 3721), or Mary Curtin, Senior Attorney, Division of Banking Supervision and Regulation (202-452-2520), Board of Governors of the Federal Reserve System.

SUPPLEMENTARY INFORMATION: On December 28, 1978, the Board of Governors of the Federal Reserve System proposed amendments to its Regulation O to implement the requirements of new section 22(h) of the Federal Reserve Act (44 FR 682, January 3, 1979). Section 22(h) governs over draft loans (subject to certain exceptions) for the aggregate amount of all loans by the bank to (a) Each of its executive officers and the officer's related interests, (b) each of its principal shareholders and the shareholder's related interests, or (c) the related interests of each of the bank's executive officers and principal shareholders.

(2) Prohibits the payment by a member bank of an overdraft of an executive officer or director on an account at the bank;

(3) Requires that every extension of credit by a member bank to executive officers, directors or principal shareholders or to any related interest of such a person (a) be made on substantially the same terms as those prevailing at the time for comparable transactions with other persons and (b) not involve more than the normal risk of repayment or present other unfavorable features; and

(4) Requires that every extension of credit by a member bank to any of its executive officers, directors or principal shareholders, or to any related interest of such a person, that would exceed $25,000 by the member bank aggregating over $25,000 to any of its executive officers, directors or principal shareholders ("bank officials") or the related interests of these persons, the comments advised that the prior approval requirement was unnecessarily harsh and would tend to discourage qualified persons from serving as bank directors due to delays they could face in obtaining credit.

After considering these comments, the Board has amended the regulation to clarify that once a line of credit has been approved by a majority of the bank's entire board of directors, drawdowns on that line of credit do not require further approval by the board of directors if two conditions are met. The regulation requires (1) that the line of credit have been approved within 14 months of the date of the drawdown; and (2) that the terms of the drawdown comply with the statute's prohibition against preferential lending and not involve more than the normal risk of repayment or present other unfavorable features. This modification is consistent with both the letter and spirit of section 22(h).

1. Prior approval by the board of directors. Most of the comments received were directed to the statute's requirement that a majority of the entire board of directors of the member bank approve in advance loans by the member bank aggregating over $25,000 to any of its executive officers, directors or principal shareholders ("bank officials") or the related interests of these persons. The comments advised that the prior approval requirement was unnecessarily harsh and would tend to discourage qualified persons from serving as bank directors due to delays they could face in obtaining credit.

2. Overdrafts. About 65 of the comments received by the Board suggested that provision be made in the regulation for inadvertent overdrafts. The regulation and the statute provide exceptions from the prohibition against payment of an overdraft when the overdraft is paid pursuant to: (1) A written, preauthorized interest-bearing loan plan that specifies a method of repayment, or (2) A written, preauthorized transfer of funds from another account of the account holder at the bank. In addition, the Board has modified the regulation to allow the payment of an inadvertent overdraft of a limited amount that will be
promptly repaid. The regulation requires the member bank to charge the director or officer the same fee charged upon the renewal or extension of credit by the bank in similar circumstances. The Board intends that this provision be used solely in the unusual case of an inadvertent overdraft. This amendment is in the Board's previous definition of extension of credit in Regulation O, with the statutory exception for interest-bearing overdraft plans, and with the purpose of section 22(h) to prevent self-dealing by bank officials.

3. Lending limit. A number of comments raised the question whether the 10 per cent lending limit of section 22(h) applies to a loan by a member bank to its parent bank holding company or to a nonbank subsidiary of that holding company. Currently, loans by a member bank to its parent bank holding company and to all other subsidiaries of that holding company (including subsidiary banks) are subject, in the aggregate, to a lending limit of 20 per cent of the member bank's capital and surplus under section 23A of the Federal Reserve Act (12 U.S.C. 371c). Under section 23A, a member bank's parent bank holding company and any other subsidiary of that holding company are considered an affiliate of the member bank. To subject loans within a bank holding company system to the aggregate lending limit of section 22(h) would, in many situations, result in an enlargement of the 20 per cent lending limit of section 23A. The Board has decided that the two statutes be interpreted consistently, as evident from the requirement in section 22(h) that the term extension of credit shall have the same meaning as in section 23A. According to the regulation excludes the lending limit of section 22(h) applies to any subsidiary of that bank holding company or to any other subsidiary of that bank holding company. The exclusion applies also to a foreign bank that controls a domestic bank and to all other subsidiaries of that holding company of which the member bank is a subsidiary.

However, a member bank's loans to its parent bank holding company and to nonbank subsidiaries of that holding company remain subject to the prior approval and preferential lending restrictions of section 22(h). In addition, a member bank's loans to a principal shareholder or executive officer of the member bank's parent bank holding company or of any other subsidiary of that bank holding company or of any other subsidiary of that bank holding company are subject to the 10 per cent lending limit and (other applicable restrictions) of section 22(h).

The Board has also excluded from coverage under section 22(h) a foreign bank that maintains a branch in the United States, whether or not the branch is insured. Under the International Banking Act of 1978 (Pub. L. 95-369), a foreign bank that has an insured branch is treated as a nonmember insured bank (12 U.S.C. 1813(h)). Without the exclusion, the foreign bank would be subject to the provisions of section 22(h), which are made applicable to nonmember insured banks as if they were member banks (12 U.S.C. 1828(j)(2)). This exclusion is consistent with the exemption from section 23A granted to such foreign banks under the International Banking Act (12 U.S.C. 1828(j)(1)) and with the requirement of that statute (12 U.S.C. 3105(d)) that the Board submit to the Congressional Banking Committees within two years a recommendation regarding limitations that would be placed on foreign banks regarding loans to their affiliates. It should be noted that section 22(h) does not apply to executive officers or to conclude that new section 22(h) should be interpreted to allow preferential lending, the Board has rejected the requested change. The Board believes the Congress has indicated a desire to prohibit preferential lending by insured banks to their executive officers, directors, or principal shareholders. Indeed, in Title VIII of PIRA, Congress has prohibited such preferential lending by banks that maintain a correspondent account relationship with each other's executive officers, directors, or principal shareholders.

5. Executive officer. The Board has continued in Regulation O its previous definition of executive officer as one who participates or is authorized to participate (other than in the capacity of a director) in major policymaking functions of a bank or company. Under section 22(g) of the Federal Reserve Act, a member bank that has an insured branch is deemed to be an "officer" of that bank holding company of which a member bank is a subsidiary and an "officer" of any other subsidiary of that holding company is deemed to be an "officer" of the member bank. While officers of a bank holding company of which a member bank is a subsidiary are thus considered officers of the member bank for purposes of section 22(h), the statute's prohibitions run only to "executive officers." Amended Regulation O makes it clear that the limitations of section 22(h) regarding member bank loans to its executive officers also apply to all executive officers of a bank holding company unless (1) the executive officer is excluded (by name or by title) from participation in major policymaking functions of the member bank by resolutions of the boards of directors of both the member bank and the other subsidiary, and (2) the executive officer of the member bank does not actually participate in major policymaking functions of the member bank.

6. Definition of Subsidiary. A number of the comments have raised the question whether a subsidiary of a member bank would be considered to be an "other subsidiary" of the member bank's parent bank holding company if, so, member bank loans to its own surplus under section 23A are subject to the lending restrictions of section 22(h). As noted in paragraph 3 above, the Board has excluded member bank loans to its bank holding company affiliates from the 10 per cent limitation of section 22(h).
Section 22(h) applies to loans by a member bank to its principal shareholders and to a company “controlled” by a principal shareholder. There does not appear to be any Congressional intent to transactions between a member bank and its own subsidiaries. In addition, the Board has long held that a credit transaction by a member bank with an operations subsidiary of the bank is not an extension of credit and is not subject to the restrictions of section 22(h). The Board’s interpretation of the term “subsidiary” does not include a subsidiary of a member bank. However, if an officer, director or principal shareholder of a subsidiary of a member bank participates, or has principal shareholder of a subsidiary "subsidiary" is, in effect part of its parent bank just as though it were a department of the bank. For these reasons and consistent with section 23A, the Board has revised Regulation O to clarify that member bank loans to its own subsidiaries are not subject to the limitations of section 22(h) including the prior approval and preferential lending to executive officers, directors and principal shareholders of such subsidiaries will not be deemed to have that same relationship with the parent member bank. To accomplish this, § 215.2(1) of the regulation specifies that the term “subsidiary” does not include a subsidiary of a member bank.

The Board has also revised the proposed regulation to allow term loans with fixed maturities (including residential mortgage loans) that were made before March 10, 1979, to be repaid in accordance with their existing payment schedules. Other loans (typically demand loans) are required to be reduced in amount to comply with the lending limit by March 10, 1980 (with two one-year extensions available for good cause). The Board has revised the proposed regulation to allow term loans with fixed maturities (including residential mortgage loans) that were made before March 10, 1979, to be repaid in accordance with their existing payment schedules. Other loans (typically demand loans) are required to be reduced in amount to comply with the lending limit by March 10, 1980 (with two one-year extensions available for good cause).

The Board has amended the regulation to clarify that an individual will not be deemed to control a company or a bank solely because of the individual’s position as a director or executive officer of the company or bank. The regulation also establishes rebuttable presumptions of control in the following two situations:

1. Where an executive officer or director controls more than 10 percent of the shares of the bank or company; or

2. Where any person owns more than 10 percent of the shares of a bank or company and no other person owns or controls a greater percentage of the institution's shares.

The appropriate Federal banking agency will examine term loans made during this interim period closely, particularly those made between February 28, 1979 (the date of the Board meeting at which amended Regulation O was adopted), and March 10, 1979, to determine if they were made to avoid the lending limit or preferential lending restrictions of the statute. If so, these loans may be subject to supervisory action by the appropriate banking agency or to further regulatory action.

The prohibitions of section 22(h) against preferential lending are prospective. Preferential loans that are outstanding on March 10, 1979, are not specifically addressed in the statute or Regulation O. However, member banks should eliminate the preferential terms on such loans as soon as practicable. If such terms are not eliminated, they may be subject to criticism. This policy applies particularly to demand loans that are within the power of the bank to call and renegotiate at any time.

Finally, consideration is being given to requiring that an extension of credit by a member bank to a person that subsequently becomes a bank officer or director be brought into compliance with the lending limit and preferential lending restrictions of §§ 215.4(a) and 215.4(c) within 2 years of the date the person becomes covered by the regulation. This 2 year time period would be subject to extension by the appropriate Federal banking agency for good cause. Such a requirement may be necessary to prevent evasions of section 22(h). Public comment is requested specifically on this possible amendment.

10. Capital and Surplus. As indicated, the lending limit of section 22(h) is based on the member bank’s capital stock and unimpaired surplus. In its original notice, the Board requested comment on whether subordinated notes and debentures should be included as capital and surplus for the purposes of this lending limit. The comments were virtually unanimous in urging the agencies to adopt a common definition of capital to avoid any inequality that might result between national and State banks. The comments were also virtually unanimous in urging that subordinated notes and debentures be included as capital. The regulation now defines a member bank’s capital stock and surplus to be an amount equal to the sum of:

(1) the “total equity capital” of the member bank as reported in its most recent consolidated report of condition,

(2) subordinated notes and debentures that have been approved as such by the appropriate Federal banking agency.
ing agency, and (3) valuation reserves created by charges to the member bank's income.

The Board's inclusion of subordinated notes and debentures in the definition of capital and surplus is solely for the purposes of the lending limit established under section 22(g) of the Federal Reserve Act. The Board believes that subordinated notes and debentures should be considered part of a member bank's capital or surplus for other purposes.

11. Section 22(g) of the Federal Reserve Act. Under the Board's proposed regulation, the lending limit of section 22(h) would not have applied to prevent an extension of credit authorized under section 22(g) of the Federal Reserve Act (which governs member bank loans to its executive officers). The Board received little favorable comment on the proposal. The proposed provision would not have been available to national banks, because they are in any event subject to a 10 per cent limit under section 5200 of the Revised Articles of Association.

The Board proposed the rule as a means to lessen the impact of section 22(h) and the proposed compliance deadlines with respect to home mortgage loans. Under section 22(h), by March 10, 1979, by State banks to their executive officers. As originally proposed, such loans would have been required to be reduced by March 10, 1980, to comply with the 10 per cent lending limit. Since the regulation now exempts home mortgage loans made before March 10, 1979, from the compliance deadline of March 10, 1980, and such mortgage loans may be reduced in accordance with their original repayment schedules, the proposed exclusion is no longer necessary. Therefore, a loan by a member bank to any of its executive officers must comply with the requirements of both sections 22(g) and 22(h).

The Board has also decided to retain in amended Regulation O a recitation of the lending limitations and reporting requirements of former Regulation O, which implemented section 22(g). However, the regulation shortens and simplifies the language of former Regulation O with respect to these provisions.

Unlike the requirements of section 22(h), which are applicable to member bank loans to executive officers of the member bank as well as to executive officers of the member bank's parent bank holding company and other subsidiaries of that bank holding company, section 22(g) is applicable only to member bank loans to its own executive officers. A great many state nonmember banks questioned whether FIRA had caused section 22(g) to apply to nonmember insured banks. The answer is that section 22(g) is not applicable, and is not not considering the regulation of FIRA to nonmember insured banks. Section 22(g) is applicable only to member banks and their loans to their own executive officers. The lending restrictions and reporting requirements of section 22(g) are now contained in §§ 215.5, 215.8, and 215.9 of amended Regulation O.

12. Extension of Credit. The regulation defines an extension of credit as a making or renewal of any loan, the granting of a line of credit, or an extending of credit in any manner whatsoever. The regulation specifically includes a purchase of securities under repurchase agreement, the issuance of a standby letter of credit, and an endorsement or guarantee. The regulation excludes certain indebtedness necessary to enable a member bank to comply with the requirements of section 22(h) and the proposed compliance deadlines with respect to home mortgage loans and bank credit card plans and other types of open end credit in an amount not to exceed $5,000 if the credit is on terms not more favorable than those offered to the general public. It should be noted that the provisions of section 22(h) do not apply to credit transactions between insured bank affiliates since an insured bank is excluded from the definition of company in section 22(h) (see footnote 6, above).

As indicated above, the term extension of credit in section 22(h) has the same meaning as in section 23A. The Board intends to interpret the term extension of credit for the purposes of section 22(h) consistently with its interpretations of section 23A.

The Board has also modified the definition of extension of credit to clarify that when a bank official or a related interest receives the proceeds or tangible economic benefit of an extension of credit, the extension of credit will be considered made to that person for purposes of section 22(h). This provision is consistent with a similar provision in section 23A and is designed to prevent evasion of the statute through the use of nominee borrowers. When a lending bank does not know, and has no reason to know, that the proceeds of the extension of credit are used for the benefit of, or transferred to, a bank official or a related interest of that person, the lending bank is not in violation of the provisions of Regulation O. The persons involved in the nominee scheme may, of course, be in violation of the regulations. The regulation also makes clear that a participation with out recourse is considered to be an extension of credit by the originating bank, but not by the originating bank.

13. Advisory Director. The Board has excluded advisory directors from coverage under the statute if they provide solely general policy advice to the board of directors and do not vote.

14. Miscellaneous. The Board has drafted these rules to effect the purposes of section 22(h) in the area of loans by a member bank to bank officials and their related interests. The Board will review the regulation periodically and adopt any modifications to the regulation that are shown by experience to be necessary or appropriate to carry out the intent of the Congress in this area or to prevent evasions of the statute.

The expanded procedures set forth in the Board's policy statement of January 15, 1979 (44 FR 3957), were not strictly followed in developing this regulation, since it was proposed for comment before the policy statement was adopted. In addition, a delay in promulgating the regulation is inappropriate in light of the necessity to meet the statute's effective date of March 10, 1979, and the necessity for providing immediate guidance to persons affected by section 22(h). In the development of this final regulation, the Board has, however, complied with the spirit and intent of its policy statement by making every effort to reduce unnecessary regulatory burdens with due regard for the purposes of the statute.

The modifications to the regulation were made after full consideration of the extensive public comments submitted to the Board. In furtherance of the Board's policy to encourage public participation in its rulemaking proceedings and in response to specific requests and comments, the Board invites further public comment on the rules for a further 60 days. The Board will consider comments and adopt any further amendments to the regulation that the Board finds are necessary or appropriate. The Board will make any changes as soon as practicable after the comment period.

The Board finds that publication of the amended Regulation O for the full 30 day period specified in 5 U.S.C. 553(d) would not be in the public interest because the statute takes effect on March 10, 1979.

Accordingly, the Board of Governors of the Federal Reserve System amends its Regulation O (12 CFR Part 215) to read as set forth below:

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
PART 215—LOANS TO EXECUTIVE OFFICERS, DIRECTORS, AND PRINCIPAL SHAREHOLDERS OF MEMBER BANKS

Sec. 215.1 Authority, purpose, and scope.

215.3 Definitions.

215.4 General Prohibitions.

215.5 Additional Restrictions on Loans to Executive Officers of Member Banks.

215.6 Exemptions of Credit Outstanding on March 10, 1979.

215.7 Records of Member Banks.

215.8 Reports by Executive Officers.

215.9 Reports by Member Banks.

215.10 Civil Penalties.

Authority: Secs. 11(i), 22(g) and 22(h), Federal Reserve Act (12 U.S.C. 248(i), 375a and 375b(7)).

§ 215.1 Authority, purpose, and scope.

(a) Authority. This part is issued pursuant to sections 11(i), 22(g), and 22(h) of the Federal Reserve Act (12 U.S.C. 248(i), 375a, and 375b(7)).

(b) Purpose and Scope. This part governs any extension of credit by a member bank to an executive officer, director, or principal shareholder of (1) the member bank, (2) a bank holding company of which the member bank is a subsidiary, and (3) any other subsidiary of that bank holding company. It also applies to any extension of credit by a member bank to (i) a company controlled by such a person and (ii) a political or campaign committee that benefits or is controlled by such a person.

§ 215.3 Definitions.

For the purposes of this part, the following definitions apply:

(a) “Company” means any corporation, partnership, trust (business or otherwise), association, joint venture, pool syndicate, sole proprietorship, unincorporated organization, or any other form of business entity not specifically listed herein. However, the term does not include (1) an insured bank (as defined in 12 U.S.C. 1813(ch)) or (2) a corporation the majority of the shares of which are owned by the United States or by any State.

(b)(1) “Control of a company or bank” means that a person directly or indirectly, or acting through or in concert with one or more persons:

(i) Owns, controls, or has the power to vote 25 percent or more of any class of voting securities of the company or bank;

(ii) Controls in any manner the election of a majority of the directors of the company or bank; or

(iii) Has the power to exercise a controlling influence over the management or policies of the company or bank.

(2) A person is presumed to have control, including the power to exercise a controlling influence over the management or policies, of a company or bank if:

(i) The person is (A) an executive officer or director of the company or bank and (B) directly or indirectly owns, controls, or has the power to vote more than 10 percent of any class of voting securities of the company or bank; or

(ii) (A) The person directly or indirectly owns, controls, or has the power to vote more than 10 percent of any class of voting securities of the company or bank, and (B) no other person owns, controls, or has the power to vote a greater percentage of that class of voting securities.

(3) An individual is not considered to have control, including the power to exercise a controlling influence over the management or policies, of a company or bank solely by virtue of the individual’s position as an officer or director of the company or bank.

(d) A person may rebut the presumption established by paragraph (b)(2) of this section by submitting to the appropriate Federal banking agency (as defined in 12 U.S.C. 1813(q)) written materials that, in the agency’s judgment, demonstrate an absence of control.

(e) “Director of a member bank” includes (1) any director of a member bank, whether or not receiving compensation, (2) any director of a bank holding company (as defined in 12 U.S.C. 1841(a)) of which the member bank is a subsidiary, and (3) any director of any other subsidiary of that bank holding company. An advisory director is not considered a director if the advisory director (1) is not elected by the shareholders of the company or bank, (2) is not authorized to vote on matters before the board of directors, and (3) provides solely general policy advice to the board of directors.

(f) “Executive officer” of a company or bank means a person who participates or has authority to participate (other than in the capacity of a director) in major policymaking functions of the company or bank, whether or not:

(1) The officer has an official title, (2) the title designates the officer as an assistant, or (3) the officer is serving without salary or other compensation.1 The chairman of the board, the president, every vice president, the cashier, the secretary, and the treasurer of a company or bank are executive officers, unless (1) the officer is excluded, by resolution of the board of directors or by the bylaws of the bank or company, from participation (other than in the capacity of a director) in major policymaking functions of the bank or company, and (2) the officer does not actually participate therein. For the purpose of §§ 215.4 and 215.7 below, an executive officer of a member bank includes an executive officer of (1) a bank holding company (as defined in 12 U.S.C. 1841(a)) of which the member bank is a subsidiary and (2) any other subsidiary of that bank holding company, unless the executive officer of the subsidiary (i) is excluded (by name or by title) from participation in major policymaking functions of the member bank by resolutions of the boards of directors of both the subsidiary and the member bank, and (ii) does not actually participate in such major policymaking functions.

1The term is not intended to include persons who may have official titles and may exercise a certain measure of discretion in the performance of their duties, including discretion in the making of loans, but who do not participate in the formulation of major policies of the bank or company and whose decisions are limited by policy standards fixed by the senior management of the bank or company. For example, the term does not include a manager or assistant manager of a branch of a bank unless that branch is not under the supervision of an executive officer or director of the member bank.

(g) “Member bank” means any banking institution that is a member of the Federal Reserve System. The term does not include any foreign bank (as defined in 12 U.S.C. 3101(b)(7)) that maintains a branch in the United States, whether or not the branch is insured (within the meaning of 12 U.S.C. 1813(b)(6)) or banked in the operation of 12 U.S.C. 1813(h) and 12 U.S.C. 1828(j)(2).

(h) “Pay an overdraft on an account” means to pay an amount upon the order of an account holder in violation of the provisions of section 197 of the Federal Reserve Act (12 U.S.C. 375m(197)).
excess of funds on deposit in the account.

(1) "Person" means an individual or a company.
(i) "Principal shareholder" means an individual or a company (other than an insured bank) that directly or indirectly, acting through or in concert with one or more persons, owns, controls, or has the power to vote more than 10 percent of any class of voting securities of a member bank or company. However, for the purposes of §215.4(c) below, this percentage shall be "more than 10 percent" if the member bank is located in a city, town, or village with a population of less than 30,000. Shares owned or controlled by a member of an individual's immediate family are considered to be held by the individual. A principal shareholder of a member bank includes (1) a principal shareholder of a bank holding company (as defined in 12 U.S.C. 1841(a)(a)) of which the member bank is a subsidiary and (2) a principal shareholder of any other subsidiary of that bank holding company.

(k) "Related interest" means (1) a company that is controlled by a person or (2) a political or campaign committee that is controlled by a person or the funds or services of which will benefit a person.

(1) "Subsidiary" has the meaning given in 12 U.S.C. 1841(d), but does not include a subsidiary of a member bank.

§215.3 Extension of credit.

(a) An extension of credit is a making or renewal of any loan, a granting of a line of credit, or an extending of credit in any manner whatsoever, and includes:

(1) A purchase under repurchase agreement of securities, other assets, or obligations;

(2) An advance by means of an overdraft, cash item, or otherwise;

(3) An issuance of a standby letter of credit, or other similar arrangement regardless of name or description; or an ineligible acceptance, as those terms are defined in §208.3(d) of this chapter;

(4) An acquisition by discount, purchase, exchange, or otherwise of any note, draft, bill of exchange, or other evidence of indebtedness upon which a person may be liable as maker, drawer, endorser, guarantor, or surety;

(5) A discount of promissory notes, bills of exchange, conditional sales contracts, or similar paper, whether with or without recourse; but the acquisition of such paper by a member bank from another bank, without recourse, shall not be considered a discount by the member bank for the other bank;

(6) An increase of an existing indebtedness, but not if the additional funds are advanced in its own protection for (i) accrued interest or (ii) taxes, insurance, or other expenses incidental to the existing indebtedness;

(7) An advance of unearned salary or other unearned compensation for a period in excess of 30 days; and

(8) Any other transaction as a result of which a person becomes obligated to pay money (or its equivalent) to a bank, whether the obligation arises directly or indirectly, or because of an endorsement on an obligation or otherwise, or by any means whatsoever.

(b) An extension of credit does not include:

(1) An advance against accrued salary or other accrued compensation, or an advance for the payment of authorized travel or other expenses incurred or to be incurred on behalf of the bank;

(2) A receipt by a bank of a check deposited in or delivered to the bank in the usual course of business unless it results in the carrying of a cash item for or the granting of an overdraft other than an inadvertent overdraft in a limited amount that is promptly repaid, as described in §215.4(d) below;

(3) An acquisition of a note, draft, bill of exchange, or other evidence of indebtedness through (i) a merger or consolidation of banks or a similar transaction by which a bank acquires assets and assumes liabilities of another bank or similar organization or (ii) foreclosure on collateral or similar proceedings for the protection of the bank Provided, That such indebtedness is not held for a period of more than three years from the date of the acquisition, subject to extension by the appropriate Federal banking agency for good cause shown;

(4) An endorsement or guarantee for the protection of a bank of any loan or other asset previously acquired by the bank in good faith or (i) any indebtedness to a bank for the purpose of protecting the bank against loss or of giving financial assistance to it; or

(5) Indebtedness of $5,000 or less arising by reason of any general arrangement by which a bank (i) acquires charge or time credit accounts or (ii) makes payments to or on behalf of participants in a bank credit card plan, check credit plan, Interest bearing overdraft credit plan of the type specified in §215.4(d) below, or similar openend credit plan: Provided: (A) The indebtedness does not involve prior individual clearance or approval by the bank other than for the purposes of determining authority to participate in the arrangement and compliance with any dollar limit under the arrangement, and (B) the indebtedness is incurred under terms that are not more favorable than those offered to the general public.

(c) Non-Interest-bearing deposits to the credit of a bank are not considered loans, advances, or extensions of credit to the bank of deposit; nor is the giving of immediate credit to a bank upon uncollected items received in the ordinary course of business considered to be a loan, advance or extension of credit to the depositing bank.

(d) For purposes of §215.4(b) and (c) below, the transaction of credit by a member bank is considered to have been made at the time the bank enters into a binding commitment to make the extension of credit.

(e) A participation without recourse is not an extension of credit by the participating bank, not by the originating bank.

(1) An extension of credit is considered made to a person covered by this part to the extent that the proceeds of the extension of credit are used for the tangible economic benefit of, or are transferred to, such a person.

§215.4 General prohibitions.

(a) Terms and Creditworthiness. No member bank may extend credit to any of its executive officers, directors, or principal shareholders or to any related interest of that person unless the extension of credit: (1) Is made on substantially the same terms and conditions, including interest rates and collateral, as those prevailing at the time for comparable transactions by the bank with other persons that are not covered by this part and who are not employed by the bank, and (2) does not involve more than the normal risk of repayment or present other unfavorable features.

(b) Prior Approval. (1) No member bank may extend credit or guarantee any credit to any of its executive officers, directors, or principal shareholders or to any related interest of that person in an amount that, when aggregated with the amount of all other extensions of credit to such a person, exceeds $25,000, unless (i) the extension of credit or line of credit has been approved in advance by a majority of the entire board of directors of that bank and (ii) the interested party has abstained from participating directly or indirectly in the voting.

(2) Approval by the board of directors under paragraph (b)(1) of this section is not required for an extension of credit that is made pursuant to a line of credit that was approved under paragraph (b)(1) of this section within 14 months of the date of the uncollected items received in the extension of credit must also be in compliance with the requirements of §215.4(a) above.
(3) Participation in the discussion, or any attempt to influence, by the board of directors regarding an extension of credit constitutes indirect participation in the voting by the board of directors on an extension of credit.

(c) Aggregate Lending Limit. No member bank may extend credit to any of its executive officers or principal shareholders or to any related interest of that person \(^4\) in an amount that, when aggregated with the amount of all other extensions of credit by the member bank to that person and to all related interests of that person, exceeds the lending limit of the member bank specified in §215.2(f) above. This prohibition does not apply to an extension of credit by a member bank to a bank holding company (as defined in 13 U.S.C. 1841(a)) of which the member bank is a subsidiary or to any other subsidiary of that bank holding company.

(d) Overdrafts. No member bank may pay an overdraft of an executive officer or director of the bank \(^5\) on an account at the bank, unless the payment of funds is made in accordance with (1) a written, preauthorized, interest-bearing extension of credit plan that specifies a method of repayment or (2) a preauthorized transfer of funds from another account of the account holder at the bank. This prohibition does not apply to payment of inadvertent overdrafts on an account in an aggregate amount of $1,000 or less: Provided, (1) The account is not overdrawn for more than 5 business days, and (2) the member bank charges the executive officer or director the same fee charged any other customer of the bank in similar circumstances.

§215.5 Additional restrictions on loans to Executive Officers of Member Banks.

(a) No member bank may extend credit to any of its executive officers, \(^6\)

\(^4\)This prohibition does not apply to member bank loans to a director of the member bank or to a related interest of the director, unless the director is also an executive officer or principal shareholder. See also the definition of principal shareholder in §215.2(c) above. In the case of a member bank located in a city, town or village with a population of less than 30,000.

\(^5\)This prohibition does not apply to the payment by a member bank of an overdraft of a principal shareholder of the member bank, unless the principal shareholder is also an executive officer or director of the member bank. This prohibition also does not apply to the payment by a member bank of an overdraft of a related interest of an executive officer, director, or principal shareholder of the member bank.

\(^6\)Sections 215.5, 215.8 and 215.9 of Regulation O implement section 212(g) of the Federal Reserve Act. As applied to member banks. For the purposes of these sections, an executive officer of a member bank does not include an executive officer of a bank holding company of which the member bank is a subsidiary or any other subsidiary of that bank holding company.

(b) No member bank may extend credit in an aggregate amount greater than $10,000 outstanding at any one time to a partnership in which one or more of the executive officers of the member bank are partners and, either individually or together, hold a majority interest. For the purposes of paragraph (c)(3) of this section, the total amount of credit extended by a member bank to such partnership is considered to be extended to each executive officer of the member bank who is a member of the partnership.

(c) A member bank is authorized to extend credit to an executive officer of the bank in an aggregate amount not to exceed:

1. $20,000 outstanding at any one time to finance the education of the executive officer's children;
2. $60,000 outstanding at any one time to finance the purchase, construction, maintenance, or improvement of a residence of the executive officer, if the extension of credit is secured by the residence and the residence is owned (or expected to be owned after the extension of credit) by the executive officer; and
3. $10,000 outstanding at any one time for a purpose not otherwise specifically authorized under this paragraph.

(d) Any extension of credit by a member bank to any of its executive officers shall be: (1) Promptly reported to the member bank's board of directors; (2) in compliance with the requirements of §215.2(a) above; (3) preceded by the submission of a detailed current financial statement of the executive officer; and (4) made subject to the condition that the extension of credit will, at the option of the member bank, become due and payable at any time that the officer is indebted to any other bank or banks in an aggregate amount greater than the amount specified for a category of credit in paragraph (c) of this section.

§215.6 Extensions of credit outstanding on March 10, 1979.

(a) Any extension of credit that was outstanding on March 10, 1979, and that would, if made on or after March 10, 1979, violate §215.4(c)(a) above, shall, within 10 days of the date the indebtedness reaches such a level, make a written report to the board of directors of the officer's bank. The report shall state the lender's name, the date and amount of each extension of credit, any security for it, and the purposes for which the proceeds have been or are to be used.

§215.9 Reports by Member Banks.

Each member bank shall include with any report made to the Federal Reserve Bank or the Comptroller of the Currency, in the case of a national bank, or to the appropriate Federal Reserve Bank, in the case of a State member bank, and explain the reasons why all the extensions of credit cannot be brought into compliance. The Comptroller or the Reserve Bank, as the case may be, is authorized, on the basis of good cause shown, to extend the March 10, 1980, date for compliance for any extension of credit for not more than two additional one-year periods.

§215.7 Records of Member Banks.

Each member bank shall maintain records necessary for compliance with the requirements of this part. These records shall (a) identify all executive officers, directors, and principal shareholders of the member bank and the related interests of these persons and (b) specify the amount and terms of each extension of credit by the member bank to these persons and to their related interests. Each member bank shall request at least annually that each executive officer, director, or principal shareholder of the member bank identify the related interests of that person.

§215.8 Reports by Executive Officers.

Each executive officer \(^7\) of a member bank who becomes indebted to any other bank or banks in an aggregate amount greater than the amount specified for a category of credit in §215.4(c) above, shall, within 10 days of the date the indebtedness reaches such a level, make a written report to the board of directors of the officer's bank. The report shall state the lender's name, the date and amount of each extension of credit, any security for it, and the purposes for which the proceeds have been or are to be used.

\(^7\)See note 4 above.
§ 215.10 Civil penalties.

As specified in section 29 of the Federal Reserve Act (12 U.S.C. 504), any member bank, or any officer, director, employee, agent, or other person participating in the conduct of the affairs of the bank, that violates any provision of this section, subject under this section to any limitation.

Effective date: March 10, 1979.


THEODORE E. ALLISON,
Secretary of the Board.

APPENDIX.—Section 5200 of the Revised

The total obligations to any national banking association of any person, copartnership, association, or corporation shall at no time exceed 15 per centum of the amount actually paid in and unimpaired and 10 per centum of its unimpaired surplus. The term "obligations" shall include the direct liability of the maker or acceptor of paper discounting with or sold to such association and the liability of the indorser, drawer, or assignee of notes or drafts secured by shipping documents, warehouse receipts, or other such documents, warehouse receipts, or other such documents transferred or securing title covering refrigerated or frozen readily marketable staples when such property is fully covered by insurance, if it is customary to insure such staples and such liability is subject under this section to any limitation.

The total obligations of a public housing agency (as defined in section 1460(h) of Title 42) or of a public housing association (as defined in the United States Housing Act of 1937, as amended); which have a maturity of not more than eighteen months shall not be subject under this section to any limitation. If obligations are secured by guarantees of any corporation wholly owned directly or indirectly by the United States: Provided, That such guarantees, agreements, or commitments are unconditional and must be paid on the payment of cash or its equivalent within 60 days after demand. The Comptroller of the Currency is hereby authorized to define the term "wholly owned" if and when he deems it necessary.

Of a local public agency (as defined in section 1460(h) of Title 42) or of a public housing agency (as defined in the United States Housing Act of 1937, as amended); which have a maturity of not more than eighteen months shall not be subject under this section to any limitation. If such obligations are secured by an agreement between the obligor agency and the Secretary of Housing and Urban Development in which the agency agrees to accept from the Secretary, and the Secretary agrees to lend to the agency, prior to the maturity of such obligations, monies in an amount which (together with any other monies irrevocably committed to the payment of interest on such obligations) will suffice to pay the principal of such obligations on maturity and with interest as set forth in such agreement, which monies under the terms of said agreement are required to be used for that purpose.
(12) Obligations insured by the Secretary of Agriculture pursuant to the Bankhead-Jones Farm Credit Act, as amended, or the Act of August 28, 1937, as amended (relating to the conservation of water resources), or sections 1471-1485 of Title 42, shall be subject under this section to a limitation of 15 per centum of such capital and surplus in addition to such 10 per centum of such capital and surplus.

(13) Obligations as endorser or guarantor of negotiable or non-negotiable installment consumer paper which carries a full recourse endorsement or unconditional guarantee by the person, copartnership, association, or corporation transferring the same, shall be subject under this section to a limitation of 15 per centum of such capital and surplus in addition to such 10 per centum of such capital and surplus.

RULING:
The Board has decided to: (1) Rescind Regulation S as no longer necessary; (2) revise and update its interpretations; and (3) send to State member banks through the Reserve Banks an announcement and explanation of the new provisions. The Board's actions to amend the regulation and interpretation, and the revision of the interpretations will not impose any new requirements not contained in the Act.

EFFECTIVE DATE: March 10, 1979.

FOR FURTHER INFORMATION CONTACT:

Supplementary information:
The Bank Service Corporation Act (the “Act”) (12 U.S.C. 1861-65), as originally adopted, required that, when a State member bank has bank services performed for it (such as check sorting and posting of interest on savings accounts), satisfactory assurances must be furnished to the Board that the performance of the services will be subject to the Board's regulation and examination to the same extent as if the services were being performed by the bank itself on its own premises. The purpose was to make certain that the appropriate Federal banking agency not be frustrated in its examination of a bank subject primarily to its supervision because the bank's records have been transferred to another organization or some other organization is carrying out part or all of the bank's functions. Regulation S, “Bank Service Arrangements” (12 CFR Part 219), was issued by the Board in 1963 to implement the Act by specifying when and in what form assurances shall be provided to the Federal Reserve System.

However, the Congress has taken a more direct approach to supervision of bank service arrangements through an amendment of the Act contained in section 303 of the Financial Institutions Regulatory and Interest Rate Control Act of 1978 (Pub. L. 95-630; 92 Stat. 3677). Effective March 10, 1979, the performance of bank services for State member banks or their subsidiaries or affiliates will be subject to regulation and examination by the Board as a matter of law without the necessity for “assurances.” A State member bank will be required to notify the Board of the existence of a bank service arrangement within 30 days after the making of the service contract, or the performance of the service, whichever occurs first. In the course of reviewing Regulation S in its Regulatory Improvement Project, the Board has concluded that the regulation will no longer be necessary and should be rescinded in the light of the legislative change. The provisions regarding “assurances” will become obsolete. The only provision of the regulation that will continue to have effect is the rule that the performance of legal, advisory, and administrative services, such as transportation of guard service, is subject to examination unless specifically requested by the Board. This rule, which essentially is an interpretation of the term “bank services” in section 1(b) of the Act (12 U.S.C. 1861(b)), will be incorporated in the Board's published interpretations. No new regulatory provisions are considered necessary to reflect the recent amendment of the Act.

As in the past, the letter notifying the Board of the bank service arrangement is to be sent to the Federal Reserve Bank in whose district the State member bank has its main office. If a bank has an existing bank service arrangement on March 10, 1979, and has already furnished assurances regarding the arrangement in compliance with Regulation S, no additional notification regarding the arrangement is necessary.

As a further effort to improve its regulations, the Board is revising, updating, and streamlining its interpretations. The only substantive rulings being added are taken from: (1) An interpretation published in the Federal Reserve Bulletin (40 Fed. Reg. 1429 (1962)) but not in the Code of Federal Regulations; and (2) the last sentence of section 219.4 relating to legal, advisory, and administrative services (discussed above).

The Board is also adding a short summary paragraph at the beginning of each interpretation to facilitate the public's finding of information and lessen the burden of reading materials that may not be relevant to the researcher's interest. Of course, if reliance is to be placed upon the interpretation, the full text must be consulted since the summary is only a paraphrase of the ruling rather than the ruling itself.

The Board is asking the Federal Reserve Banks to notify State member banks of the statutory and regulatory changes and to explain compliance with the amended Act.

The procedures of 5 U.S.C. 553(b) regarding notice, public participation and deferred effective date were not followed in connection with the regulatory changes because: (1) The Board finds that public participation is unnecessary since the rescission of the regulation will result in neither the granting of authority to the persons regulated, nor the imposition or relaxing of any requirements; and (2) rulemaking procedures do not apply to...
interpretive rules. For similar reasons, the expanded rulemaking procedures set forth in the Board’s policy statement of January 15, 1975 (44 F.R. 3057) do not apply.

To implement these regulatory changes, the following actions are being taken under the Board’s authority in 12 U.S.C. 1861-65:

**PART 219—[REVOKED]**

1. 12 CFR Part 219 is hereby revoked.*

**PART 250 MISCELLANEOUS INTERPRETATIONS**

2. The table of contents of 12 CFR Part 250 is amended by adding at the end of the table a new heading and three new section titles to read as follows:

-BANK SERVICE ARRANGEMENTS-

-§ 250.300 Kinds of bank-servicers subject to Board examination under the Bank Service Corporation Act.

-§ 250.301 Scope of investment authority and notification requirement under the Bank Service Corporation Act.

-§ 250.302 Applicability of Bank Service Corporation Act to bank credit card service organization.

-3. 12 CFR Part 250 is amended by adding new sections §§ 250.300–250.302 immediately after a new heading, “BANK SERVICE ARRANGEMENTS,” to read as follows:

-BANK SERVICE ARRANGEMENTS-

-§ 250.300 Kinds of bank-servicers subject to Board examination under the Bank Service Corporation Act.

-§ 250.301 Scope of investment authority and notification requirement under the Bank Service Corporation Act.

-§ 250.302 Applicability of Bank Service Corporation Act to bank credit card service organization.

Text (a) Section 2(a) of the Bank Service Corporation Act (12 U.S.C. 1861-65) provides that “no limitation or prohibition otherwise imposed by any provision of Federal law exclusively relating to banks shall prevent any two or more banks from investing not more than 10 per cent of the paid-in and unimpaired capital and unimpaired surplus of each of them in a bank service corporation.” This 10 percent investment ceiling applies to loans and other advances of funds, as well as the purchase of stock. The Act, however, does not authorize a State bank to invest in a bank service corporation if the bank is not permitted to do so under the applicable State law.

(b) “Bank service corporation” is defined in section 10(c) of the Act to mean “a corporation organized to perform bank services for two or more banks, each of which owns part of the capital stock of such corporation, and at least one of which is subject to examination by a Federal supervisory agency.” Section 4 of the Act states that “no bank service corporation may engage in any activity other than the performance of bank services for or on behalf of banks.” Thus, the investment authority created by section 2(a) is limited to corporations that are engaged solely in the provision of “bank services” to banks, as that term is defined in the Act.

(c) In addition to its grant of investment authority, the Act also requires State member banks to notify the Board within 30 days of the execution of a contract for “bank services” or the actual provision of such services, whichever occurs first. Moreover, the Act authorizes the Board to regulate and examine the performance of “bank services.” Thus, the scope of the Act’s notification and examination requirements also is limited to “bank services.”
The term “bank services” is defined in section 1(b) of the Act to mean “services such as check and deposit sorting and posting, computation and posting of interest and other credits and charges, preparation and mailing of checks, statements, notices, and similar items, or any other clerical, bookkeeping, accounting, statistical, or similar functions performed for a bank.”

(c) Bearing importantly upon the meaning of “bank services” is the following quotation from the Report of the Senate Committee on Banking and Currency: “The authority to examine and supervise banks has been, and must be vigorously exercised. At the same time, sound discipline must be used. Banks have always employed others to do many things for them, and they will have to continue to do so, and the bill is not intended to prevent this or to make it more difficult. For example, banks have employed lawyers to prepare trust and estate accounts and to prosecute judicial proceedings for the settlement or administration of estates. They have employed accountants to prepare earnings statements and balance sheets. Banks have employed public relations and advertising firms. And banks have employed individuals or firms to perform all kinds of administrative activities, including armored car and other transportation services, guard services and, in many cases, other mechanical services needed to run the bank’s buildings. It is not expected that the banking regulatory agencies would find it necessary to examine or regulate any of these agents or representatives of a bank, except under the most unusual circumstances. The authority is intended to be limited to banking functions as such.” (S. Rep. No. 2105, 87th Cong. 3 (1922)).

(1) On the basis of the Act’s definition of “services,” the limitation contained in section 4 of the Act, and the preceding quotation from the Act’s legislative history, it is apparent that the term “bank services” is essentially limited to clerical and similar services. The term would not usually be regarded as including legal, advisory, and administrative services, such as transportation or guard services.

(g) Thus, State member banks generally may rely on the Act to justify investment only in a corporation that is engaged solely in performing one or more of the services contained in the Act, as amended, and only if those services are provided solely to banks. Investment in a corporation providing any other services, such as the type of services described in the above quotation from the Act’s legislative history, generally is not permitted on the basis of the Act, unless such services are legitimately incidental to the provision of “bank services” by that corporation.

(ii) Since the notification required by section 5 of the Act, as amended, also is based on the provision of “bank services,” such notification need only be provided with regard to the provision of one or more of the services enumerated in section 1(b) of the Act as a service similar to one of those services.

§ 250.302 Applicability of Bank Service Corporation Act to bank credit card service organization.

**Summary.** Although a non-profit, no-stock service organization in which no bank has made an investment is not a “bank service corporation” as defined in the Bank Service Corporation Act, that organization’s credit card servicing activities are “bank services” as defined in the Act and thus subject to the notification requirement of section 5 of the Act.

The Board of Governors has considered whether the Bank Service Corporation Act (12 U.S.C. 1861-65), is applicable where a bank credit card plan of a State member bank and other banks used the facilities of a non-profit, no-stock service organization.

(b) The functions of the service organization include the following: (1) Performing cardholder accounting for participating banks; (2) developing information concerning each credit card and holder, including such holder’s current balance owing to the card issuing bank and the amount of such balance that is delinquent; (3) assisting in procedures relating to the presentation and settlement of drafts and credit memoranda; (4) assisting in procedures relating to the presentation and settlement of drafts and credit memoranda; (4) developing procedures relating to credit card security control; (5) upon telephonic request, advising merchants and participating banks respecting credit authorizations above certain specified limits; and (6) compiling lists of participating merchants.

(c) The Board expressed the view that because the service organization has no stock and the State member bank does not otherwise invest therein by “the making of a loan, or otherwise, except a payment for rent earned, goods sold and delivered, or services rendered prior to the making of such payment” (section 1(d) of the Act), the service organization is not a “bank service corporation” within the meaning of section 1(e) of the Act.

(d) However, the Board concludes that the functions described above do constitute “bank services” as defined in section 1(b) of the Act. Accordingly, the State member bank is required to notify the Board (through the appropriate Federal Reserve Bank) of the performance of the services for the bank in accordance with section 5 of the Act.

**Effective date:** March 10, 1979.


THEODORE E. ALLISON, Secretary of the Board.

[FR Doc. 79-7207 Filed 3-8-79; 8:45 am]

[6210-01-M]

PART 226—TRUTH IN LENDING

Amendment to Regulation Z to Conform to Statutory Change Prohibition Against Surcharges; Extension

AGENCY: Board of Governors of the Federal Reserve System.

**ACTION:** Final rule.

**SUMMARY:** Section 226.4(d)(4) of Regulation Z, which implements section 167(a) of the Truth in Lending Act (15 U.S.C. 1604), makes it illegal for a creditor to impose a surcharge because payment for goods or services is made by credit card. This prohibition was due to expire on February 27, 1979.

On November 10, 1978, the Financial Institutions Regulatory and Interest Rate Control Act (Pub. L. 95-530) was enacted. Section 1501 of that law (92 Stat. 2713) extended the prohibition against surcharges to February 27, 1981. Section 226.4(d)(4) of Regulation Z is being amended to conform to that statutory extension.

In accordance with § 262.2(e) of its regulations (12 CFR 262.2(e)), the Board deems it unnecessary to publish this regulatory amendment for comment prior to final adoption.

**EFFECTIVE DATE:** March 5, 1979.

FOR FURTHER INFORMATION CONTACT:


**TEXT OF AMENDMENT:**

Pursuant to the authority granted under section 105 of the Truth in Lending Act (15 U.S.C. 1604), the Board amends Regulation Z, 12 CFR 226.4(d)(4), to read as follows:

§ 226.4 Determination of finance charge.

(1) * * *

(4) No creditor in any sales transaction may impose a surcharge. This
SUPPLEMENTARY INFORMATION:
By a notice of proposed rulemaking, SPD-50B, 43 FR 38907, September 7, 1978, the Board proposed consumer protection amendments to its Public Charter rule, 14 CFR Part 380. The proposal was based on an April 1976 petition by the Board's former Office of the Consumer Advocate (since merged into the Bureau of Consumer Protection) and on the comments on SPD-80, 41 FR 45024, October 14, 1976, an advance notice of proposed rulemaking.

The proposed amendments would entitle participants to refunds when there are major changes in their charter packages. This would be done by requiring operator-participant contracts to contain certain terms and making the refunds a direct regulatory obligation. SPD-50B also proposed to improve participants' awareness of what they will and will not get, and what risks may be involved, when they purchase charter trips. This would be done by (1) requiring charter advertising to include certain information, (2) requiring charter operators to obtain signed contracts from prospective participants before collecting any money from them, (3) establishing print size requirements for the contracts, and (4) requiring a space on the contract form for participants to request details of optional insurance. Simplified procedures for filling Public Charter prospectuses were also proposed. Finally, SPD-50B invited comments on the possibility of requiring operators to obtain permits before marketing charters.

Simplified procedures for franchising of consumer agencies and organizations, air carriers and air carrier associations, charter operators and operator associations, a travel agents' association, and others. For the reasons discussed below we have decided against a permit or licensing requirement and generally in favor of the rest of the proposal, with some changes in detail.

PRELIMINARY MATTERS
Section 401(n)(2) of the Federal Aviation Act of 1958, as amended by the Airline Deregulation Act of 1978, Pub. L. 95-504, states that "no rule, regulation, or order of the Board shall restrict the marketability, flexibility, accessibility, or variety of charter trips, or, in any manner, restrict the flexibility of charter tours." Some commenters have cited this language to argue that the Board should not be issuing this rule. This, however, ignores key legislative history. Congress specifically contemplated the adoption of consumer protection rules like these. SPD-50B was outstanding when the Deregulation Act was passed, and the Conference Report stated that:

"The limitations on the Board's power to restrict the flexibility of charter tours is not intended to limit the Board's authority to adopt regulations for the protection of consumers. H. Rept. No. 95-1778, October 12, 1978, p. 63.

Therefore, there is no statutory bar to adoption of this rule.

Nevertheless, some commenters would have us terminate this rulemaking and leave the matter of charter consumer protection to the Federal Trade Commission (FTC) suggesting that that agency is a more appropriate one to adopt this sort of rule. The FTC itself, however, does not agree, and advocates the adoption of our proposal. It feels that it is reasonable for operators who have allocated between operators and participants, the burden of the uncertainty that is inherent in charter transportation. The FTC stated that the rule could go a long way toward protecting consumers, that it would mean only further delay. The Commission also concluded that the continued consumer abuses by charter operators would necessitate entirely different remedies. Moreover, to wait for another proposal to be developed and published and for comments to be submitted and analyzed would mean only further delay. The Board's staff will continue to monitor consumer abuses by scheduled tour operators. It cannot seriously be contended, however, that the continued viability of the charter mode depends entirely on the kinds of unfair practices that we are prohibiting here.

The National Air Carrier Association (NACA) asserts that we should hold an evidentiary hearing to determine whether the rule should be expanded to include tour operators using scheduled service. This proceeding is clearly rulemaking as defined in the Administrative Procedure Act, 5 U.S.C. 551 et seq. (APA) and the procedures fol-
lowed have been in accordance with those prescribed in that Act. An oral hearing on the merits is not legally required, nor is one needed. The problems addressed in this proceeding have surfaced many times in our staff’s review of charter prospectus filings and enforcement investigations of charter operators.

All parties have been afforded the opportunity to submit arguments in initial and reply comments. Affected persons have thus had ample opportunity to make their case in this proceeding. Nothing in the comments has persuaded the Board that oral proceedings would be of help to the Board or would serve any purpose other than delay. Therefore, the Board finds that it would not be in the public interest to postpone its decision pending further proceeding.

That this proceeding is rulemaking and not adjudicative in nature is also fatal to NACA’s claim that the personnel of the Bureau of Consumer Protection (BCP) are barred from any non-public ex parte participation in the development of the rule. The APA’s separation of functions requirement, 5 U.S.C. 554(d), applies only to adjudications, which by definition do not include rulemaking. Similarly, the Board’s separation of functions rule, 14 CFR 300.4(a), on which NACA relies, applies only to hearing cases. The relevant provisions for rulemaking proceedings are found in 14 CFR 300.2, which addresses only communications between Board employees and any person who is not a Board employee.

It is true that this proceeding began with a publicly filed petition from the Board’s former Office of the Consumer Advocate (OCA). The public filing reflected the then-current view that a quasi-independent office could provide more effective representation of consumer interests in Board proceedings than a regular staff component. The staff of OCA were at all times the Board’s own employees, to whom the Board was entitled to turn for advice. Accordingly, the Board finds that there is nothing improper in the former OCA staff or any other Board employees acting as a part of the agency and giving advice on this matter.

Several commenters suggested that we establish a consumer protection fund and arbitration procedure for resolution of charter consumer disputes. Although this might well be a good idea and will be examined further, it does not justify postponing this rule. Even if such a remedial scheme were to be adopted, it would supplement, and not substitute for, the scheme we are adopting today. The fund and arbitration procedure are only a method to simplify litigation and to protect participants from tour operator defaults due to insolvency. Such a system is of no use to a consumer who cannot use it because the operator-participant contract is unfair to begin with. The consumer protection rule we are adopting here should help to ensure the participant fair treatment by the operator or, if necessary, from a court or arbitrator.

LICENSING

In SPDR-50B, we invited comments on a possible requirement that charter operators obtain a permit before doing business, while indicating reluctance to impose any such licensing scheme. The reasons for this reluctance were described in that notice and SPDR-50, the advance notice, and were largely concurred in by the commenters.

Many of these commenters feared that our proposed system would be burdensome and could be used to restrict entry, thereby resulting in increased competition and increased consumer protection. On the other hand, the FTC thought that our proposal, in which permits would be granted and renewed freely, with only a record of previous non-compliance with the regulations as an impediment to continued operation, was too speculative to be defensible. Others hoped that licensing would improve the charter operators’ image and ensure some formal review of them. Nevertheless, many of these supporters of licensing still feared that the scheme could gain a momentum of its own and eventually be used in ways that are anticompetitive or burdensome.

We share these concerns and in addition feel that the beneficial aspects of licensing can be achieved by other, less burdensome means. We are amending the exemption set forth in §380.20, which constitute the operator’s basic authority to enter into a charter operation. In its current form, the exemption is contingent only on the operator’s compliance with Part 380. Moreover, the exemption attaches to flights or flight programs, so that a noncompliance only terminates the exemption for the particular flight or flights with respect to which it occurred. Termination of the exemption thus provides little if any sanction beyond that for the noncompliance itself. We are therefore amending §380.20 to make the exemption depend also on compliance with any special conditions that have been imposed on that operator to ensure compliance with the rest of Part 380. Among the conditions might be prior approval of operator-participant contracts or solicitation materials, or that prospectuses include evidence of binding commitments for hotel rooms. The need for such conditions in particular cases would be the subject of a Board proceeding.

The Airline Deregulation Act recently granted the Board the power to impose civil penalties, which can serve as an extra deterrent to potential offenders. This power and the opportunity to impose conditions on exemptions reduce the need for permits as a prerequisite to entry. The Act also establishes a policy that is opposed to additional restraints on market entry. These factors, with our own policy of avoiding unneeded regulatory burdens, convince us that our initial reluctance was justified and that a licensing scheme should not be adopted at this time.

MAJOR CHANGES

The most important and widespread problem with charters addressed by the proposal is major changes in the charter program relative to what the participants expect. In the most typical situation, the operator has reserved the right, in the contract with the participant, to make the substitu- tion or other amendments that the participant later objects to. The issue is therefore how much freedom the operator will have to include these clauses in its contracts. In order to deal with this problem, certain changes in cities, dates, hotels, etc. are proposed to be defined as major, regardless of the contract’s terms. For major changes that operators knew about before departure, the participant would be entitled to cancel and receive a full refund. For major changes that the operator did not know about until after departure, the participant could reject the substituted hotel or flight and receive a partial refund. The practical effect of this scheme would be to prohibit charter operators from reserving the right to make major changes freely.

This general approach was supported by the FTC, the American Society of Travel Agents (ASTA), the U.S. Office of Consumer Affairs (OCA/HEW), the New York City Department of Consumer Affairs, the Aviation Consumer Action Project (ACAP), and others as a necessary step to ensure fair treatment of charter passengers. It was opposed by NACA, the Air Charter Tour Operators Association (ACTOA), the United States Tour Operators Association (USTOA), and many charter operators as unnecessarily burdensome and unfair to charter operators. Some suggested that to cover the risk of cancel- lations, operators would have to raise their prices to such an extent that charters would become unmarketable. As we stated in SPDR-50B, however:

To the degree that costs would increase for operators who make major changes often, this approach may be viewed as cutting off the extreme low end of the scale of price/service options for consumers. The changes that would be de-

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
nation cities.

The comments have not persuaded us to abandon this general approach, particularly in the charter context, and the details of the rule, discussed below, will reduce the burden of compliance.

Cities. SPDR-50B proposed that any change in the origin or destination city of any leg of a charter be considered major, regardless of the terms of the contract, unless the change would affect merely the order in which cities on a tour were to be visited. The main issue was the treatment of “area fillings.” With an area filing, a charter operator advertises a charter in several different cities as if it will depart from each, or for several destinations as if there will be separate flights to each, when in reality there will only be a single flight. In some cases, passengers have been told at the last minute that their flight will leave from another city, to which they must travel by bus.

Two approaches were proposed to allow operators the flexibility of area fillings while protecting individual participants against unexpected changes. The first option was to allow operators to contract with direct carriers for alternative origin or destination cities, and to test the market in each of these departure cities and for multiple destinations. However, the operator’s contract with each participant could name only one origin city and one destination city. The operator’s selection of the actual cities would constitute a major change for those participants whose contracts named other cities, so they could cancel with a full refund. All solicitation materials would have to disclose that the actual cities had not yet been selected.

The second proposed option was to provide operators more flexibility by allowing individual contracts to name alternative cities. As long as the actual cities were among the named alternatives, there would be no major change and hence no entitlement to a refund. The solicitation materials would have to name all the possible cities and say that the selection would be at the operator’s option. This statement, along with a more specific description of the participant’s lack of cancellation rights, would also have to appear in the contract.

SPDR-50B invited comments not only on these two options, but also combinations of them, including different treatment for origin and destination cities.

Most commenters favored the greater flexibility of the second option. Adventure Tours wanted the Board to give the operators the choice of following either option. (This is implicit in the language that is more liberal than the first.) ACAP and Donald L. Pevsner preferred the first option, fearing that the more stringent disclosure accompanying the second option would be major. Although there is some merit in the FTC suggestion, on balance we find that our available information does not justify imposing this restriction on tour operators. While the absence of a change in the origin city. However, to require disclosure of the alternative cities, in which participants agree to assume these risks in exchange for a presumably lower price. The opportunity to name alternatives might result in not only lower prices, but also a greater availability of charter flights that it would otherwise not be worthwhile to market at all. It becomes particularly important, however, to require disclosure of the alternatives and make sure that operators do not intentionally or recklessly calculate one long enough before departure that participants can adjust their plans.

We have therefore decided to classify operator-participant contracts that name alternative cities in a special category, which we have called “operator-participant option plan” contracts. The rules for this category are set out in new §380.33a. In addition to the information required in all contracts, an operator’s option plan contract must state (1) all the alternative cities, (2) that the selection of the actual cities is at the charter operator’s option and will not entitle the participant to a refund, and (3) that the operator will notify the participant of the selection of the actual cities at least 10 days before departure. This information must be highlighted on the contract form along with other important information, as discussed below under the heading “Operator-Participant Contracts.” The contract form itself must be labeled “OPERATOR’S OPTION PLAN” in bold-faced capital letters at least ¼ inch high. Similarly, all advertising for a charter must, if it states a price for an operator’s option plan contract, clearly and conspicuously (1) identify that price as being for the operator’s option plan, (2) name all the possible cities, and (3) state that the selection of the actual cities is at the charter operator’s option. Also, operators and agents must not misrepresent to prospective participants, either orally or in advertising, the probability that a particular city will be selected. As with the second option, which is more liberal than the first, the operator has notified the participant of its city selection, the use of any other city will be a major change that entitles the participant to a refund, even if that other city is among the alternatives named in the contract.

The FTC said that for tours going to several places, a change in the number of days of stay to which the passenger is committed would be major. Although there is some merit in the FTC suggestion, on balance we find that our available information does not justify imposing this restriction on tour operators.

We have made a small drafting change in the rule’s characterization of cities. As used in the proposal and the discussion above, “origin” and “destination” cities were essentially the same. For example, for a New York-Paris round-trip charter, New York would be the origin city and Paris, the destination. That terminology is inadequate for discussing charters that visit several cities or that do not return to the city from which they began. Therefore, the final rule is stated in terms of the origin and destination city of each flight leg of a charter trip. New York would thus be both the origin city of the outbound leg and the destination city of the return leg in the New York-Paris example.

Dates. As proposed, any change in the departure or return date shown in the operator-participant contract would be major, unless it resulted merely from a flight delay. Such an exception is necessary because even a short flight delay can change the date of a flight scheduled to leave late at

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
night. There was a limit on the exception, based on an already outstanding proposal on flight delays by direct air carriers (EDR-343, 42 FR 46426, December 29, 1977). EDR-343 proposed to allow a direct air carrier 6 hours to provide substitute transportation; after that, the charter operator would be entitled to make its own arrangements at the direct carrier's expense. SPDR-50B proposed to allow the charter operator 6 more hours to secure alternative transportation before a date change (if one occurred during the 12-hour period) would be considered a major change giving participants a right to a refund.

Thus, assuming both rules were adopted as proposed, for a charter scheduled to leave at 11 pm the direct carrier would have until 5 am, and the charter operator until 11 am the next day, to provide transportation. With a 9 am scheduled departure, the direct carrier would have until 3 pm and then the charter operator would have until midnight to provide substitute transportation.

Many charter operators objected to this proposed scheme, arguing that it unfairly made them responsible for the delays caused by direct air carriers. Most of these commenters appear to have misunderstood the scheme, treating the operator's 6-hour period as though it began to run with the originally scheduled departure time. Other commenters, while understanding the proposal, still argued that the operator's 6 hours would not be enough time.

The Board has not yet taken final action on EDR-343, the earlier proposal, and the rule adopted today does not link major changes directly to flight delay protection. Instead, it specifies that any date change that does not result from a flight delay will be considered a major change. So that passengers on delayed flights are not completely unprotected, however, the rule specifies that any delay of more than 48 hours will be considered a major change, entitling them to a refund. After taking final action on EDR-343, we will reexamine this requirement.

To make sure that operators cannot evade the effect of this rule by designating avoidable date changes as flight delays, any date change that the operator knows of more than 2 days before the scheduled departure date will be considered a major change in any event. To our knowledge, there are few bona fide flight delays (e.g., those caused by equipment malfunctions or adverse weather) that the operator knows about more than 2 days in advance.

For the reasons discussed above, under "Cities", we have also decided to allow charter operators to specify alternative dates in their contracts with participants, as long as they follow the operator's option plan rules. The operator must notify participants, of the earliest possible date of the flight before the earliest possible date for the outbound trip, rather than merely 10 days before the actual date. Similarly, if an operator's option plan contract states alternatives for both dates and cities, the operator must give notice of the actual cities at least 10 days before the earliest possible departure date.

Hotels. SPDR-50B proposed that the substitution of any hotel not named in the operator-participant contract be considered a major change. The charter operator could name alternative hotels in the contract, but it could not merely reserve the right to substitute hotels of "similar", "comparable", or "equal" quality since the vagueness of these terms, as a practical matter, permits virtually unlimited substitutions, and this has been a major source of consumer complaints. The proposal would also invite the advisability of requiring operators to include in their prospectuses certifications that they had binding commitments with enough hotels to accommodate a sold-out charter.

The FTC, ACAP, OCA/HEW, New York City Department of Consumer Affairs, and others supported the proposed treatment of hotels as necessary to ensure that participants receive the services that they expect. Many charter operators objected to this aspect of the proposal, arguing that it is unfair to hold the operator responsible when the change is caused by a hotel's overbooking or other failure to honor its commitment to the operator. These commenters also objected to the characterization of terms like "similar" as vague, arguing that they could be made objective by tying them to a rating system of an independent third party. There are too many different rating systems, however, and none of them is well enough accepted to be incorporated into the rule. Moreover, hotels with the same rating could still differ in ways that are important to participants, such as their nearness to a beach. We recognize that hotel changes are often beyond the control of the operator. That does not dispense the rule, however. The real question is how to allocate the risk of these changes between operators and participants, and we remain persuaded that this risk should be imposed on the operator. Since the operator is free to list in the contract as many alternative hotels as it wishes, the imposition is not serious. As we stated in SPDR-50B, the practical effect of this definition would merely be to require operators to be more careful when they begin marketing a charter that they have backup arrangements with enough hotels to accommodate the expected number of participants. At the same time, participants would be put on notice of the full range of possibilities.

The educational tour operators argued that they should be permitted unlimited substitutions, since students do not care where they stay. We are not persuaded that this is true. To the extent that it is, however, students would have no objection to a list of alternative accommodations. The rule therefore includes no special provision for educational tours.

ACAP suggested that operators be required to have binding commitments for hotel rooms when they file prospectuses. Most commenters, however, agreed with the proposal's tentative conclusion that the variety of possible contractual arrangements makes it difficult to state the precise meaning of "binding". Moreover, there does not appear to be a need for such a requirement. This rule guarantees a degree of certainty about hotels to participants. Operators can be expected to obtain whatever degree of commitment from hotels their business judgment dictates is necessary to meet their obligations to participants.

Charter Travel Corporation (CTC) stated that the Board lacks the legal power to make consumer protection rules that affect land arrangements. We find that this contention is without merit, and that the Board has authority derived from both statutory and case law.

Section 411 of the Federal Aviation Act, 49 U.S.C. 1381, gives us the power to "investigate and determine whether any air carrier or ticket agent has or is engaged in unfair or deceptive practices or unfair methods of competition in air transportation or the sale thereof." This section grants the Board jurisdiction over package tours sold in conjunction with air transportation. When tour operators sell air tours, the ground packages are an integral part of the sale of air transportation. The land arrangement is not offered as an enterprise separate from the air transportation, but rather to further the use of that air service. Likewise, the consumer purchases the land package directly with the air transportation. The two aspects of the tour are inextricably tied and can be regulated accordingly.

"Prices." SPDR-50B proposed to define as major any increase of 10 percent or more in the price to a participant that occurs by the 10th day before departure. Price increases after the 10th day would be prohibited outright.

There were three types of opinions on this aspect of the proposal. Some commenters thought that allowing any price increase would open the door to automatic last-minute in-
creases up to the Board's limit. Others considered any ceiling as unfair in the present operator cancellation instability. Most accepted the 10 percent ceiling as a compromise between the participant's interest in protection against last-minute or precipitous increases, and the operator's need to preserve the ability to respond to increases in its costs.

The proposed price provision is not unfair to operators, despite the uncertainty in their costs. In fact, a strong case can be made that during any price increase as major. Price flexibility is rare in other consumer purchase contracts, although it is common in commercial contracts. Retail sellers typically absorb the uncertainty in their costs by pricing their goods or services accordingly. In SPDR-50B, however, we had tentatively selected the 10 percent limit on increases as a compromise, to alleviate the impact of the rule on the sales of the operator.

Several commenters objected to the refund scheme, particularly for hotels. They argued that, instead of being entitled to cancel upon a hotel substitution or reject it for a partial refund if it occurred after departure, the participant would be entitled to receive only a refund of the difference in value between the promised and the substituted hotel. "Difference in value," however, is a subjective concept, since any change could be made. If the operator is not likely to satisfy a participant who is unhappy with the substitute, the amount would usually be far too small to discourage bad faith substitutions. Therefore, the refund scheme is generally adopted as proposed.

There are some changes in the timing of required notifications and refunds, however, in response to objections to the practicability of the proposed deadlines. Many commenters stated that 7 days to provide notice is too short because mailing time will consume an uncertain but substantial portion of that period. Some suggested 10 days as the limit while others argued that notice should be considered made when sent instead of when received. The latter suggestion has been adopted, with a slight change. Where the proposed rule stated that notification be given "in any event before departure", receipt is critical since a mere mailing immediately before departure would be of no help to the participant. The final rule therefore states that, for a change that the operator first knows of less than 10 days before scheduled departure, the operator must get the message to the participant as soon as possible. For a major change that the operator knows of 10 or more days before scheduled departure, the notification must be sent within 7 days after the operator first knows of it, but in any event by the 10th day before departure.

Refunds will also be considered made when sent rather than when received. The time for refunds is extended to 14 days, in recognition of the delay caused by the escrow system for charter operators. There is no requirement that refunds be received in any event before scheduled departure. (The proposed rule included such a requirement for refunds to be given per §380.30(t) of the rule adopted today.)

American Express suggested that charter operators' notification duties be considered satisfied by giving notice to travel agents rather than to participating individuals. The proposal was not adopted. Timely notice to participants is what is necessary. The travel agent need not disclose addresses to the operator as long as the operator arranges for the agent to notify the participants. In these situations it is the operator's responsibility to ensure that the agent sends the notification within (even where it is not accepted) does not disclose participants' addresses to the operator, the operator must ensure that the agent transmits the addresses to the operator. The former provision is designed, however, to preserve remedies for participants who choose not to accept a refund. That is necessary to ensure that the availability of the refund (even where it is not accepted) does not, as a matter of contract law, cut off other legal remedies. To clarify the interaction of these two requirements, the former one has been revised by adding to the contract a statement that the operator may condition a refund on the participant's waiver of additional remedies. This expanded statement appears in §380.30(c) of the rule adopted today.

The Board is also considering prohibiting the charter operator from conditioning the refund on the participant's waiver of additional remedies. Another possibility would be to require a "cooling off" period so that participants who are confronted with major changes would not have to decide on the spot whether to accept a refund or rely on other legal remedies. Board action on this subject would be on the basis of further notice of proposed rulemaking.

**SOLICITATION MATERIALS**

The proposed definition of "solicitation material" was broad, and included materials used by or on behalf of a charter operator to solicit participants who have not yet signed charter-price by increasing the price to the participants who are confronted with major changes was as follows: If an operator increases, and the operator's need to preserve the ability to respond to increases in its costs.

The proposed price provision is not unfair to operators, despite the uncertainty in their costs. In fact, a strong case can be made that during any price increase as major. Price flexibility is rare in other consumer purchase contracts, although it is common in commercial contracts. Retail sellers typically absorb the uncertainty in their costs by pricing their goods or services accordingly. In SPDR-50B, however, we had tentatively selected the 10 percent limit on increases as a compromise, to alleviate the impact of the rule on the sales of the operator.

Several commenters objected to the refund scheme, particularly for hotels. They argued that, instead of being entitled to cancel upon a hotel substitution or reject it for a partial refund if it occurred after departure, the participant would be entitled to receive only a refund of the difference in value between the promised and the substituted hotel. "Difference in value," however, is a subjective concept, since any change could be made. If the operator is not likely to satisfy a participant who is unhappy with the substitute, the amount would usually be far too small to discourage bad faith substitutions. Therefore, the refund scheme is generally adopted as proposed.

There are some changes in the timing of required notifications and refunds, however, in response to objections to the practicability of the proposed deadlines. Many commenters stated that 7 days to provide notice is too short because mailing time will consume an uncertain but substantial portion of that period. Some suggested 10 days as the limit while others argued that notice should be considered made when sent instead of when received. The latter suggestion has been adopted, with a slight change. Where the proposed rule stated that notification be given "in any event before departure", receipt is critical since a mere mailing immediately before departure would be of no help to the participant. The final rule therefore states that, for a change that the operator first knows of less than 10 days before scheduled departure, the operator must get the message to the participant as soon as possible. For a major change that the operator knows of 10 or more days before scheduled departure, the notification must be sent within 7 days after the operator first knows of it, but in any event by the 10th day before departure.

Refunds will also be considered made when sent rather than when received. The time for refunds is extended to 14 days, in recognition of the delay caused by the escrow system for charter operators. There is no requirement that refunds be received in any event before scheduled departure. (The proposed rule included such a requirement for refunds to be given per §380.30(t) of the rule adopted today.)

American Express suggested that charter operators' notification duties be considered satisfied by giving notice to travel agents rather than to participating individuals. The proposal was not adopted. Timely notice to participants is what is necessary. The travel agent need not disclose addresses to the operator as long as the operator arranges for the agent to notify the participants. In these situations it is the operator's responsibility to ensure that the agent sends the notification within (even where it is not accepted) does not disclose participants' addresses to the operator, the operator must ensure that the agent transmits the addresses to the operator. The former provision is designed, however, to preserve remedies for participants who choose not to accept a refund. That is necessary to ensure that the availability of the refund (even where it is not accepted) does not, as a matter of contract law, cut off other legal remedies. To clarify the interaction of these two requirements, the former one has been revised by adding to the contract a statement that the operator may condition a refund on the participant's waiver of additional remedies. This expanded statement appears in §380.30(c) of the rule adopted today.

The Board is also considering prohibiting the charter operator from conditioning the refund on the participant's waiver of additional remedies. Another possibility would be to require a "cooling off" period so that participants who are confronted with major changes would not have to decide on the spot whether to accept a refund or rely on other legal remedies. Board action on this subject would be on the basis of further notice of proposed rulemaking.

**SOLICITATION MATERIALS**

The proposed definition of "solicitation material" was broad, and included materials used by or on behalf of a charter operator to solicit partici-
pation in a Public Charter. All solicitation materials would have to include the direct air carrier's name, the charter operator's name, and a statement that the flight is a charter. A statement referring to the contract for further information about conditions applicable to the charter was also proposed, but only for advertising that states prices for flights. Any solicitation material that named a hotel but did not name every hotel listed in the operator-participant contract would also have to state that substitutions might be made. Additional disclosure requirements related to alternative cities are discussed above under the heading "Major Changes."

OTC Tours objected to the definition of "solicitation material" as too broad, stating that it could make the operator liable for the content of material that it had never seen or heard. The words "on behalf of," however, adequately limit the coverage of the rule to distributions for which the operator can fairly be held responsible.

A&CAP suggested that the operator's address also be included in all ads. Such a requirement is not being adopted for the reason that it was not proposed. Since the address is available in the operator-participant contract, the extra benefit to consumers of having it in the advertising is not worth the burden it would impose on marketing. In particular, it could encourage participants to bypass travel agents in their bookings to the disadvantage of both agents, who may have paid for the advertising, and operators, who may wish to sell only through agents.

The FTC suggested that advertising also include the departure times of the initial and final flight legs, the specific location of hotels, and definitions of any terms used to describe hotels. OCA/HEW wanted the quality and location of restaurants included as well as hotel locations. These suggestions are not being adopted. Flight times are often not established until shortly before the departure date, so they could not be included. In our judgment, imposition of such strict requirements in all advertising would be a burden not justified by benefits to consumers.

A&CAP Tours saw no need for a statement referring to the contract for further information. As noted in the proposal, however, it is important to alert prospective participants to the existence of those contracts at an early stage. The final rule therefore includes this requirement.

For these reasons, the requirements for solicitation materials are adopted as proposed, except that a statement that the flight is a charter need not be included. We find that such information would not significantly inform consumers, especially now that many of the former distinctions between charters and other air services have been removed.

**Operator-Participant Contracts**

SPDR-50B proposed to prohibit the collection of any money from prospective participants until they have signed operator-participant contracts. This provision was supported by the FTC, OCA/HEW, New York City Department of Consumer Affairs, A&CAP, and others, as necessary to ensure that participants can make informed choices before committing their money. Many charter operators opposed it, arguing that it is unnecessary and would severely restrict the marketing of charters.

We consider this prohibition to be important. To make an informed choice, the consumer must be able to inspect the terms of the purchase before paying his money. After that, as noted in SPDR-50B, participants have become psychologically committed to the purchase, even if as a legal matter they are entitled to withdraw without doing so. It is arguable that they consider unsatisfactory. The argument that the signature requirement will impair the marketing of charters appears to rest on the expectation that many consumers will delay their booking until they have read the contract or be reluctant to sign it at all. Operators can minimize the likelihood of this, however, by writing their contracts in clear, understandable English with a print format that does not discourage reading. Then, potential customers who decide not to sign would presumably be making their decisions on the basis of the terms of the agreement, which is as it should be.

The signature requirement has been redrafted so that it applies only to acceptance by the operator. Retail agents will not have to obtain signatures when accepting money for unspecified flights. They do need to obtain the signature before sending the money to the operator, however, because otherwise the operator under the rule may not accept it. Operators that receive money without contracts having been signed must return it.

The proposal specified that if a member of a family traveling together paid for the group, that member could sign the contract on behalf of the group. CTC stated that requiring the signer to be a family member is too restrictive, and that it should be enough "that a signer designate himself as the representative of a group that will travel together." We agree that this provision should be more flexible. CTC's suggestion is not being adopted, however, since any person could so "designate himself." Instead, the rule specifies that if a member of any group traveling together pays for the group, that member can sign the contract on behalf of the group. Operators and agents should note that this provision does not address whether a person's signature actually commits the group members to the terms of the operator-participant contract. It concerns only the prohibition against operators collecting money without having first obtained a signature.

Whether one group member has actual authority to bind another to the contract will be a question of fact and agency law in each case.

The proposed rule would require operators to return all of a participant's money within 2 business days after receiving it if the charter and all the specific alternatives that the participant has chosen are fully booked. The operator could retain the money and try to make other arrangements for the participant only if authorized by the participant. The proposal would have prevented the participant from giving this authorization until after being notified that no space was available.

Many commenters stated that the 2-business-day deadline is too strict, and particularly objected to the prohibition against advance authorizations to hold money when the requested charter is full. The final rule gives operators 7 days, as suggested by ACTOA and ASTA. The prohibition against advance authorizations is replaced by a space on the contract form for participants to indicate their consent to the retention of their money. When the operator retains the money, it must notify the participant within 7 days that the charter is full and the money is being retained. This change will simplify the handling of funds while serving the proposed prohibition's original purpose—to guarantee that the consent is informed.

SPDR-50B proposed to require that operator-participant contracts be printed in at least 7-point type, and that certain particularly important elements of the contracts be printed in boldface type at least 50 percent larger than the rest. The print minimum was generally approved by the commenters and is being adopted as proposed. NACA suggested that boldface type would be adequate to highlight the important terms without being any larger than the rest of the contract. The American Automobile Association suggested that capital letters would suffice. The final rule accommodates these suggestions.

Due to a typographical error in the notice of proposed rulemaking, the particular contract terms to be highlighted were not identified correctly. Using the paragraph designations of § 360.52 of the final rule, they are (a), the charter operator's name and ad-
RULES AND REGULATIONS

Charles, (f), a statement about payments to the escrow account, (g), a statement about the operator's cancellation rights, (h), a statement that the participant's cancellation rights are limited, and (i) and (j), statements about participants' refund rights when there are major changes. Statements in the operator's option plan contracts about alternative dates and cities must also be highlighted.

Several commenters stated that if contracts must state cities and flight dates there would have to be a separate printing, for each flight in a series of charters, of contracts that are otherwise identical. That is incorrect. A common practice has been for the operator to print a brochure describing an entire program, with a single contract form attached. The contract incorporates the necessary information by reference, usually to the detachable booking or reservation form. That practice, if the cancellation occurs less than 10 days before departure, the notification need not be written but it must be made as soon as possible and in any event before departure. To ensure, speedier notice to participants of their need to make other arrangements, SPDR-50B proposed to reduce the 15-day period to 7 days. This aspect of the proposal is adopted with the variation discussed above for the timing of notifications of major changes. Thus, for cancellations that occur 10 or more days before scheduled departure, written notice must be sent within 7 days but in any event by the 10th day before scheduled departure. If the cancellation occurs less than 10 days before scheduled departure, the operator must get the message to participants as soon as possible.

SPDR-50B proposed that operator-participant contracts for international flights include a warning statement about possible restrictions imposed by foreign governments and possible denials of landing rights. Several commenters stated that such a statement would be unnecessary if the foreign governments involved have already agreed to recognize country-of-origin charter rules or granted landing rights for the particular charter. This final rule includes exceptions for these situations.

SPDR-50B also proposed to increase the level of the bond required of charter operators who use the bonding of the travel agency as additional protection of participants' funds. The current requirement is $5,000 per flight up to a maximum of $50,000 for a series of 10 or more air-only charters. For option-air-ground-package charters it is $10,000 per flight up to a maximum of $100,000 for a series of 10 or more. Several charter rules that were replaced by the Public Charter rule, however, required $10,000 per flight up to a maximum of $200,000 for a series of 20 or more. Although those rules covered charters with mandatory ground packages, SPDR-50B proposed that level of bonding for all Public Charter operators, regardless of whether a ground package is included. The only objection to this proposal was made jointly by Europa Travel Service, Jetaway, Inc., and Trans Globe Tours. They stated that it was unfair to operators of air-only charters, and that the double bond would be well in excess of the operators' potential liability. We disagree. Even at $10,000 per air-only charter, the bond amount is very small in relation to actual charter prices. It might supplant an extero system that does not always work perfectly. Moreover, inflation since the $5,000 level was originally established has added to the need for an increase. The bond requirements for Public charters are therefore amended as proposed.

PROSPECTUS FILING REQUIREMENTS

Charter operators are currently required to file a prospectus that includes, among other things, a flight schedule, itinerary, sample solicitation materials, and copies of the charter contract (between the operator and the carrier), operator-participant contract, surety bond, and depository agreement (if any). The Board's staff has 15 days to review these documents for compliance with Board regulations, during which the charter cannot be advertised or sold. SPDR-50B proposed to simplify this filing system by requiring only statements that the necessary agreements had been entered into, in place of copies of the actual documents. A reduction of the review period to 10 days was also proposed.

The simplification of the filing scheme was generally supported by the comments as a reduction of the procedural impediments to marketing charters. OTC Tours, however, wanted that form of automation to continue, stating that this is the only way the Board can be sure that direct air carriers are not charging different operators different prices for the same service. Requirements for the contract filing requirement merely for this purpose is unnecessary, however, since the Board has ample authority to obtain information from carriers about their price practices when there is reason to believe that those practices are unjustly discriminatory. Adventure Tours suggested that the proposed scheme is not really a simplification since it requires the execution of new documents. In the same vein, NACA suggested that operators be given the option of submitting copies of the relevant agreements, as they do already, instead of separate statements that the agreements have been entered into. We are not adopting this suggestion for several reasons. First, the failure to reject a prospectus containing actual contracts creates an unjustified appearance of Board approval of the contract. Second, the statements also contain necessary certifications that the flight schedule has been mailed to and received by the depository bank (if any) and surety company. Finally, even if the execution of the one-page statement poses in some cases a greater burden on the charter operator than the production of a copy of the underlying agreement, the extra burden is negligible.

Several commenters objected to the ban on advertising and sales during the 10-day review period, with some suggesting that advertising be permitted with the caveat “subject to CAB approval.” Others urged that the review period should be reduced further. The ban on advertising and sales is merely a continuation of the existing rule. It is being retained to prevent the marketing of charters without a certificate of service. Charter operators also noted that the Board's staff can, under delegated authority, waive the 10-day ban when justified by an emergency or other circumstances. Finally, while agreeing generally with the 10-day ban, urged that we make clear that this provision would not prevent a retail travel agent from accepting a deposit from a client for a specified or unspecified charter tour regardless of whether a prospectus has been filed. Frequently retail agents receive deposits from clients with the understanding that the travel
RULES AND REGULATIONS

agent will select a charter offering for the client.

There is no prohibition against travel agents' accepting money for unspecified charters, regardless of whether a prospectus has yet been filed for the charter ultimately selected. Acceptance of money for a particular charter, however, would tend to indicate that there had already been a violation of the marketing ban by the charter operator, in making information available to the travel agent about the charter. An agent's acceptance on behalf of an operator would also be a violation. The ban is stated broadly: "No charter operator shall operate, sell, receive money from any prospective participant for, or offer to sell or otherwise advertise a charter" during the 10-day review period.

Accordingly, the simplified prospectus procedures are being adopted as proposed, except for the following changes: (1) The requirement that prospectuses include the tour itinerary, when ground packages are offered, is retained. Thus charter marketing can be monitored for enforcement purposes. (2) The statements will identify the proposed flight schedule by a number. Without an identification scheme, the references to flight schedules would be ambiguous. The numbers will be assigned by charter operators, with no duplication among any one operator's prospectuses. (3) The maximum span of a series of charters included in a single prospectus is extended from 180 days to 1 year, in response to a suggestion by CTC. (4) Proposed § 380.25(f) would have continued the requirement that operators send statements to direct air carriers affirming that all participants have entered into conforming operator-participant contracts. Several commenters suggested that these statements be sent to the Board instead of the direct air carrier. The signature requirement for these contracts has made the statement unnecessary, however, so it has been dropped entirely.

EFFECTIVE DATES

The operator-participant contract requirements (§§ 380.31 and 380.32), the related major change provisions (§ 380.33), the operator's option plan rules (§ 380.33a), and the notification requirements of § 380.12 will apply to operator-participant contracts entered into on or after May 1, 1979, but only with respect to charters that are scheduled to depart on or after July 1, 1979. If a contract specifies alternative departure dates, we will consider the charter as being scheduled to depart before July 1, 1979, only if all the alternatives are before that date. After May 1, 1979, if an operator receives from a prospective participant a signed but noncomplying contract form, the operator shall not accept the contract, but may respond by sending back a complying form.

As with the contract provisions, the requirements of § 380.30 will apply to solicitation materials distributed or broadcast on or after May 1, 1979, but only for charters that are scheduled to depart on or after July 1, 1979.

The prospectus filing requirements of amended §§ 380.25, 380.28, and the new Appendices B through D will be submitted to the General Accounting Office for review under the Federal Reports Act. The effective date of these amendments and the conforming amendments of §§ 380.2, 380.18, 380.23, and 380.40, unless the Board hereafter indicates otherwise, is May 1, 1979. This date reflects the inclusion of a 45-day period that that statute allows for such review (44 U.S.C. 3512(c)(2)).

Since it does not appear practicable to key the increased surety bond levels to flight dates, the amendment of § 380.34 will apply to all flights covered by prospectuses filed on or after May 1, 1979.

The revocation of § 380.43 relieves a restriction and creates no additional burden, so it is effective immediately. The amendment of § 380.43, concerning conditions on exemptions, does not itself create any additional burden because actual conditions will only be imposed after a separate proceeding, in which the need for any lead time can be considered. Therefore this amendment is also effective immediately.

THE RULE

In light of the above, the Civil Aeronautics Board amends Part 380 of its Special Regulations, Public Charters (14 CFR Part 380) as follows:

1. The Table of Contents is amended by redesignating § 380.25, adding new §§ 380.30 and 380.31, redesignating § 380.32, and adding new § 380.33, § 380.33a, and Appendices B through D, to read:

PART 380—PUBLIC CHARTERS

Sec. 380.25 Prospectus filing and related requirements.

380.30 Solicitation materials.

380.31 General requirements for operator-participant contracts.

380.32 Specific requirements for operator-participant contracts.

Sec. 380.33 Major changes in itinerary or price; refunds.

Appendix A
Appendix B
Appendix C
Appendix D

2. Section 380.2 is amended by replacing "380.25(a)(1) and (2)" with "380.25" in the definition of "foreign charter operator" and adding the following definition of "solicitation material":

§ 380.2 Definitions.

"Solicitation material" includes all advertisements in print or electronic media, brochures, and any other materials prepared or distributed by or on behalf of a charter operator to solicit participation in a Public Charter.

3. In § 380.12, paragraph (b) is amended to read:

§ 380.12 Cancellation by charter operator and notice to participants.

(b) If the charter operator cancels a charter 10 or more days before the scheduled date of departure, the operator must notify each participant in writing within 7 days after the cancellation but in any event not less than 10 days before the scheduled departure date of the outbound trip. If a charter is canceled less than 10 days before scheduled departure (i.e., for circumstances that make it physically impossible to perform the charter trip), the operator must give the message to each participant as soon as possible.

4. In § 380.18, paragraph (e) is amended to read:

§ 380.18 Charters for special events.

(e) The 10-day waiting period specified in § 380.25(a) of this part shall not apply to operations under this section to the extent that it would prohibit advertising or sale of the charter after the Board has notified the charter operator that advertising or sale may begin.

5. Section 380.20 is amended in part to read:

§ 380.20 Exemption.

Charter operators (other than foreign charter operators) are relieved from the following provisions of the Act to the extent necessary to enable them to organize and arrange Public Charters. This exemption applies only if and so long as they comply with this
part and any conditions that the Board has imposed on their operations to ensure such compliance.

§ 380.23 Charters that originate in a foreign country.

(b) Notwithstanding the other provisions of this part, a charter operator who is a citizen of the United States shall not be subject to the following requirements with respect to Public Charters that originate in a foreign country:

§ 380.25
§ 380.28
§ 380.30-380.35

7. Section 380.25 is amended to read:

§ 380.25 Prospectus filing and related requirements.

A charter operator may organize and operate a Public Charter only in accordance with this part, and subject to the following conditions:

(a) No charter operator shall operate, sell, receive money from any prospective participant for, or offer to sell or otherwise advertise a charter or series of charters until at least 10 days after filing with the Board (Special Authorities Division, Bureau of Pricing and Domestic Aviation) a Public Charter prospectus as described in § 380.38.

(b) If within 10 days after the filing the Board notifies the charter operator that it has rejected the prospectus for noncompliance with this part, the prohibitions set forth in paragraph (a) of this section shall continue until the Board notifies him that it has accepted the prospectus.

(c) The following deviations from a filed prospectus may be made only in accordance with paragraph (d) of this section:

(1) The addition or cancellation of any flight;

(2) A change in any flight date, origin city, or destination city; and

(3) A change in or addition of any direct air carrier, surety company, or depository bank.

(d) The charter operator shall amend the prospectus to reflect any change described in paragraph (c) of this section. The amendment shall be filed in the manner and form used for the original prospectus. It shall become effective 10 days after filing unless the operator is notified otherwise.

(e) The charter operator shall notify the depository bank (if any) and the surety company of any change described in paragraph (c)(1) or (c)(2) of this section not later than when he files a prospectus amendment to reflect the change. If the surety company is unable to adjust the bond as required by the change, it shall notify the Board (Special Authorities Division, Bureau of Pricing and Domestic Aviation) of this fact within 2 business days after receiving notice of the change from the charter operator.

8. Section 380.28 is amended to read:

§ 380.28 Charter prospectus.

(a) The charter prospectus shall include an original and one copy of the following:

(1) From the charter operator and the direct air carrier: (i) the proposed flight schedule, listing the origin and destination cities, dates, type of aircraft, number of seats, and charter price for each flight; (ii) the tour itinerary (if any) including hotels (name and length of stay at each), and other ground transportation services; and (iii) a statement that they have entered into a charter contract that covers the proposed flight schedule, that the contract complies with all applicable Board regulations, and that a copy of the contract has been sent to the depository bank (if any) and the charter operator’s surety company. The schedule shall be identified with a number assigned by the charter operator that does not duplicate any schedule numbers assigned by that operator to other proposed flight schedules. The proposed flight schedule, tour itinerary (if any), and statement shall be in the form set out in Appendix B to this part.

(2) From the charter operator and the surety company, a statement: (i) that they have entered into a surety bond covering the proposed flight schedule that complies with § 380.34, including the amount of the bond, the number assigned to it by the surety, and the amount of any outstanding claims against it, and (ii) that the surety has received the proposed flight schedule. The statement shall identify the proposed flight schedule by the schedule number assigned by the charter operator in accordance with paragraphs (a)(1) of this section. If there are any outstanding claims against the bond, the charter operator and surety company shall also state that they have executed a rider increasing the bond by the amount of the claims, or that the surety will separately pay any claims for which it may be liable without impairing the bond or reducing the amount of its coverage. These statements shall be in the form set out in Appendix C to this part.

(3) If a depository agreement is used, a statement from the charter operator, the direct air carrier, and the depository bank: (i) that they have entered into a depository agreement covering the proposed charter flight that complies with § 380.34, and (ii) that the bank has received a copy of the proposed flight schedule. The statement shall identify the proposed flight schedule by the schedule number assigned by the charter operator in accordance with paragraph (a)(1) of this section. This statement shall be in the form set out in Appendix D to this part.

(b) Each of the statements described in paragraph (a) of this section shall include the names and addresses of the parties to it, and the originals shall be signed by those parties.

(c) The prospectus may cover a series of charters performed by one charter operator if the departure of the last charter is not more than one year after the departure of the first.

(d) If the prospectus covers a series of charters and the air transportation will be performed by more than one direct air carrier, the prospectus shall include separate statements in accordance with paragraphs (a)(1) and (a)(3) of this section to cover the flights that will be performed by each direct carrier.

9. A new § 380.30 is added, to read:

§ 380.30 Solicitation materials.

(a) All solicitation materials for a public charter shall include the name of the charter operator and the name of the direct air carrier.

(b) Any solicitation material that states a price per passenger shall also include one of the following:

(1) A statement referring to the operator-participant contract for further information about conditions applicable to the charter; or

(2) The full text of the operator-participant contract.

(c) Except as set forth in § 380.33a for operator’s option plan contracts, if the charter prospectus names alternative dates or cities, any solicitation material that states a price per passenger shall also state that the actual dates or cities have not yet been selected. If that is the case.

(d) Any solicitation material that names a hotel but does not name every hotel named in the operator-participant contract shall also state that substitutions may be made.

10. A new § 380.31 is added, to read:

§ 380.31 General requirements for operator-participant contracts.

(a) No money shall be accepted by a charter operator from a prospective participant unless the participant has agreed to the conditions of the charter by signing an operator-participant contract, as described in § 380.32. If a member of a group that will travel together pays for the group, that
member may sign the contract on behalf of the group.

(b) The contract form may include a space that participants may check to authorize the charter operator to retain their money while attempting to make other arrangements for them if there is no space available on the flight or on specific alternative flights they have requested.

(c) If there is no space available on the flight or specific alternative flights requested by the participant, the operator shall return all the participant's money within 7 days after receiving it unless the participant, in accordance with paragraph (b) of this section, has authorized the operator to retain the payments while the operator attempts to make other arrangements for the participant. If the operator retains the payments while attempting to make other arrangements for the participant, it shall notify the participant of this fact within 7 days after receiving the payments. For the purposes of this paragraph, receipt of money by a travel agent on behalf of a charter operator will not be considered as receipt by the operator.

(d) Except as set forth in §380.33a for budget plan contracts, the operator-participant contract shall not specify alternative dates for the outbound or return flights, or alternative origin or destination cities for any flight leg.

(e) The contract form shall be printed in 7-point or larger type. The statements required by paragraphs (a), (f), (h), (i) and (o) of §380.32 shall be printed so as to contrast with the rest of the contract, by the use of bold-faced type, capital letters, or a type size that is at least 50 percent larger than that used for the rest of the contract.

(f) The contract form shall include a space that participants may check to indicate that they wish to be furnished details of trip cancellation, health, and accident insurance.

(g) The contract form shall be designed so as to enable participants to retain a copy of the general terms and conditions after signing it. The specific information supplied by participants (such as choices of dates, cities, or other options) need not be retainable.

11. A new §380.32 is added, to read:

§380.32 Specific requirements for operator-participant contracts.

Contracts between charter operators and charter participants shall state:

(a) The name and complete mailing address of the charter operator;

(b) The name of the direct air carrier, the dollar amounts of that carrier's liability limitations for participants' baggage as set forth in its tariffs, the type and capacity of the aircraft to be used for the flight, and the conditions governing aircraft and equipment substitutions;

(c) The dates of the outbound and return flights, except that alternative dates may be stated as set forth in §380.33a for operator's option plan contracts;

(d) The origin and destination cities of each flight leg, except that alternative cities may be stated as set forth in §380.33a for operator's option plan contracts;

(e) The amount and schedule of payments;

(f) If a depository agreement as provided in §380.34(b) is used: That all checks and money orders must be made payable to the escrow account at the depository bank (identifying bank) or, when the charter is sold to the participant by a retail travel agent, checks and money orders may be made payable to the agent, who must in turn make his check payable to the escrow account at the escrow bank;

(g) The tour itinerary, if any, including the name and location of the hotels, length of stay at each, and other ground accommodations and services that are part of the tour;

(h) That the charter operator is not liable for major changes but in no event later than departure, the participant may cancel, and that a full refund will be made to the participant within 14 days after canceling;

(i) That upon a post-departure notification of a major change, the participant may reject the substitute hotel or the changed date, origin, or destination of a flight leg and be sent, within 14 days after the return date of the charter, a refund of the portion of his payments allocable to the hotel accommodations or air transportation not provided;

(j) That the participant's rights and remedies set forth in the contract, including the procedures for major changes, shall be in addition to any other rights or remedies available under applicable law, although the operator may condition a refund on the participant's waiver of additional remedies;

(k) That trip cancellation, health, and accident insurance is available and that the operator will furnish details of the insurance to participants who check the space provided for this purpose on the contract form;

(l) That the name and address of the surety company issuing the surety bond and that unless the charter participant files a claim with the charter operator or, if he is unavailable, with the surety, within 60 days after termination of the charter, the surety shall be released from liability under the bond to that participant;

(m) For international flights only: That additional restrictions may be imposed on the flight by the foreign governments involved, and that if landing rights are denied by a foreign government, the flight will be canceled with a full refund to the participant. This statement need not be included in the contract if (1) the prospectus includes a certification by the charter operator and the direct air carrier that landing rights have been obtained from all the foreign governments involved, or (2) all the foreign governments involved have adopted country-of-origin rules for charterworthiness;

(n) That the charter operator is the principal and is responsible to the participants for all services and accommo-
§ 380.33 Major changes in itinerary or price; refunds.

(a) For the purposes of this section, "major change" means any of the following:

(1) A change in the departure or return date shown in the operator-participant contract for, if the contract states alternative dates, the date designated to the participant by the charter operator in accordance with § 380.33a(b), unless the change results from a flight delay. In any event, however, a date change that the operator knows of more than 2 days before the scheduled flight date, and any delay of more than 48 hours, will be considered a major change.

(2) A change in the origin or destination city shown in the operator-participant contract for any flight leg (or, if the contract states alternative cities, the city designated to the participant by the operator in accordance with § 380.33a(b)), unless the change affects only the order in which cities named in a tour package are visited.

(3) A substitution of any hotel that is not named in the operator-participant contract for any flight leg (or, if the contract states alternative cities, the city designated to the participant by the operator in accordance with § 380.33a(b)), unless the change affects only the order in which cities named in a tour package are visited.

(4) A price increase to the participant that occurs 10 or more days before departure and results in an aggregate price increase of more than 10 percent.

(b) The charter operator shall not increase the price to any participant less than 10 days before departure.

(c) The charter operator shall notify all participants of major changes, as required by the operator-participant contracts. The operator shall at the same time notify the participants of their rights to refunds and, if applicable, that acceptance of a refund constitutes a waiver of their legal rights.

(d) Except as otherwise specified, notifications and refunds required by this part are considered made at the time they are mailed or sent by an equivalent method.

(e) The charter operator shall make all refunds described in the operator-participant contract within the time limits set forth in paragraphs (c), (n), (r), and (s) of § 380.32, as applicable.

13. A new § 380.33a is added, to read:

§ 380.33a Operator's option plan.

(a) For the purposes of this part, an operator's option plan contract is an operator-participant contract that states alternative dates for the outbound or return flights, or alternative origin or destination cities for any flight leg.

(b) Operator's option plan contracts shall state, in addition to the information required by § 380.32, that the selection of the actual dates or cities, as applicable, is at the charter operator's option and will not entitle the participant to a refund, and that the operator will notify the participant of the actual dates or cities at least 10 days before the earliest of any alternative dates for the outbound flight.

(c) Contract forms for all operator's option plan contracts shall be labeled "OPERATOR'S OPTION PLAN" in bold-faced capital letters at least 1/4 inch high. The statement required by paragraph (b) of this section and the statement of alternative dates (§ 380.32(c)) or alternative cities (§ 380.32(d)), as applicable, shall be printed so as to contrast with the rest of the contract, as set forth in § 380.31(c).

(d) Any solicitation material that states a price per passenger for an operator's option plan contract shall clearly and conspicuously (1) identify that price as being for the operator's option plan, (2) name all the possible dates or cities, as applicable, and (3) state that the selection of the actual dates or cities is at the charter operator's option.

(e) Charter operators and their agents shall not misrepresent to prospective participants, orally, in solicitation materials, or otherwise, the probability that any particular city or date will be selected from among the alternatives named in an operator's option plan contract.

(f) The charter operator shall notify all participants with operator's option plan contracts of the actual dates or cities, as applicable, as required by the contracts.

14. In § 380.34, paragraph (b)(1) is amended to read:

§ 380.34 Surety bond and depository agreement.

• • • • •

(b) • • • • •

(1) The charter operator shall furnish a surety bond in an amount of at least $10,000 times the number of flights, except that the amount need not be more than $200,000. The liability of the surety to any charter participant shall not exceed the amount paid by the participant to the charter operator for that charter.

• • • • •

15. Section 380.40 is amended to read:

§ 380.40 Charter not to be performed unless compliance with part.

(a) For all Public Charters other than foreign-originating charters organized by a direct air carrier, a direct air carrier shall not perform air transportation in connection with such a charter unless (i) the charter is conducted in accordance with Subpart B and § 380.42, and (ii) the charter operator conforms to all requirements of this part that are applicable to charter operators within the Board's jurisdiction, other than §§ 380.25, 380.28, 380.30-36, and 380.50.

§ 380.43 [Reserved]

18. Section 380.43, Record retention, is revoked and reserved.

17. Appendices B through D are added, to read as set forth below.


Note: Appendices B through D which are CAB Forms 380-B, 380-C, and 380-D respectively, are not shown in the Code of Federal Regulations. Copies of these forms may be obtained from the Distribution Section, Publications Services Division, Civil Aeronautics Board, Washington, D.C. 20428.


By the Civil Aeronautics Board:

PHYLIS T. KAYLOR,
Secretary.

APPENDIX B

STATEMENT OF CHARTER OPERATOR AND DIRECT AIR CARRIER FLIGHT SCHEDULE NUMBER

1. Name and address of charter operator:

2. Name and address of direct air carrier:

3. Proposed date and routing of each flight:

4. Type of aircraft and number of seats:

5. Charter price for each flight:

6. Tour itinerary (if any) including hotels (name and length of stay at each), and other ground accommodations and services:

We, (charter operator) and (direct air carrier), certify, that we have entered into a charter contract on (date) that covers the flight schedule described above. The contract complies with all applicable Civil Aeronautics Board regulations. A copy of the flight schedule has been sent to (depositary bank).

*Omit the bracketed portion if no depositary bank is used.
we have entered into a depository agreement on (date). This depository agreement covers proposed flight schedule number --, a copy of which has been received by -- (depository bank). The depository agreement complies with §380.34 of the Civil Aeronautics Board's Special Regulations (14 CFR §380.34).

By:

(Signature and date)

(Title)

DIRECT AIR CARRIER

By:

(Signature and date)

(Title)

APPENDIX C

STATEMENT OF CHARTER OPERATOR AND SURETY COMPANY

We, _______ (charter operator) and _______ (surety company), certify that we have entered into a surety bond, No. __________ (bond number), in the amount of $__________, on _______ (date). This bond covers proposed flight schedule number __________ (flight schedule number), a copy of which has been received by _______ (surety company). This bond complies with §380.34 of the Civil Aeronautics Board's Special Regulations (14 CFR §380.34).

By:

(Signature and date)

(Title)

CHARTER OPERATOR

By:

(Signature and date)

(Title)

SURETY COMPANY

APPENDIX D

STATEMENT OF CHARTER OPERATOR, DIRECT AIR CARRIER AND DEPOSITORY BANK

We, _______ (charter operator) and _______ (direct air carrier), and _______ (depository bank) certify, that

2 In place of this sentence, the following statement may be used: "(charter company) will separately pay any claims for which it may be liable without impairing the bond or reducing the amount of its coverage.

SUMMARY: Procedures for accrediting laboratories under the National Voluntary Laboratory Accreditation Program (NVLAP) were established on February 25, 1976 (43 FR 6163-6165). On October 25, 1978 (43 FR 49612-49618), the Department of Commerce (hereinafter referred to as Department) proposed to redesignate the existing NVLAP procedures as 16 CFR Part 7a and to add optional procedures 15 CFR Part 7b which would allow Federal agencies to use the program without relinquishing their authority to decide if accreditation programs are needed. The optional procedures would also allow the agencies to suggest criteria for evaluating laboratories. The primary purpose of these optional procedures is to make NVLAP available for use by Federal agencies with specific regulatory and public service responsibilities, thereby increasing the potential utilization of the program and the benefits which can be obtained from such a single, unified laboratory accreditation program. These optional procedures are also designed to reduce the time necessary to begin operating specific accreditation programs.

Twenty-four comments have been received on the proposed optional procedures. The issues raised in these comments and the conclusions reached by the Department are described under the heading "Evaluation of Comments" in the Supplementary Information section of this notice. The optional procedures promulgated by this notice are similar to the proposal published in the Federal Register notice of October 25, 1978, except that: 1. Provision has been made to publish in the Federal Register requests received from these other agencies along with the names and addresses of the responsible officials in those agencies; 2. The comment period for responding to the proposed criteria for use in these Federal agency programs has been extended from 60 to 90 days to facilitate the preparation and submission of public comment; 3. The proposed provision which would allow a Federal agency to request a Governmental Laboratory Accreditation Criteria Committee has been eliminated. A description of the comments received and the reasons for these changes are included under the Supplementary Information section of this notice.

EFFECTIVE DATES: These procedures become effective as of March 9, 1979.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION: On October 25, 1978, the Department of Commerce proposed to establish optional procedures for use by Federal agencies in accrediting laboratories under NVLAP. The optional Federal agency programs which may be covered by these procedures are:

1. Regulatory programs, usually related to public health and safety, where mandatory standards and test methods are established by rule based on specific authorities and responsibilities assigned to a Federal agency by statute; and

2. Public service programs where standards and test methods are of a voluntary nature and for which a Federal agency has been given specific statutory authority and responsibility.

These optional procedures for Federal agency program needs will be designated as Part 7b of Title 15 CFR. The existing NVLAP procedures formerly designated as Parts 7a and 7b of Title 15 CFR will be designated Part 7a—National Voluntary Laboratory Accreditation Program: General.

The optional Part 7b procedures eliminate the requirement for the Secretary of Commerce (hereinafter referred to as the Secretary) to make a finding of need described in §§7a.4 and 7a.5 of the original NVLAP procedures. Under these optional procedures, the head of the Federal agency involved, rather than the Secretary of Commerce, determines whether a need exists to accredit testing laboratories that serve a specific product of interest to that agency. This is appropriate, and in the case of certain regulatory programs necessary, since such a finding of need is the statutory responsibility of the Federal agency with the regulatory or service program authority over such product in a specific application.

These optional Part 7b procedures also make possible the elimination of the requirement in the original procedures that the Secretary of Commerce establish a criteria committee to develop and recommend general and specific criteria for accrediting testing laboratories. The head of the concerned Federal agency may elect to submit recommended general and specific criteria directly to the Secretary for consideration, or may choose to use the relevant provisions of NVLAP (section 7a.6) by requesting the Secretary to establish a National Laboratory Accreditation Criteria Committee (NLACC) to develop and recommend such criteria. All criteria recommended are expected to be compatible with criteria established in existing NVLAP Part 7a programs or to include a detailed explanation of the reasons for deviating from those criteria.

As in the original NVLAP procedures, the Secretary will be responsible for the proposed general and specific criteria published in the Federal Register for public comment. Comments received in response to such Federal Register notice will be analyzed by the Department of Commerce in cooperation with designated representatives of the requesting Federal agency. The final criteria will be published by the Secretary. Accreditations issued under these procedures will be made by the Secretary based upon the evaluation of applicant laboratories by the National Bureau of Standards.

EVALUATION OF COMMENTS

Twenty-four comments were received in response to the proposed optional procedures. The comments have been carefully considered and evaluated, and a report has been prepared entitled, "Summary and Analysis Report of Public Comments on Proposed Part 7b, " in response to Proposed Optional Laboratory Accreditation Procedures Designed for Federal Agency Needs." This report and a copy of the comments have been prepared and are available for inspection and copying in the Department's Central Reference and Records Inspection Facility, Room 3317, Main Commerce Building, 14th Street between Constitution Avenue and E Street, NW, Washington, D.C. 20230.

Eighteen of the respondents were from Federal agencies, six were from private organizations. An evaluation of the key issues raised by these respondents is contained in the following paragraphs.

1. Do the proposed Part 7b procedures fill a need? Nine of the respondents seemed to concur in the need for these NVLAP Part 7b procedures. Eight of these responses were from government agencies. In this regard the comments of the Federal Trade Commission (FTC) seem most appropriate, and the Department agrees with the FTC that the benefits of NVLAP can be realized only if it is implemented in numerous product areas.

These optional Part 7b procedures were designed to recognize the specific authority and responsibility of other Federal agencies while attempting to maintain consistency in numerous product areas under the overall umbrella of NVLAP.

A trade association recognized that NVLAP Part 7b procedures might be "extremely helpful," particularly to provide manufacturers with an alternative to an industry association program. However, it opposed a mandatory NVLAP approach.

Two Federal agencies discouraged development of NVLAP Part 7b in product areas of their interest, primarily because these agencies already have accreditation programs underway and indicated that such a program would not be effective and may cause confusion. Another Federal agency, in its comments, suggested that these NVLAP procedures would not be appropriate for the same reason, unless the procedures were modified considerably to give the requesting Federal agency much more authority in the accreditation procedures.

The Department is attempting to provide a service for the public and for other Federal agencies which will assure the availability of accredited laboratories in product areas where such accreditation is needed. NVLAP is a voluntary program and is not intended to compete directly with other ongoing programs. If a Federal agency has no need for a NVLAP program, then none will be requested under these optional procedures and none will be developed. However, if a Federal agency does wish to use NVLAP, the Department will develop a program only on the basis that the Department retain its authority to promulgate the criteria, conduct the inspection and evaluation of applicant laboratories, and grant the accreditation. Otherwise, the benefits of the program, so succinctly stated in the FTC response, will not be met and NVLAP would end up as a loose umbrella of federated accreditation systems with (perhaps) similar characteristics. Nothing, however, precludes other Federal agencies from adopting NVLAP-like procedures to their own needs.

A major nonprofit testing and certification organization suggested that the existing procedures (Part 7a) be revised to provide for a higher degree of involvement and control by the Federal agency involved. Such was the intent of optional Part 7b, and its language is compatible with the existing Part 7a procedures to the extent possible.

In summary, ten respondents seemed to favor the development of Part 7b and four opposed such development or placed such severe conditions on the procedures as effectively to preclude development of the program as envisaged under the NVLAP concept.

On balance, having carefully considered and weighed the various views pro and con, the Department believes that the optional Part 7b procedures should be published in final form.

2. Should the Department of Commerce be required to find that there is a need to establish a laboratory accreditation program (LAP) for a product whose characteristics are regulated in some manner by a Federal agency? Two respondents representing private interests objected to provisions of the Part 7b procedures...
which would eliminate the requirement for a formal finding of need procedure contained in the original NVLAP procedures (Part 7a). Elimination of that finding and associated requirements was proposed because the Department did not believe that another Federal agency, having statutory authority and responsibility in relation to specific products, would be able to or wish to permit the Department of Commerce to find that a need for an accreditation program did or did not exist, no matter what procedures were employed to make such a finding. If this premise is correct, then many Federal agencies which may need to avail themselves of NVLAP programs might pass up opportunities to do so, and the Department believes that this would seriously limit the benefit to the public which the NVLAP programs can provide. Most Federal agencies which responded appear to find the optional procedures more acceptable than the procedures of Part 7a, although two agencies indicated that the requesting Federal agency did not have enough authority over the accreditation procedures under the new Part 7b.

The respondents also presumed that a Federal agency would ask the Department to establish a laboratory accreditation program (LAP) without using that agency’s own procedures to determine if a need existed. For this reason the Department has added to the optional procedures a requirement (section 7b.4(g)(5)) that the requesting Federal agency provide, with its request for an accreditation program, a description of the procedures followed (if any) in making the determination of need, and a statement (section 7b.4(e)) that the request for a NVLAP program under these optional procedures will be published by the Department in a manner consistent with the name, address and telephone number of the Federal agency official making the request, so that public inquiry as to the need for such a program could be addressed directly to the agency in the approval process.

The change in the procedures with respect to the finding of need in certain specific cases where other Federal agencies have been assigned authority and responsibility would also reduce the time required to implement the program. Although this was not the primary purpose in eliminating the finding of need provision of the original procedures, it is clearly desirable if respondents view the original procedures as too time-consuming to implement.

3. Should a National Laboratory Accreditation Criteria Committee be required for all programs implemented under NVLAP procedures? Three respondents representing private inter-

tests objected to the possibility of eliminating the establishment of a National Laboratory Accreditation Criteria Committee and the involvement of the Secretary by this Committee. In this view, the role of the Criteria Committee may not be clear. General and specific criteria to be used in the program are developed and recommended to the Secretary by this Committee. However, the use of these criteria in evaluating a laboratory’s capability to perform any one test method is part of the NVLAP operating process and will vary depending upon the test method. For instance, precision and accuracy values to be achieved in using a test method are not part of the criteria. Industry knowledge, experience and other expertise in the design or application of products is absolutely essential in using the criteria to evaluate the laboratory’s capability to perform a test method in any given situation. It is true that in the past the Criteria Committee has served as the principal source of information relative to precision and accuracy data and other application factors. However, this Committee was not the only source since considerable expertise resided in the National Bureau of Standards in committees which developed the test methods, and in many elements of industry which volunteered pertinent information and study results. The Department does not believe that allowing a Federal agency to recommend criteria without the use of a Criteria Committee will seriously affect the quality or quantity of data so necessary if these accreditation programs are appropriately implemented.

Two of the respondents object to provisions in the proposal which would provide for the establishment of a Governmental Laboratory Accreditation Criteria Committee (GLACC). The Department agrees that such provision is not necessary to fulfill the intent of these optional procedures. If the Federal agency does not recommend criteria, then a National Laboratory Accreditation Criteria Committee will be formed to recommend such criteria. All provisions relative to the establishment of a GLACC in 7b.6(a)(1) have been deleted in these final procedures.

With regard to the nature of the criteria, it is anticipated that they will be very similar from one product to the next. The general criteria, requiring general information about the laboratory and the information supplied by the laboratory, will remain essentially identical from one LAP to the next. The specific criteria, requiring detailed information about a laboratory’s capability to perform specific tests, will also be essentially identical for all test methods from one LAP to the next. However, the information supplied by the laboratory will be different for each test method for which accreditation is sought, since each test method makes specific demands of equipment, and procedures. It is the Department’s intent to strive for such similarity in the criteria so that testing laboratories being accredited under a number of different NVLAP product categories will not have to supply similar data in different formats, but rather only additional data as needed to evaluate new test methods being added to their accreditation status. It is for this reason, and because the Department is concerned that any criteria used be sufficient and implementable, that the procedures call for the Secretary to publish the proposed criteria. Recommendations, whether from a criteria committee or from a Federal agency, will be published insofar as they are compatible with existing procedures, are implementable, and are reasonably sufficient. Sound analysis and persuasive logic will be needed before a major change in the criteria from those already published in one product category is accepted for publication as the proposed criteria for a new product area. Such changes are conceivable because of the differences in the industry structure in different product areas, but are likely to be few in number. For these reasons, the alternatives given in the optional Part 7b procedures are believed to be appropriate.

In addition, the Department agrees that, because the public will have few opportunities to become involved in a LAP as it develops, more time should be given to review and comment on the proposed criteria after they are published in the Federal Register. Section 7b.8(a) has been revised to allow 90 days for submittal of comments.

4. A number of respondents individually questioned a wide variety of aspects about the program. One respondent questioned whether or not a laboratory had to perform all the test methods in the program in order to be accredited. The proposed optional Part 7b procedures do not explicitly address this question. However, there is a precedent which may be relied upon in dealing with this issue. In the program as currently being implemented for accrediting laboratories which test thermal insulation products under Part 7a procedures, laboratories may apply for accreditation under only one or for any number of the tests covered in the program. A laboratory need not establish its competence to perform all the tests in the program in order to be accredited. This is expected to be true using Part 7b procedures.
Another respondent suggesting that the period of accreditation should be not less than three years, asked for clarification on how the accreditation of laboratories will be announced, and suggested that existing accreditation programs should be a basis for accreditation where they exist. It is contemplated that the terms of the accreditation status will vary depending on the product, but that a formal statement of accreditation will be issued every year. For products where the state-of-the-art is relatively stable, e.g., concrete, longer periods of time between certain aspects of evaluation, such as on-site examinations, perhaps up to three years, may be appropriate. For products undergoing significant change, e.g., thermal insulation, shorter periods of time may be appropriate. The choice of the period for each aspect of evaluation is a program operations decision, not part of the criteria. The announcement of the laboratory’s accreditation status is described in section 7b.17(c); a monthly Federal Register announcement of actions taken will be published. Because of the need to have compatible criteria for the different programs, it is not likely that NVLAP will recognize other existing accreditation programs for accreditation under NVLAP. However, it is also not likely that NVLAP will be implemented in product areas where such accreditation programs already exist unless a need for such can be demonstrated.

One Federal agency responded that in-house laboratory capabilities must be maintained because of legal constraints and because a regulatory circumstance where an outside laboratory could be used for product testing purposes could not be envisioned. The decision whether or not to make use of the procedures, any determination of potential major economic consequences for the general economy, for individual industries, geographic regions, levels of government, or specific elements of the population. While these proposed regulations are not subject to the Executive Order, we have determined that they would not, in and of themselves, have such major economic consequences. It is only in the implementation of these regulations by the development of a laboratory accreditation program for a given product that economic consequences could be determined. In the Part 7a procedures, such determination may be included as part of the final finding of need made by the Secretary as published in the Federal Register. However, for these Part 7b procedures, any determination of potential major economic consequences would be the responsibility of the Federal agency to which the proposal was directed.

An expanded definition of the word “product” and a request to include test development activities where no mandatory test method existed were suggested by another respondent. The definition proposed appeared to limit severely the definition of product, not expand it. Defining test methods is really the work of a standards making body and is an activity which the Department will not enter into through this program. The purpose of NVLAP is to evaluate the capability of applicant testing laboratories to use existing testing methods, not to develop them. The provision allowing the renewal of accreditation procedures for each agency who would not, in and of themselves, have such major economic consequences. It is only in the implementation of these regulations by the development of a laboratory accreditation program for a given product that economic consequences could be determined. In the Part 7a procedures, such determination may be included as part of the final finding of need made by the Secretary as published in the Federal Register. However, for these Part 7b procedures, any determination of potential major economic consequences would be the responsibility of the Federal agency to which the proposal was directed. Promulgation of 15 CFR Part 7b Procedures. The Department is satisfied that, based on public comments received in response to the proposed 15 CFR Part 7b procedures, the procedures should be adopted to facilitate the use of a consistent approach to laboratory accreditation in a variety of product areas of interest to other Federal agencies.


JORDAN J. BARUCH, Assistant Secretary for Science and Technology.

15 CFR Part 7a—National Voluntary Laboratory Accreditation Program: General. Part 7 CFR Title 15 entitled “Procedures for a National Voluntary Laboratory Accreditation Program” as published in the Federal Register, Volume 41, Number 38, Wednesday, February 25, 1976 (pages 63-6168) is hereby redesignated Title 15 CFR Part 7a—National Voluntary Laboratory
Accreditation Program: General. Each section thereunder shall be denominated as Title 15 CFR to read as follows:

§ 7b.1 Purpose.
(a) The term "Secretary" means the Secretary of Commerce or the Secretary’s designee.
(b) The term "Product" includes the plural thereof and means a type or a category of manufactured goods, constructions, installations, and natural and/or processed materials or those associated services whose characterization, classification, or functional performance determination is specified by standards.
(c) The term "Criteria Committee" means a National Laboratory Accreditation Criteria Committee appointed by the Secretary under these procedures (i.e., Parts 7a or 7b).
(d) The term "person" means associations, companies, corporations, educational institutions, firms, government agencies at the Federal, State, and local level, partnerships, and societies, as well as divisions thereof, and individuals.
(e) The term "testing laboratory" means any "person" as defined above whose functions include testing, analyzing or inspecting "products," as defined above, and/or evaluating the designs or specifications of such "products" according to the requirements of applicable standards.
(f) The term "general criteria" means those characteristics of a testing laboratory commonly found in, and generally expected of, such a laboratory serving product under consideration. See in this connection § 7b.7(a).
(g) The term "specific criteria" means those detailed requirements deemed essential to assuring an acceptable examination and evaluation of the testing function performed by a testing laboratory in performing specific tests related to identified standards for the product under consideration. See in this connection § 7b.7(a).

§ 7b.2 Description and goal of program.
(a) This program extends the provisions of the National Voluntary Laboratory Accreditation Program (NVLAP) (Title 15 CFR Part 7a) to examine the professional and technical competence of testing laboratories that serve government regulatory and public interests needs. Testing laboratories that meet the qualifications established pursuant to the procedures set out below will be accredited by the Department of Commerce. This program will also require accredited laboratories to maintain their qualification status through periodic checks and examinations. In conjunction with the NVLAP Part 7a program, this program will seek, through coordination and consultation, to maximize benefits derived from other testing laboratory examination and accreditation activities. In this way, it is intended that the program will avoid duplication of other testing laboratory examination or accreditation programs conducted by the public and private sectors.
(b) The intended goal of this program is to serve, on a timely basis, the needs of Federal agencies by accreditating testing laboratories. Achievement of this goal would be attained by providing a uniformly acceptable base of clearly defined criteria for professional and technical competence in testing laboratories and by establishing a background of experience necessary to the orderly development of a uniform laboratory accreditation system designed to serve national needs as they develop.

§ 7b.3 Definitions.
(a) The term "Secretary" means the Secretary of Commerce or the Secretary’s designee.
(b) The term "Product" includes the plural thereof and means a type or a category of manufactured goods, constructions, installations, and natural and/or processed materials or those associated services whose characterization, classification, or functional performance determination is specified by standards.
(c) The term "Criteria Committee" means a National Laboratory Accreditation Criteria Committee appointed by the Secretary under these procedures (i.e., Parts 7a or 7b).
(d) The term "person" means associations, companies, corporations, educational institutions, firms, government agencies at the Federal, State, and local level, partnerships, and societies, as well as divisions thereof, and individuals.
(e) The term "testing laboratory" means any "person" as defined above whose functions include testing, analyzing or inspecting "products," as defined above, and/or evaluating the designs or specifications of such "products" according to the requirements of applicable standards.
(f) The term "general criteria" means those characteristics of a testing laboratory commonly found in, and generally expected of, such a laboratory serving product under consideration. See in this connection § 7b.7(a).
(g) The term "specific criteria" means those detailed requirements deemed essential to assuring an acceptable examination and evaluation of the testing function performed by a testing laboratory in performing specific tests related to identified standards for the product under consideration. See in this connection § 7b.7(a).

§ 7b.4 Request to establish a laboratory accreditation program (LAP).
(a) Any Federal agency responsible for regulatory or public service programs established pursuant to statute which has determined there is a need to accredit testing laboratories within the context of its programs may request the Secretary to establish a Laboratory Accreditation Program (LAP) based on these Part 7b procedures.

§ 7b.5 Establishment of criteria with which to accredit laboratories.
(a) Laboratories will be accredited on the basis of their conformance to general and specific accreditation criteria established pursuant to statute which serves the product identified in paragraph (b)(2) of this section.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
make for an effective testing laboratory. The specific criteria will be based on the requirements of the relevant rules, standards, and test methods for which accreditation is sought.

(b) Laboratory accreditation criteria may be recommended to the Secretary by the requesting Federal agency or may be developed by a National Laboratory Accreditation Criteria Committee described in the NVLAP procedures (newly redesignated §7a.6). The choice of which approach to use will lie with the Federal agency requesting the program.

(c) The Secretary will decide, after consultation with the requesting Federal agency, on the precise language of the proposed general and specific criteria to be published by the Secretary in the Federal Register. In making the decision, the Secretary will consider:

(1) The needs and scope of the program of the requesting agency;

(2) Compatibility with other criteria already established and being used in other LAPs; and

(3) The nature and content of other relevant public and private sector laboratory accreditation programs.

§7b.6 Establishment and functions of a national laboratory accreditation criteria committee.

(a) In those instances where a Federal agency declines to recommend laboratory accreditation criteria, the Secretary will establish a National Laboratory Accreditation Criteria Committee in order to develop and recommend general and specific criteria for accrediting laboratories serving the product specified.

(b) Membership in each National Laboratory Accreditation Criteria Committee thus established shall consist of a combination of Federal, State, and local government personnel and qualified representatives chosen from among producers, users, consumers, testing laboratories, academia, and general interest groups, in accordance with the relevant provisions of the NVLAP procedures (redesignated §7a.6 of Part 7 CFR Title 15).

§7b.7 Development and recommendation of criteria for accrediting testing laboratories.

(a) In developing the criteria, the Secretary, and either the requesting Federal agency (in those cases where it has elected to recommend general and specific criteria to the Department) or the Criteria Committee, shall consider factors such as:

(1) For general criteria pertaining to testing laboratories:

(i) Organization;

(ii) Staff;

(iii) Physical plant;

(iv) Operational processes;

(v) Control procedures;

(vi) Quality assurance; and

(vii) Professional and ethical business practices, as appropriate.

(b) For specific criteria pertaining to testing laboratories:

(i) Personnel and equipment qualifications required of the testing laboratory function;

(ii) Requirements applicable to proficiency sample programs;

(iii) Application requirements;

(iv) Initial and periodic examination and audit procedures; and

(v) Professional and technical qualifications of personnel who examine testing laboratories.

(2) No action will be taken or criteria developed that would prohibit the accreditation under this program of a testing laboratory solely on the basis of that laboratory's association or nonassociation with manufacturing, distributing or vending organizations, or because the testing laboratory is a foreign firm.

(3) No action will be taken under this program to develop a product standard, a test method standard, or a comparable administrative rule;

(4) The Secretary, under this program, will not ask for or accept confidential business data, trade secrets, or any other proprietary information.

§7b.8 Publication of proposed criteria.

(a) Upon its development of the general and specific criteria for accrediting testing laboratories, the Secretary will make such proposed criteria available in the Federal Register to the requesting Federal agency where it has elected to recommend general and specific criteria to the Secretary, or the Criteria Committee shall forward its recommendations for such criteria to the Secretary for consideration.

(b) Interested persons wanting to express their views in an informal hearing shall notify the Secretary of that desire within twenty (20) days after such proposed criteria are published in the Federal Register. Upon receipt by the Secretary of such request, informal public hearings shall be held so as to give all interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to the opportunity to make written submissions. If deemed appropriate by the Secretary, such hearings will be held at two locations, one of which shall be east of the Mississippi River and the other west thereof. Notice of such hearings shall be published in the Federal Register at least twenty (20) days in advance thereof. A transcript will be kept of any oral presentation.

(1) All written and oral comments that are furnished in response to the invitation made by this notice will be filed in the Central Reference and Records Inspection Facility, Room
such comments. After considering

ing, 14th Street between

tary deems it appropriate to do so,
charges established
shall establish fees and charges for ex-
financial arrangement for this program,
Standards, as authorized by section 12
agencies to serve on each Criteria
representatives, designated by those
forts will include opportunities for

criteria to the

gram.

tary in which those agencies have an
agencies. The coordination ef-
creditation program carried out under
mies (other than the requesting
participation
meaningful cooperation, input, and

criteria from further

al and specific criteria to further
consideration.

§ 7b.9 ‘Coordination with Federal agencies.

As a means of assuring effective and
meaningful cooperation, input, and
participation by those Federal agen-
cies (other than the requesting
agency) that have an interest in and
may be impacted by the laboratory ac-
creditation program carried out under
these procedures, the Secretary shall
undertake to communicate and con-
sult with appropriate officials within
those agencies. The coordination ef-
forts will include opportunities for
representatives, designated by those
agencies to serve on each Criteria
Committee established by the Secre-
tary in which those agencies have an
interest.

§ 7b.10 Establishment of fees and charges.

(a) The Secretary in conjunction with the use of the Working Capital Fund of the National Bureau of Standards, as authorized by section 12 of the Act of March 3, 1901, as amend-
ed (15 U.S.C. 278b), or any similar fi-
nancial arrangement for this program, shall establish fees and charges for ex-
amining, accrediting, and auditing
testing laboratories. The fees and
charges established by the Secretary, which may be revised when the Secre-
tary deems it appropriate to do so, shall be in amounts calculated to
enable the self-sufficiency of this pro-
gram. A separate notice will be pub-
lished in the Federal Register simul-
aneously with the notice of proposed
general and specific criteria referred to in § 7b.8(a). Such notice will set out
a schedule of estimated fees and
charges the Secretary proposes to es-
tablish. The notice would be furnished
for information and guidance purposes
only in order that the public may
evaluate the proposed criteria in light
of the expected fees to be charged.

(b) At such time as the Secretary
publishes the notice announcing the
final general and specific criteria re-
ferred to in § 7b.11, the Secretary
shall also simultaneously publish a
separate notice in the Federal Regis-
ter setting forth the final schedule of fees that will be charged testing la-
boratories that serve a specific product.
The effective date of such final sched-
ule of fees shall be the same as the
date on which the final general and
specific criteria are to take effect.

(c) Revisions, if any, to the fees and
charges established by the Secretary
under paragraph (a) of this section
shall be published in subsequent Fed-
eral Register notices and shall take
effect not less than thirty (30) days
after the date of publication of such
notice. Mention of such revisions shall
also be published in the appropriate
quarterly reports referred to in § 7b.17(a).

§ 7b.11 Participation of testing labora-
ories.

(a) Each testing laboratory serving a
product for which final general and
specific criteria have been promulgat-
ed under § 7b.8(c)(1), and desiring to be accredited under this program, will
notify the Secretary of its desire pur-
suant to the provisions of such crite-
ria.

(b) After receipt and evaluation of the
testing laboratory’s application
and information contained therein,
the secretary shall, upon the accept-
ce thereof, notify the applicant test-
laboratory and the National
Bureau of Standards in writing of the
specific applicable examination re-
quirements for accreditation and the
fees and charges for such examination
and accreditation. If the application
is not accepted, the Secretary shall
notify the applicant testing laboratory of the reasons for rejection of its ap-
plication, and such testing laboratory may reapply under § 7b.13(d) after cor-
recting the deficiencies set out in the
Secretary’s notification of rejection.
Alternatively, the applicant testing
laboratory shall have thirty (30) days
to request a hearing pursuant to 5
U.S.C. 556. In the event, however, that
the applicant testing laboratory re-
quests a hearing within that thirty
(30) day period the Secretary’s rejec-
tion shall be stayed until the hearing
held pursuant to 5 U.S.C. 556.

(c) A testing laboratory desiring to
be accredited under this program to
serve the product identified by the
Secretary under § 7b.4(b) in accord-
ance with the administrative rules,
standards, and test methods identified
must meet the general and specific cri-
teria promulgated by the Secretary.

(d) Upon receipt by the National
Bureau of Standards of the applicant
testing laboratory’s written response
pertaining to the specific applicable
examination requirements and of the
fees and charges specified in para-
graph (b) of this section, the National
Bureau of Standards, on behalf of the
Secretary, will arrange for by contract
or will itself conduct the examination
in accordance with the examination
requirements of the Secretary. In all
cases where testing laboratories are
examined, the National Bureau of
Standards will assure that the person-
nel used by the contractor or by the
National Bureau of Standards possess
the professional and technical qualifi-
cations as may be set out in the specif-
ic criteria promulgated under § 7b.8(c)(1). If the National Bureau of
Standards conducts the examination,
the resultant examination report will
be forwarded to the Secretary. In
cases where the examination report is
prepared by a contractor, the National
Bureau of Standards, before making
payment thereunder or forwarding
the report to the Secretary, will review
the report to assure that the contract
terms have been fulfilled.

(e) The Secretary, after reviewing the
examination report furnished under paragraph (d) of this section, will make a determination granting or
proposing to deny accreditation to the
applicant testing laboratory, not later
than twenty (20) working days follow-

ing the date on which the report is re-
cieved. If the determination is not
made within such time limit, the Secre-
tary shall notify the applicant test-
laboratory in writing of the reasons for
the delay. Upon making such determi-
ation, the Secretary will notify the
testing laboratory in writ-
ing of its accreditation status. If the
Secretary proposes to deny accredi-
tation to an applicant testing laboratory, the
notification will state the reasons
for such proposed denial.

(f) If an applicant testing laboratory
is notified by the Secretary of a pro-
posal to deny accreditation, the test-
laboratory shall have thirty (30)
days from the date of receipt of such
notification to request a hearing under
the provisions of 5 U.S.C. 556. The
Secretary’s proposed denial shall
become final through the issuance of a
written decision to the applicant in the
event that the applicant does not
appeal such notification by the end of
that thirty (30) day period. In the event,
however, that the applicant

FEDERAL REGISTER, VOL 44, NO. 4—FRIDAY, MARCH 9, 1979
testing laboratory requests a hearing within that thirty (30) day period, the Secretary's proposed denial shall be stayed until the hearing held pursuant to 5 U.S.C. 556.

§7b.12 Reference to accredited status.

Except as limited under §7b.7(c)(3), a testing laboratory accredited under this program may use the following statement on its letterhead and in professional, technical and trade publications: "Accredited by the Department of Commerce, National Laboratory Accreditation Program for (appropriate wording as authorized under this program)."

§7b.13 Revocation or termination of accreditation of a testing laboratory.

(a) If the Secretary finds that a testing laboratory which has been accredited violated the terms of its accreditation or the provisions of this Part 7b, the Secretary shall terminate that laboratory's accreditation.

(b) Upon receipt of a notice from the Secretary of such notice, which shall set forth the reasons for the proposed revocation, the testing laboratory shall have thirty (30) days from the date of receipt of such notice to request a hearing under the provisions of 5 U.S.C. 556. The Secretary shall notify that testing laboratory of the proposed revocation of its accreditation.

(c) A testing laboratory may at any time terminate its participation and responsibilities under this NVLAP Part 7b program or withdraw its application for accreditation by giving written notice to the Secretary. Upon receipt of such notice, the Secretary shall terminate further processing of the testing laboratory's application for accreditation. If such testing laboratory has been accredited, the Secretary shall terminate that laboratory's accreditation. The Secretary shall notify the testing laboratory that its accreditation has been terminated pursuant to its request.

(d) If the Secretary ceases the accreditation of testing laboratories that serve a specific product under §7b.14, it may withdraw the testing laboratory's accreditation of a testing laboratory to test a specific product under that section, such testing laboratory will be refunded the unexpended part of the examination fees or charges paid by such testing laboratory for such testing under this program: Provided, however, that no such testing laboratory will be refunded its original application fee, if any, to be accredited to serve a specific product.

§7b.16 Amendment or revision of criteria.

The Secretary, the requesting Federal agency in those cases where it recommended general and specific criteria to the Secretary, or a Criteria Committee acting at the request of the Secretary, may undertake the development of amendments or revisions of any applicable general or specific criteria previously promulgated by the Secretary by following the same procedures pertaining to the original development of such criteria.

§7b.17 User information and reports.

(a) For each specific product for which a NVLAP Part 7b program exists, the Secretary shall publish a quarterly report noting all actions regarding such matters as accreditations, revocations, the establishment of fees and charges, the promulgation of general and specific criteria and any amendments or revisions to such criteria. Such publications shall clearly state that testing laboratories accredited by the Secretary under these procedures are in no manner immune from the necessity of being in compliance with all legal obligations and responsibilities imposed by existing Federal, State, and local laws, ordinances, and regulations, including those relating to consumer protection and antitrust prohibitions.

(b) The Secretary will also prepare an annual report summarizing all activities carried out under these procedures which shall include a listing of all testing laboratories accredited by the Secretary during the year to which the annual report relates.

(c) As a means of giving prompt notice to the public of accreditation action taken, the Secretary shall, in addition, to the reports called for under this section, publish in the Federal Register all actions taken during the preceding month which grant, revoke, terminate, or result in the withdrawal of the accreditation of a testing laboratory. Such notice shall include the name and address of the testing laboratory concerned, and a brief explanation of the action taken by the Secretary with respect to that laboratory.
§ 7b.18 Support function.

The Secretary is authorized to make provisions for administrative and technical support and staff services as may be needed to carry out this program. The Secretary is also authorized to negotiate for and use funds and personnel of the requesting Federal agency as such funds and personnel are authorized for use by the requesting agency.

(FR Doc. 79-943 Filed 3-8-79; 8:45 am)

[6355-01-M]

Title 16—Commercial Practices

CHAPTER II—CONSUMER PRODUCTS SAFETY COMMISSION

PART 1700—POISON PREVENTION PACKAGING

Exemption of Mebendazole From Child-Protection Packaging Requirements

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Commission amends provisions of the child-resistant packaging regulations to exempt mebendazole in packages containing no more than 600 mg. of the drug. (Mebendazole is an anthelmintic drug used to treat common worm infestations in humans.) This action is taken because the Commission has found that child-resistant packaging for this product is not necessary for the protection of young children from serious personal injury or illness.

DATE: The effective date of this exemption is March 9, 1979.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

BACKGROUND

In the Federal Register of April 16, 1973 (38 FR 9431), a regulation (21 CFR 295.2(a)(10), subsequently recodified as 16 CFR 1700.14(a)(10)) was issued under the Poison Prevention Packaging Act of 1970 (the "PPPA") establishing child protection packaging requirements for human oral prescription drugs in order to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting these substances.

RULES AND REGULATIONS

On July 11, 1974, the Consumer Product Safety Commission received a petition (PP 75-2) from the Ortho Pharmaceutical Corporation (Ortho), 3 Oaktree Boulevard, Raritan, New Jersey, requesting an exemption from the special packaging requirements for "Mebendazole" (mebendazole) in tablet form in packages containing not more than 600 mg. of the drug. Mebendazole is an anthelmintic drug used in the treatment of common worm infestations in man. Special packaging is currently required for this drug by the Commission's regulation covering human prescription drugs in oral dosage form at 16 CFR 1700.14(a)(10). The Commission denied Ortho's petition on June 5, 1975, citing the apparent lack of an approved New Drug Application (NDA) that would allow the obtaining of meaningful human experience data, and the denial of the petition by the company submitted information as a supplement to its original petition. Additional information was furnished by the company on October 21, 1975 and February 10, 1976. The Commission has treated the supplementary information as a new petition (PP 77-2).

Mebendazole is believed to exert its anthelmintic effects by interference with glucose uptake in susceptible worms while having no effect on human glucose metabolism. Currently, Vermox<sup>®</sup> is supplied in child-resistant blister packs of six 100 mg. tablets each.

After considering the petition, human experience data as reported to the National Clearinghouse for Poison Control Centers, and medical and scientific literature and having consulted, pursuant to section 3 of the Poison Prevention Packaging Act (PPPA) of 1970, with the Technical Advisory Committee on Poison Prevention Packaging established in accordance with section 6 of the act, the Consumer Product Safety Commission concluded that an exemption from the special packaging requirements of 16 CFR 1700.14(a)(10) should be proposed for mebendazole in tablet form in packages containing not more than 600 mg. (42 FR 53901; October 20, 1977).

The Commission's decision to propose the exemption was based on the low oral toxicity of the drug and human experience data showing few accidental ingestions and few adverse reactions.

RESPONSE TO PROPOSAL

The Commission received two comments in response to its proposal to exempt packages of mebendazole tablets containing not more than 600 mg. of the drug from the child-resistant packaging requirements.

1. The American Society of Hospital Pharmacists supported the exemption for this drug, pointing out that "there is minimal danger of toxicity from ingestion of this drug by children."

The society also recommended "that the Commission respond to such petitions by establishing exemptions from the Poison Prevention Packaging Act based on a determination of the maximum quantity of a drug which can be ingested by a child without significant effect" (emphasis supplied). With regard to the latter recommendation, however, the Commission notes that since children differ significantly in their susceptibility to the toxic effects of a drug, an attempt to set a maximum allowable level can involve a complex balancing of factors. In a case such as the exemption for mebendazole, where there is no apparent need for setting a level other than that requested by the petitioner, it would be an inefficient use of the Commission's limited resources to conduct a research program for the purpose of establishing some higher level that would also be acceptable. Therefore, the Commission concludes that based on presently available data, the level should be maintained in the final exemption at 600 mg., as proposed.

2. The other comment on the proposal was from the Accident and Poison Prevention Committee of the American Academy of Pediatrics (AAP). AAP opposed granting the exemption because it believes that the data on toxicity to small children are insufficient and because there did not seem to be a therapeutic reason for the exemption.

AAP's comment concerning the sufficiency of the toxicity data was prompted, in part, by the following statement in the package insert for Vermox<sup>®</sup>: "This drug has not been extensively studied in children under two years; therefore, in the treatment of children under two years the relative benefit/risk should be considered." AAP concludes from this that "there is insufficient evidence for lack of toxicity for a statement to be included in the package insert."

The manufacturer of Vermox<sup>®</sup> has informally told the Commission that clinical trials have not been conducted in the United States with children under two years of age. However, the fact that the manufacturer of the drug chooses not to make an affirmative recommendation for very young children does not detract from the evidence of lack of toxicity that is available from other sources.

AAP also refers to four cases of ingestion that have been recorded by the Belgium Poison Control Center.
and that were referred to in the
Federal Register document that
proposed the exemption. AAP states that
eight children, without information as to
the doses or the ages of the persons
who were poisoned, are insufficient
for concluding that mebendazole is safe
for children in the one- to two-year-old
range in an overdose situation. Howev-
er, the Committee considers the
small number of reported ingestions
and the fact that none of them was se-
rious to be significant, even without
age and dosage information. In addi-
tion, there is ample evidence of the
low toxicity of this drug from other
sources.

The acute oral toxicity of the drug
has been investigated in twelve species
of experimental animals and found to
be of a low order. Toxicity in animal
tests is measured by the median lethal
dose, or LD-50 (i.e., the dose which
causes death in half the test animals).
Extrapolating from the LD-50 values
which were obtained in the four spe-
cies in which it was possible to
induce death, a 10 kg. child would
have to ingest more than 12.8 grams of
mebendazole in order to approach the
estimated LD-50 dosage. The proposed
exemption is limited to the much
lower dosage of 600 mg. of mebenda-
zo.

Studies submitted by the petitioner
indicate that mebendazole has been
evaluated in 4,567 patients, including
177 children less than six years old. Of
those 4,567 individuals studied, only 16
(0.34%) experienced adverse reactions,
which consisted of minimal gastroin-
testinal side-effects apparently related
to the expulsion of worms and not to
the drug itself.

Based on the data discussed above,
the Commission believes there is
ample evidence of the low toxicity of
this drug in children under two years
of age.

AAP also states that "there seems to
be no therapeutic reason why a non-
complying package is requested." Al-
though the presence of a therapeutic
reason would be a factor in favor of
granting an exemption, the absence of
such a reason does not relate to the
statutory requirement that the special
packaging must be required in order
to protect children from serious personal
illness or injury to children.

Because this rule grants an exemp-
tion, the requirement of the Adminis-
trative Procedure Act that publication
shall be made not less than 30 days
before the effective date (5 U.S.C.
553(d)) is not applicable, and the ex-
emption is therefore effective immedi-
ately.

Accordingly, pursuant to the provi-
sions of the Poison Prevention Packag-
ing Act of 1970 (Pub. L. 91-601; secs. 2,
3, 5; 84 Stat. 1670-1672; 15 U.S.C. 1471,
1472, 1474) and under authority vested
in the Commission by the Consumer
Protection Safety Act (Pub. L. 92-577,
sec. 30(a); 86 Stat. 1231; 15 U.S.C.
2079a(a)), the Commission amends Sub-
chapter E, Chapter II, of Title 16 of the
Code of Federal Regulations by adding
to §1700.14 a new paragraph (a)(10)(xii)
reading as follows (the intro-
ductive portion of paragraph (a)(10),
although unchanged, is includ-
ed below for context):

§1700.14 Substances requiring special
packaging.

(a) Substances. * * *

(10) Prescription drugs. Any drug
for human use that is in a dosage form
intended for oral administration and
that is required by Federal law to be
dispensed only by or upon an oral or
written prescription of a practitioner
licensed by law to administer such
drug shall be packaged in accordance
with the provisions of §1700.15(a), (b),
and (c), except for the following:

* * * * *

(xiii) Mebendazole in tablet form in
packages containing not more than
500 mg. of the drug, and containing no
other substance subject to the provi-
sions of this section.

Effective date. This amendment is
effective March 9, 1979.

[4110-03-M]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG
ADMINISTRATION, DEPARTMENT OF
HEALTH, EDUCATION, AND WEL-
FARE

SUBCHAPTER B—FOOD FOR HUMAN
CONSUMPTION

[Docket No. 78-0433]

PART 184—DIRECT FOOD SUB-
STANCES AFFIRMED AS GENER-
ALLY RECOGNIZED AS SAFE

Cocoa Butter Substitute From Palm
Oil; Extension of Comment Period;
Correction

AGENCY: Food and Drug Administra-

ACTION: Correction.

SUMMARY: In FR Doc. 79-3805 ap-
pearing in the Federal Register of
Friday, February 2, 1979, the following
corrections are made:

(1) On page 6706 in the fourth line of the
summary, the word "tentatively" is deleted and
in the seventh line, "food additive" is
changed to "ingredient";

(2) On page 6707 in the left column,
the line from the top of the page is
changed by inserting the word "substit-
tute" between the words "butter" and
"from."

EFFECTIVE DATE: March 9, 1979.

FOR FURTHER INFORMATION
CONTACT:

Corbin T. Miles, Bureau of Foods
(HEPP-335), Food and Drug Adminis-
tration, Department of Health, Edu-
cation, and Welfare, 200 C Street
SW., Washington, D.C. 20204, 202-
472-4750.


WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Regulatory Affairs.

[FR Doc. 79-7027 Filed 3-8-79; 8:45 am]

PART 520—ORAL DOSAGE FORM
NEW ANIMAL DRUGS NOT
SUBJECT TO CERTIFICATION

Diethylcarbamazine Citrate Tablets

AGENCY: Food and Drug Administra-

ACTION: Final rule.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979

[4110-03-M]
SUMMARY: The animal drug regulations are amended to reflect approval of a new animal drug application (NADA) providing for safe and effective use of an anthelmintic tablet as an aid in treatment of ascarid infections in dogs (Toxocara canis and Toxascaris leonina) and prevention of heartworm disease in dogs. The application was filed by Evsco Pharmaceutical Corp.

EFFECTIVE DATE: March 9, 1979.

FOR FURTHER INFORMATION CONTACT:

Henry C. Hewitt, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: Evsco Pharmaceutical Corp., P.O. Box 12992, Harding Highway, Buena, NJ 08310, filed an NADA (100-690V) providing for use of diethylcarbamazine citrate tablets as an aid in treatment of ascarid infection in dogs (Toxocara canis) and cats (Toxocara canis and Toxascaris leonina) and prevention of heartworm disease (Dirofilaria immitis) in dogs.

In accordance with the freedom of information regulations and § 514.11 (c)(2)(ii) of the animal drug regulations (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application is released publicly. The summary is available for public examination at the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

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 § 520.622a by revising paragraph (a) (2) and (3)(ii), to read as follows:

§ 520.622a Diethylcarbamazine citrate tablets.

(a) * * *
(2) Sponsors. (i) See Nos. 000010 and 010042 in § 510.600(c) of this chapter for use as in paragraph (a)(3)(ii) (a) and (b) of this section.
(ii) See No. 017030 for use as in paragraphs (3)(ii) (a) and (c) of this section.

(3) * * *
(ii) Indications for use. (a) For prevention of heartworm disease (Dirofilaria immitis) in dogs.
(b) As an aid in treatment of ascarid (Toxocara canis) and Toxascaris leonina) infections in dogs and cats.

This approval did not involve review of the original application and does not constitute reaffirmation of the safety and efficacy of the drug.

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 (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), Part 520 is amended in § 520.580 by revising paragraphs (c)(1) and (d)(1) to read as follows:

§ 520.580 Dichlorophen and toluene capsules.

(c)(1) Sponsor. Nos. 000010, 000081, 000298, 000856, 010290, 011519, 011536, 011614, 015653, 017115, and 022851 in § 510.600(c) of this chapter.

(d)(1) Sponsor. Nos. 000124, 000850, and 011716 in § 510.600(c) of this chapter.

Effective date. This regulation becomes effective (insert date of publication in the Federal Register).

(21 CFR 5.83).


LESTER CRAWDORD,
Director, Bureau of Veterinary Medicine.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Dichlorophene and Toluene Capsules

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of a supplemental new animal drug application (NADA) filed by Tutag Pharmaceuticals, Inc., providing revised labeling for anthelmintic capsules used in dogs and cats.

EFFECTIVE DATE: March 9, 1979.

FOR FURTHER INFORMATION CONTACT:

Robert G. Griffith, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: Tutag Pharmaceuticals, Inc., 2599 W. Midway Blvd., Broomfield, CO 80020, filed a supplemental NADA (102–073V) providing for addition of the divided dosage regimen to the labeling for dichlorophene-toluene capsules used for treating dogs and cats for certain helminth infections.

The firm’s application for its capsules was originally approved on September 14, 1976 for the single dose regimen. The capsules are similar to those reviewed by the National Academy of Sciences/National Research Council (NAS/NRC), approval of which is reflected in the regulations in 21 CFR 520.580. That approval is for both the single and divided dose regimen. Because Tutag’s divided dose regimen is identical to that of the NAS/NRC capsules, this supplement is approved on the basis of generic equivalence.

This approval did not involve review of the original application and does not constitute reaffirmation of the safety and efficacy of the drug.

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 (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), Part 520 is amended in § 520.522 by revising paragraphs (a) and (b)(1) to read as follows:

§ 520.522 Implantation or injectable form new animal drugs not subject to certification.

Aegis

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is resussing certain sections of the animal drug regulations regarding diatrizoates. This resuissance consists of nonsubstantive and editorial changes that conform the regulations to current United States Pharmacopoeia (USP) nomenclature.

EFFECTIVE DATE: March 9, 1979.
SUPPLEMENTARY INFORMATION

Sections 520.562 and 522.1362 of the animal drug regulations (21 CFR 520.562 and 522.1362) contain provisions for oral solution and injection forms of "meglumine diatrizoate and sodium diatrizoate." In addition, §522.564 (21 CFR 522.564) provides for use of an injectable form of "sodium diatrizoate and meglumine diatrizoate." The section numbers were assigned as a result of the general recodification published in the Federal Register of March 27, 1976 (40 FR 13892).

The agency is revising the names of these drugs to conform to current USP nomenclature. As a result, the drugs will appear in the regulations under the single designation "diatrizoate nomenclature. As a result, the drugs

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), Parts 520 and 522 are amended as follows:

1. Part 520 is amended:
   a. By adding new §520.563 to read as follows:

   §520.563 Diatrizoate meglumine and diatrizoate sodium oral solution.
   (a) Specifications. Diatrizoate meglumine oral solution is a water soluble radiopaque medium containing 65 percent diatrizoate meglumine and 10 percent diatrizoate sodium.

   b. By deleting §520.362 Meglumine diatrizoate and sodium diatrizoate oral solution.

   2. Part 522 is amended:
   a. By adding new §522.563 to read as follows:

   §522.563 Diatrizoate meglumine and diatrizoate sodium injection.
   (a) Specifications. Diatrizoate meglumine and diatrizoate sodium injection contains 34.3 percent diatrizoate meglumine and 35 percent diatrizoate sodium, or 66 percent diatrizoate meglumine and 10 percent diatrizoate sodium, in sterile aqueous solution.

   b. Sponsor. See No. 000003 in §510.600(c) of this chapter.

   (c) Conditions of use. (1) It is indicated for radiography of the gastrointestinal tract in dogs and cats. (2) It is administered orally at a dosage level of 0.5 to 1.0 milliliter per pound of body weight by gavage or stomach tube. It is administered rectally at a dosage level of 0.5 to 1.0 milliliter per pound of body weight diluted with 1 part of the drug to 5 parts of water.

   (3) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

   §520.1362 [Deleted]

   b. By deleting §520.1362 Meglumine diatrizoate and sodium diatrizoate injection and §522.1362 Meglumine diatrizoate and sodium diatrizoate injection.

   Effective date. This regulation is effective March 9, 1979.


   Dated: March 5, 1979.

   LESTER M. CRAWFORD,
   Director, Bureau of Veterinary Medicine.

   [F.R. Doc. 79-7142 Filed 3-8-79; 8:45 a.m]

[4410-09-M]

CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

PART 1310—PIPERIDINE REPORTING AND PURCHASER IDENTIFICATION

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: This rule is issued to establish interim regulations to implement Section 203(b)(2) of Title II—PCP Criminal Penalties and Piper-
dine Reporting—of Pub. L. 95–633, “The Psychotropic Substances Act of 1978,” as required by Section 203(b)(2). Specifically, Section 203(b)(2) requires that final interim regulations be promulgated not later than 75 days after the date of the enactment of Pub. L. 95–633, to detail the manner and extent of piperdine reporting and customer identification requirements of Section 202(b) of Title II of the Act.

**EFFECTIVE DATE:** The effective date of this part is April 9, 1979.

**FOR FURTHER INFORMATION CONTACT:**

**SUPPLEMENTARY INFORMATION:**
A notice was published in the Federal Register on December 11, 1978 (43 FR 57922) proposing to establish reporting and identification of purchaser requirements pursuant to Section 203(b)(2) of Title II—PCP Criminal Penalties and Piperdine Reporting—of Pub. L. 95–633 “The Psychotropic Substances Act of 1978.” All interested persons were given until January 10, 1979 to submit their comments or objections in writing regarding this proposal.

Two manufacturers and one importer responded to the Notice. The importer (BASF Wyandotte) suggested that reporting of each importation within a seven-day period would be burdensome and reporting of total importation should be limited to an annual import statement by reputable importers. The Drug Enforcement Administration (DEA) believes that §1310.06 Exemptions, as revised from proposed §1310.05, provides adequate relief for this concern. DEA also believes that semi-annual reporting is justified.

Both manufacturers requested several definitional clarifications and changes in wording to preclude misinterpretation. These comments have resulted in adding a section of definitions, renumbering of the proposed sections and wording changes in these sections. DEA believes the revised sections satisfy all substantive comments made concerning the original proposal.

Therefore, under the authority vested in him by the Act and by regulations of the Department of Justice, the Administrator of the Drug Enforcement Administration hereby orders that new Part 1310 be added to Title 21 of the Code of Federal Regulations as follows:

---

### RULES AND REGULATIONS

#### PART 1310—PIPERDINE REPORTING AND PURCHASER IDENTIFICATION

Sec. 1310.01 Definitions.

1310.02 Persons required to report.

1310.03 Contents of report.

1310.04 Frequency and format of reports.

1310.05 Purchaser identification.

1310.06 Exemptions.

**Authority:** Sec. 203(b)(2) of Title II, Pub. L. 95–633, 21 U.S.C. 830 note, 92 Stat. 3776.

§1310.01 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) The term “piperdine” includes its salts and acyl derivatives;

(b) The term “individual purchaser” means a human being not acting as an agent or official of a business entity (e.g., company, corporation, partnership) or an accredited academic institution;

(c) The term “person” includes any individual, corporation, business trust, partnership, association, or other legal entity.

§1310.02 Persons required to report.

Any person who distributes, transfers, sells, ships or imports piperdine, unless exempted in accordance with §1310.04(c) shall report:

(a) Each importation of any quantity of piperdine and each transfer from the importer of record to any purchaser who is not the importer of record;

(b) Each shipment of piperdine in any quantity to any individual or entity other than an individual;

(c) All thefts or significant losses of piperdine.

§1310.03 Content of reports.

Reports required under §1310.02 shall include at least the following:

1. The name, address and age of the individual;

2. The type of identification which the individual purchaser presents to confirm his identity with corresponding identification numbers;

3. The quantity and form of piperdine;

4. The date shipped and method of shipment (company truck, picked up by customer, etc.);

5. The name and address of the shipper;

6. The name and title of the person authorizing the shipment; and

7. The intended use of the piperdine.

(b) In the case of shipment to an entity other than an individual:

1. The name and address of the entity;

2. The name, address and title of the person ordering or receiving the piperdine;

3. The type of identification presented to confirm the identity of the person and the entity;

4. The quantity and form of piperdine;

5. The date shipped and method of shipment;

6. The name and address of the shipper;

7. The name and title of the person authorizing shipment; and

8. The intended use of the piperdine.

§1310.04 Frequency and format of reports.

(a) All reports required to be made under this part shall be submitted to the Drug Enforcement Administration office nearest the reporter’s place of business, not later than seven (7) days after the distribution, shipment or importation.

(b) Reporting forms will be provided by the Drug Enforcement Administration as soon as they are available and may then be obtained from the nearest Drug Enforcement office. In the meantime; reports may be submitted on plain bond paper or business letterhead provided they contain the required information. A suggested format for reporting is given below:

<table>
<thead>
<tr>
<th>Supplier-Importer:</th>
<th>Name</th>
<th>Business phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>City ____________________________ State Zip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name of person authorizing shipment</td>
<td>Title</td>
<td></td>
</tr>
<tr>
<td>Purchaser:</td>
<td>Name</td>
<td>Business phone</td>
</tr>
<tr>
<td>City ____________________________ State Zip</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name of person requesting shipment</td>
<td>Title</td>
<td></td>
</tr>
<tr>
<td>Shipping address (if other than purchaser):</td>
<td>Street</td>
<td>City ____________________________ State Zip</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Identification:</td>
<td>Purchase Order No.</td>
<td>Drivers License No.</td>
</tr>
<tr>
<td>Method of shipment:</td>
<td>Company Truck</td>
<td>Common Carrier</td>
</tr>
<tr>
<td>Quantity and Form:</td>
<td>Quantity</td>
<td>In Transit</td>
</tr>
<tr>
<td>Intended use of piperdine:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
thereafter each person who distributes, ships or imports piperidine shall submit to the Drug Enforcement Administration office nearest his place of business a complete list of all purchasers of piperidine to which the shipper has made shipment within the six (6) months immediately preceding each reporting date as hereinabove required. Such lists need only contain the name and address of the purchaser and the quantity and date of each shipment to that purchaser.

§ 1310.05 Purchaser identification.

Each person required to report under Section 310(a) of the Act (21 U.S.C. 830) shall establish a system of requiring positive identification of all persons who purchase or receive piperidine from them. The Drug Enforcement Administration recommends that such identification consist of at least a letterhead and signature of the purchaser or his agent in the case of business entities and the usual identification (e.g., drivers license/credit card combination) required for credit transactions for sales to individuals. However, alternative systems of positive identification may be acceptable after review and approval by the appropriate Regional Director of the Drug Enforcement Administration.

§ 1310.06 Exemptions.

Requests for exemption from reporting:

(a) Any person who distributes, ships, sells or imports piperidine may request exemption from reporting shipments to the Drug Enforcement Administration upon his certification that a specific purchaser is known by him to be a customer who has established legitimate business credentials for piperidine purchases. Such certification may be on plain bond paper or letterhead signed by a responsible party and shall be submitted to the Drug Enforcement Administration office nearest the person’s place of business.

(b) Any person who imports piperidine may request exemption from the seven-day reporting requirement for importation, provided that each importation is reported in accordance with § 1310.04(c).

(c) Intra-company transfers or on-site transfers between affiliated companies of piperidine where the piperidine is not removed from the control of either the transferring company or the affiliated company are exempted from the seven-day reporting requirement upon request.

The Drug Enforcement Administration will inform the person requesting the exemption of its approval or disapproval within thirty (30) days following receipt of the request.

This order, and the interim regulations issued hereunder, are effective April 9, 1979.

Dated: March 1, 1979.

PETER B. BENSINGER, Administrator, Drug Enforcement Administration.

[FR Doc. 79-7178 Filed 3-5-79; 8:45 am]

Title 23—Highways

CHAPTER I—FEDERAL HIGHWAY ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

SUBCHAPTER B—NATIONAL FLOOD INSURANCE PROGRAM

PART 771—ENVIRONMENTAL IMPACT AND RELATED STATEMENTS

Authority Citation

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notification of authority citation.

SUMMARY: At 43 FR 20978, May 16, 1978, the Federal Highway Administration amended FHWA environmental regulations to allow the processing as nonmajor Federal actions of projects having only a minimal effect upon properties protected by section 4(f) of the Department of Transportation Act or section 106 of the National Historic Preservation Act. This document adds the authority citation under which the amendment was issued.

EFFECTIVE DATE: May 19, 1978.

FOR FURTHER INFORMATION CONTACT:

Robert G. Clour, Environmental Programs Division, 202/426-0106, or Marguerite L. Price, Office of the Chief Counsel, 202/426-0791.

SUPPLEMENTARY INFORMATION: The proper authority citation for the rule document 78-13222 which amended 23 CFR Part 771 published at 43 FR 20978 is as follows:

(18 U.S.C. 470f, 652(a), 1301; 23 U.S.C. 128, 138, 315; 42 U.S.C. 4322(c) and (d), 7401; 49 U.S.C. 1653(f); 49 CFR 1500; and 49 CFR 1.49(b))

Issued on: March 1, 1979.

LORENZO CASANOVA, Chief Counsel.

[FR Doc. 79-7155 Filed 3-8-79; 8:43 am]
property insurance agent or broker serving the eligible community, or from the National Flood Insurance Program. The effective date of conversion to the Regular Program will not appear in the Code of Federal Regulations except for the page number of this entry in the Federal Register.

The entry reads as follows:

\[1915.2\] List of Communities with Minimal Flood Hazard Areas.

State, County and Community Name
Indiana, Porter, City of Valparaiso
Michigan, St. Joseph, Village of Colon
Michigan, Wayne, City of Inkster
Ohio, Cuyahoga, City of Broadview Heights
Ohio, Butler, City of Middletown
Ohio, Cuyahoga, Village of Oakwood
Ohio, Summit, Village of Peninsula
Pennsylvania, Wyoming, City of Wyoming
Pennsylvania, Lycoming, Township of Mill Creek
Pennsylvania, York, Borough of New Freedom
Louisiana, St. Helena Parish, Village of Montpelier


In accordance with Section 7(o)(4) of the Department of Housing and Urban Development Act, Section 324 of the Housing and Community Amendments of 1968, Pub. L. 95-557, 92 Stat. 2080, this rule has been granted waiver of Congressional review requirements in order to permit it to take effect on the date indicated.


Gloria M. Jimenez, Federal Insurance Administrator.

[FR Doc. 79-6809 Filed 3-8-79; 8:45 am]

PART 1917—APPEALS FROM PROPOSED FLOOD ELEVATION DETERMINATIONS

Final Flood Elevation Determination for the City of Hilliard, Franklin County, Ohio

AGENCY: Federal Insurance Administration, HUD.

ACTION: Final rule.

SUMMARY: Final base (100-year) flood elevations are listed below for selected locations in the Village of Jefferson, Ashtabula County, Ohio. These base (100-year) flood elevations are the basis for the floodplain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

EFFECTIVE DATE: The date of issuance of the flood insurance rate map (FIRM), showing base (100-year) flood elevations, for the City of Hilliard, Franklin County, Ohio.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the final elevations for Franklin County are available for review at 3800 Municipal Square, Hilliard, Ohio.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

The Federal Insurance Administrator gives notice of the final determinations of flood elevations for the City of Hilliard, Franklin County, Ohio.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-334, 87 Stat. 590, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 91-172), 42 U.S.C. 4001-4128, and 24 CFR 1917.4(a)). An opportunity for the community or individuals to appeal this determination to or through the community for a period of ninety (90) days has been provided. No appeals of the proposed base flood elevations were received from the community or from individuals within the community.

The Administrator has developed criteria for floodplain management in flood-prone areas in accordance with 24 CFR Part 1910.

The final base (100-year) flood elevations for selected locations are:

<table>
<thead>
<tr>
<th>Source of flooding</th>
<th>Location</th>
<th>Elevation in feet, national geodetic vertical datum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clover Groff</td>
<td>South corporate limit ...</td>
<td>927</td>
</tr>
<tr>
<td></td>
<td>Just downstream of Scioto Darby Creek Road</td>
<td>940</td>
</tr>
<tr>
<td>Hayden Run</td>
<td>East corporate limit ...</td>
<td>909</td>
</tr>
<tr>
<td></td>
<td>640 feet upstream of Avery Road</td>
<td>910</td>
</tr>
<tr>
<td></td>
<td>1,400 feet upstream of Avery Road</td>
<td>912</td>
</tr>
<tr>
<td>Tudor Ditch</td>
<td>East corporate limit ...</td>
<td>870</td>
</tr>
<tr>
<td></td>
<td>56 feet upstream of Parkview Lane</td>
<td>875</td>
</tr>
<tr>
<td></td>
<td>940 feet upstream of Parkview Lane</td>
<td>880</td>
</tr>
<tr>
<td></td>
<td>Just downstream of ConRail</td>
<td>889</td>
</tr>
<tr>
<td>Hamilton Ditch</td>
<td>East corporate limit ...</td>
<td>869</td>
</tr>
</tbody>
</table>


In accordance with Section 7(o)(4) of the Department of HUD Act, Section 324 of the Housing and Community Amendments of 1978, Pub. L. 95-557, 92 Stat. 2080, this rule has been granted waiver of Congressional review requirements in order to permit it to take effect on the date indicated.

Issued: January 22, 1979.

Gloria M. Jimenez, Federal Insurance Administrator.

[FR Doc. 79-6790 Filed 3-8-79; 8:45 am]
ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the final elevations for the Village of Jefferson are available for review at the Village Hall, 27 East Jefferson Street, Jefferson, Ohio.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW, Washington, D.C. 20210, 202-755-5581 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION:

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448), 42 U.S.C. 4001-4126, and 24 CFR 1917.4(a)). An opportunity for the community or individuals to appeal this determination to or through the community for a period of ninety (90) days has been provided. No appeals of the proposed base flood elevations were received from the community or from individuals within the community.

The Administrator has developed criteria for flood plain management in flood-prone areas in accordance with 24 CFR Part 1910. The final base (100-year) flood elevations for selected locations are:

<table>
<thead>
<tr>
<th>Location</th>
<th>Elevation in feet</th>
<th>National geodetic vertical datum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cemetery Creek</td>
<td>568</td>
<td></td>
</tr>
<tr>
<td>200 feet upstream of Poplar Street</td>
<td>568</td>
<td></td>
</tr>
<tr>
<td>500 feet upstream of Poplar Street</td>
<td>570</td>
<td></td>
</tr>
<tr>
<td>250 feet downstream of Elm Street</td>
<td>572</td>
<td></td>
</tr>
<tr>
<td>250 feet upstream of Elm Street</td>
<td>574</td>
<td></td>
</tr>
<tr>
<td>Just downstream of Chestnut Street</td>
<td>582</td>
<td></td>
</tr>
<tr>
<td>Just upstream of Chestnut Street</td>
<td>584</td>
<td></td>
</tr>
<tr>
<td>200 feet upstream of Chestnut Street</td>
<td>585</td>
<td></td>
</tr>
</tbody>
</table>

In accordance with Section 7(o)(4) of the Department of HUD Act, Section 324 of the Housing and Community Amendments of 1978, Pub. L. 95-557, 92 Stat. 5577, this rule has been granted waiver of Congressional review requirements in order to permit it to take effect on the date indicated.


GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[4210-01-M]

PART 1917—APPEALS FROM PROPOSED FLOOD ELEVATION DETERMINATIONS

Final Flood Elevation Determination for the City of Mentor-on-the-Lake, Lake County, Ohio

AGENCY: Federal Insurance Administration, HUD.

ACTION: Final rule.

SUMMARY: Final base (100-year) flood elevations are listed below for selected locations in the City of Mentor-on-the-Lake, Lake County, Ohio. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

EFFECTIVE DATE: The date of issuance of the flood insurance rate map (FIRM), showing base (100-year) flood elevations, for the City of Mentor-on-the-Lake, Lake County, Ohio.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the final elevations for the City of Mentor-on-the-Lake are available for review at the City Hall, 5860 Andrews Road, Mentor-on-the-Lake, Ohio.

FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW, Washington, D.C. 20210, 202-755-5581 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION:
The Federal Insurance Administrator gives notice of the final determinations of flood elevations for the City of Mentor-on-the-Lake, Lake County, Ohio. This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448), 42 U.S.C. 4001-4126, and 24 CFR 1917.4(a)). An opportunity for the community or individuals to appeal this determination to or through the community for a period of ninety (90) days has been provided. No appeals of the proposed base flood elevations were received from the community or from individuals within the community.

The Administrator has developed criteria for flood plain management in flood-prone areas in accordance with 24 CFR Part 1910.

The final base (100-year) flood elevations for selected locations are:

<table>
<thead>
<tr>
<th>Location</th>
<th>Elevation in feet</th>
<th>National geodetic vertical datum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lake Erie</td>
<td>570</td>
<td></td>
</tr>
</tbody>
</table>

(National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968, 24 CFR 1917.4(a)). An opportunity for the community or individuals to appeal this determination to or through the community for a period of ninety (90) days has been provided. No appeals of the proposed base flood elevations were received from the community or from individuals within the community.

In accordance with Section 7(o)(4) of the Department of HUD Act, Section 324 of the Housing and Community Amendments of 1978, Pub. L. 95-557, 92 Stat. 5577, this rule has been granted waiver of Congressional review requirements in order to permit it to take effect on the date indicated.

Issued: January 24, 1979.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

(FR Doc. 79-6792 Filed 3-8-79; 8:45 am)

[4210-01-M]

Docket No. FT-4642

PART 1917—APPEALS FROM PROPOSED FLOOD ELEVATION DETERMINATIONS

Final Flood Elevation Determination for the Village of Waite Hill, Lake County, Ohio

AGENCY: Federal Insurance Administration, HUD.

ACTION: Final rule.

SUMMARY: Final base (100-year) flood elevations are listed below for selected locations in the Village of Waite Hill, Lake County, Ohio. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evi-
Source of flooding | Location | Elevation in feet, national geodetic vertical datum
---|---|---
Chagrin River | At confluence of East Branch Chagrin River (corporate limit) | 618
| 0.9 miles upstream of Riverside Drive. | 625
| 0.62 miles downstream of Eagle Road. | 636
| Upstream side of Eagle Road. | 644
| Upstream corporate limit. | 651
East Branch Chagrin River | At confluence with Chagrin River | 618
| 0.4 miles upstream of Northeast Round 1-90. | 629
| 0.64 miles downstream of Markell Road. | 638

**SUPPLEMENTARY INFORMATION:**

The Federal Insurance Administrator gives notice of the final determinations of flood elevations for the City of Duncan, Stephens County, Oklahoma.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448), 42 U.S.C. 4001-4128, and 24 CFR 1917.4(a)). An opportunity for the community or individuals to appeal this determination to or through the community for a period of ninety (90) days has been provided, and the Administrator has resolved the appeals presented by the community.

The Administrator has developed criteria for flood plain management in flood-prone areas in accordance with 24 CFR Part 1910.

The final base (100-year) flood elevations for selected locations are:

<table>
<thead>
<tr>
<th>Source of flooding</th>
<th>Location</th>
<th>Elevation in feet, national geodetic vertical datum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claridy Creek</td>
<td>Just upstream of Seminole Street.</td>
<td>1063</td>
</tr>
<tr>
<td></td>
<td>Just downstream of Belts D Furniture</td>
<td>1080</td>
</tr>
<tr>
<td></td>
<td>Avenue.</td>
<td>1102</td>
</tr>
<tr>
<td></td>
<td>Just upstream of Elk Avenue.</td>
<td>1130</td>
</tr>
<tr>
<td>Cow Creek</td>
<td>Just upstream of State Highway 7 culvert.</td>
<td>1071</td>
</tr>
<tr>
<td></td>
<td>Just downstream of Elk Avenue.</td>
<td>1140</td>
</tr>
<tr>
<td></td>
<td>Just downstream of Park Boulevard.</td>
<td>1085</td>
</tr>
<tr>
<td></td>
<td>Just downstream of Main Street.</td>
<td>1107</td>
</tr>
<tr>
<td></td>
<td>Just downstream of Plato Road.</td>
<td>1182</td>
</tr>
<tr>
<td>Tributary B</td>
<td>Just upstream of Beech Street.</td>
<td>1100</td>
</tr>
<tr>
<td></td>
<td>Just upstream of Park Avenue.</td>
<td>1100</td>
</tr>
<tr>
<td></td>
<td>Approximately 100 feet downstream of Pocan Avenue.</td>
<td>1110</td>
</tr>
<tr>
<td></td>
<td>Just downstream of State Highway 7.</td>
<td>1000</td>
</tr>
</tbody>
</table>


**FOR FURTHER INFORMATION CONTACT:**

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.
In accordance with Section 706(X) of the Department of Housing and Urban Development Act, Section 324 of the Housing and Community Amendments of 1978, Pub. L. 95-557, 92 Stat. 2080, this rule has been granted waiver of Congressional review requirements in order to permit it to take effect on the date indicated.

Issued: January 22, 1979.

GLORIA M. JIMENEZ, Federal Insurance Administrator, (F.R. Doc. 79-6794 Filed 3-8-79; 8:45 a.m)

[4210-01-M]

(Docket No. FI-4569)

PART 1917—APPEALS FROM PROPOSED FLOOD ELEVATION DETERMINATIONS

Final Flood Elevation Determinations for the City of Drain, Douglas County, Oregon

AGENCY: Federal Insurance Administration, HUD.

ACTION: Final rule.

SUMMARY: Final base (100-year) flood elevations are listed below for selected locations in the City of Drain, Douglas County, Oregon. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

EFFECTIVE DATE: The date of issuance of the flood insurance rate map (FIRM), showing base (100-year) flood elevations, for the City of Riddle, Oregon.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the final elevations for the City of Riddle, are available for review at City Hall, 2nd Avenue, Riddle, Oregon.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5951 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the final determinations of flood elevations for the City of Riddle, Oregon.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1383 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968) (Pub. L. 92-414). This rule has been granted waiver of Congressional review requirements in order to permit it to take effect on the date indicated.


GLORIA M. JIMENEZ, Federal Insurance Administrator, (F.R. Doc. 79-6795 Filed 3-8-79; 8:45 a.m)

[4210-01-M]

(Docket No. FI-4569)

PART 1917—APPEALS FROM PROPOSED FLOOD ELEVATION DETERMINATIONS

Final Flood Elevation Determination for the City of Riddle, Douglas County, Oregon

AGENCY: Federal Insurance Administration, HUD.

ACTION: Final rule.

SUMMARY: Final base (100-year) flood elevations are listed below for selected locations in the City of Riddle, Douglas County, Oregon. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

EFFECTIVE DATE: The date of issuance of the flood insurance rate map (FIRM), showing base (100-year) flood elevations, for the City of Riddle, Oregon.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the final elevations for the City of Riddle, are available for review at City Hall, 2nd Avenue, Riddle, Oregon.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5951 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the final determinations of flood elevations for the City of Riddle, Oregon.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1383 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968) (Pub. L. 92-414). This rule has been granted waiver of Congressional review requirements in order to permit it to take effect on the date indicated.


GLORIA M. JIMENEZ, Federal Insurance Administrator, (F.R. Doc. 79-6795 Filed 3-8-79; 8:45 a.m)

[4210-01-M]

(Docket No. FI-4569)

PART 1917—APPEALS FROM PROPOSED FLOOD ELEVATION DETERMINATIONS

Final Flood Elevation Determination for the City of Riddle, Douglas County, Oregon

AGENCY: Federal Insurance Administration, HUD.

ACTION: Final rule.

SUMMARY: Final base (100-year) flood elevations are listed below for selected locations in the City of Riddle, Douglas County, Oregon. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

EFFECTIVE DATE: The date of issuance of the flood insurance rate map (FIRM), showing base (100-year) flood elevations, for the City of Riddle, Oregon.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the final elevations for the City of Riddle, are available for review at City Hall, 2nd Avenue, Riddle, Oregon.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5951 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the final determinations of flood elevations for the City of Riddle, Oregon.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1383 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968) (Pub. L. 92-414). This rule has been granted waiver of Congressional review requirements in order to permit it to take effect on the date indicated.


GLORIA M. JIMENEZ, Federal Insurance Administrator, (F.R. Doc. 79-6795 Filed 3-8-79; 8:45 a.m)
FR 17804, November 28, 1968), as amended (42 U.S.C. 4001-4128); and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7719.)

In accordance with Section 7(o)(4) of the Department of HUD Act, Section 324 of the Housing and Community Amendments of 1978, Pub. L. 95-557, 92 Stat. 2060, this rule has been granted waiver of Congressional review requirements in order to permit it to take effect on the date indicated.


GLORIA M. JIMENEZ,
Federal Insurance Administrator.

(FR Doc. 79-6799 Filed 3-8-79; 8:45 am)

[4210-01-M] (Docket No. FI-4249)

PART 1917—APPEALS FROM FLOOD ELEVATION DETERMINATION AND JUDICIAL REVIEW

Final Flood Elevation Determination for the City of Chester, Delaware County, Pennsylvania

AGENCY: Federal Insurance Administration, HUD.

ACTION: Final rule.

SUMMARY: Final base (100-year) flood elevations are listed below for selected locations in the City of Chester, Delaware County, Pennsylvania. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

EFFECTIVE DATE: The date of issuance of the flood insurance rate map (FIRM), showing base (100-year) flood elevations, for the Township of Cleveland, Delaware County, Pennsylvania, is available for review at the Cleveland Township Municipal Building, Fisherdale, Pennsylvania.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the final elevations for the Township of Cleveland, Delaware County, Pennsylvania, are available for review at the Municipal Building Annex, 5th and Welsh Streets, Chester, Pennsylvania.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION:
The Federal Insurance Administrator gives notice of the final determinations of flood elevations for the City of Chester, Delaware County, Pennsylvania.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448), 42 U.S.C. 4001-4128, and 24 CFR 1917.4(a)). An opportunity for the community or individuals to appeal this determination to or through the community for a period of ninety (90) days has been provided. No appeals of the proposed base flood elevations were received from the community or from individuals within the community.

The Administrator has developed criteria for flood plain management in flood-prone areas in accordance with 24 CFR Part 1910.

The final base (100-year) flood elevations for selected locations are:

<table>
<thead>
<tr>
<th>Source of flooding</th>
<th>Location</th>
<th>Elevation in feet</th>
<th>National geodetic vertical datum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ridley Creek</td>
<td>Corporate limits</td>
<td>41</td>
<td></td>
</tr>
<tr>
<td></td>
<td>upstream</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chester Park Dam</td>
<td>32</td>
<td></td>
</tr>
<tr>
<td></td>
<td>upstream</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chester Park Dam</td>
<td>31</td>
<td></td>
</tr>
<tr>
<td></td>
<td>downstream</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>East 25th Street</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td></td>
<td>upstream</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Interstate Route 65</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td></td>
<td>upstream</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>4th Street upstream</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chester Creek</td>
<td>Corporate limits</td>
<td>28</td>
</tr>
<tr>
<td></td>
<td>upstream</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chester Park Dam</td>
<td>31</td>
<td></td>
</tr>
<tr>
<td></td>
<td>upstream</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>8th Street upstream</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2nd Street upstream</td>
<td>13</td>
<td></td>
</tr>
</tbody>
</table>


In accordance with Section 7(o)(4) of the Department of HUD Act, Section 324 of the Housing and Community Amendments of 1978, P.L. 95-557, 92 Stat. 2060, this rule has been granted waiver of Congressional review requirements in order to permit it to take effect on the date indicated.

Issued: January 5, 1979.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

(FR Doc. 79-6799 Filed 3-8-79; 8:45 am)
base flood elevations were received from the community or from individuals within the community.

The Administrator has developed criteria for flood plain management in flood-prone areas in accordance with 24 CFR Part 1910.

The final base (100-year) flood elevations for selected locations are:

<table>
<thead>
<tr>
<th>Source of flooding</th>
<th>Location</th>
<th>Elevation in feet, national geodetic vertical datum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roaring Creek</td>
<td>Covered Bridge No. 10</td>
<td>621</td>
</tr>
<tr>
<td></td>
<td>Bridge No. 11</td>
<td>645</td>
</tr>
<tr>
<td></td>
<td>Bridge No. 12</td>
<td>692</td>
</tr>
<tr>
<td>South Branch Roaring Creek</td>
<td>Confluence with Mugser Run</td>
<td>613</td>
</tr>
<tr>
<td>Mugser Run</td>
<td>Bridge No. 21</td>
<td>647</td>
</tr>
<tr>
<td></td>
<td>Bridge No. 22</td>
<td>661</td>
</tr>
<tr>
<td></td>
<td>Confluence with South Branch Roaring Creek</td>
<td>613</td>
</tr>
<tr>
<td></td>
<td>Township Route 316</td>
<td>692</td>
</tr>
<tr>
<td></td>
<td>Johnson Covered Bridge</td>
<td>663</td>
</tr>
</tbody>
</table>

SUMMARY: Final base (100-year) flood elevations were received for the Borough of Everson, Fayette County, Pa. ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the final elevations for the Borough of Everson, Fayette County, Pa., are available for review at the Everson Borough Building, Brown Street, Everson, Pa.

FOR FURTHER INFORMATION CONTACT:
Mr. Richard Krinn, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW, Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.


In accordance with Section 7(o)(4) of the Department of HUD Act, Section 324 of the Housing and Community- Amendments of 1978, Pub. L. 95-557, the administrator of the national flood insurance program (NFIP), showing base (100-year) flood elevations, for the Borough of Everson, Fayette County, Pa., are available for review at the Everson Borough Building, Brown Street, Everson, Pa.

FOR FURTHER INFORMATION CONTACT:
Mr. Richard Krinn, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW, Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the final determinations of flood elevations for the Town-
ship of Franklin, Columbia County, Pa.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448), 42 U.S.C. 4001-4126, and 24 CFR 1917.4(a)). An opportunity for the community or individuals to appeal this determination to or through the community for a period of ninety (90) days has been provided. No appeals of the proposed base flood elevations were received from the community or from individuals within the community.

The Administrator has developed criteria for flood plain management in flood-prone areas in accordance with 24 CFR Part 1910.

The final base (100-year) flood elevations for selected locations are:

<table>
<thead>
<tr>
<th>Source of flooding</th>
<th>Location</th>
<th>Elevation in feet, national geodetic vertical datum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Susquehanna River</td>
<td>Confluence with Roaring Creek.</td>
<td>497</td>
</tr>
<tr>
<td>Roaring Creek</td>
<td>Old Concrete Dam (Upstream)</td>
<td>481</td>
</tr>
<tr>
<td></td>
<td>Covered Bridge No. 6 (Upstream)</td>
<td>552</td>
</tr>
<tr>
<td></td>
<td>Bridge No. 7 (Upstream)</td>
<td>597</td>
</tr>
<tr>
<td></td>
<td>State Route 487 (Upstream 109), Upstream Corporate Limits</td>
<td>599</td>
</tr>
<tr>
<td>South Branch</td>
<td>Bridge No. 24 (Upstream)</td>
<td>573</td>
</tr>
<tr>
<td>Roaring Creek</td>
<td>Bridge No. 25 (Upstream)</td>
<td>600</td>
</tr>
<tr>
<td></td>
<td>Legislative Route 40091 (Upstream)</td>
<td>612</td>
</tr>
</tbody>
</table>

The final base (100-year) flood elevations for selected locations were received from the community or from individuals within the community.

The Administrator has developed criteria for flood plain management in flood-prone areas in accordance with 24 CFR Part 1910.

The final base (100-year) flood elevations for selected locations are:

<table>
<thead>
<tr>
<th>Source of flooding</th>
<th>Location</th>
<th>Elevation in feet, national geodetic vertical datum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fishing Creek</td>
<td>State Route 44 (Upstream), Railroad Street (Upstream), Interstate Route 80 (Upstream)</td>
<td>478</td>
</tr>
<tr>
<td></td>
<td>State Route 42 (Upstream), Interstate Route 80</td>
<td>492</td>
</tr>
<tr>
<td></td>
<td>Township Road 819 (Upstream), Upstream Corporate Limits</td>
<td>545</td>
</tr>
</tbody>
</table>

NATIONAL FLOOD INSURANCE ACT OF 1968 (Title XIII of the Housing and Urban Development Act of 1968, effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended (42 U.S.C. 4001-4126); and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7710.)

In accordance with section 7(o)(4) of the Department of HUD Act, Section 324 of the Housing and Community Amendments of 1978, Pub. L. 95-557, 92 Stat. 2080, this rule has been granted waiver of Congressional review requirements in order to permit it to take effect on the date indicated.

Issued: January 24, 1979.

GLORIA M. JIMENEZ
Federal Insurance Administrator
(FR Doc. 79-5801 Filed 3-8-79; 8:45 am)

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
tions are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

**EFFECTIVE DATE:** The date of issuance of the flood insurance rate map (FIRM), showing base (100-year) flood elevations, for the Borough of Herndon, Northumberland County, Pa.

**ADDRESS:** Maps and other information showing the detailed outlines of the flood-prone areas and the final elevations for the Borough of Herndon, Northumberland County, Pa., are available for review at the Borough Municipal Building, Main Street, Herndon, Pa.

**FOR FURTHER INFORMATION CONTACT:**

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 1704, Seventh Street SW, Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

**SUPPLEMENTARY INFORMATION:** The Federal Insurance Administrator gives notice of the final determinations for selected locations in the Township of Locust, Columbia County, Pa. These base (100-year) flood elevations are listed below for selected locations in the Township of Locust, Columbia County, Pa. These final base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

**EFFECTIVE DATE:** The date of issuance of the flood insurance rate map (FIRM), showing base (100-year) flood elevations, for the Township of Locust, Columbia County, Pa.

**ADDRESS:** Maps and other information showing the detailed outlines of the flood-prone areas and the final elevations for the Township of Locust, Columbia County, Pa., are available for review at the Borough Municipal Building, Main Street, Herndon, Pa.

**FOR FURTHER INFORMATION CONTACT:**

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 1704, Seventh Street SW, Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

**SUPPLEMENTARY INFORMATION:** The Federal Insurance Administrator gives notice of the final determinations for selected locations in the Township of Locust, Columbia County, Pa.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234, 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968) and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7719.)

In accordance with Section 7(o)(4) of the Department of HUD Act, Section 324 of the Housing and Community Amendments of 1978, P.L. 95-557, 92 Stat. 2080, this rule has been granted waiver of Congressional review requirements in order to permit it to take effect on the date indicated.

Issued: January 24, 1979.

GLORIA M. JIMENEZ, Federal Insurance Administrator.
(FR Doc. 78-6802 Filed 3-8-79; 8:45 am)

[4210-01-M]

(Docket No. FI-4817)

PART 1917—APPEALS FROM PROPOSED FLOOD ELEVATION DETERMINATIONS

Final Flood Elevation Determination for the Township of Locust, Columbia County, Pa.

AGENCY: Federal Insurance Administration, HUD.

ACTION: Final rule.

SUMMARY: Final base (100-year) flood elevations are listed below for selected locations in the Township of Locust, Columbia County, Pa. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

**EFFECTIVE DATE:** The date of issuance of the flood insurance rate map (FIRM), showing base (100-year) flood elevations, for the Township of Locust, Columbia County, Pa.

**ADDRESS:** Maps and other information showing the detailed outlines of the flood-prone areas and the final elevations for the Township of Locust, Columbia County, Pa., are available for review at the Borough Municipal Building, Main Street, Herndon, Pa.

**FOR FURTHER INFORMATION CONTACT:**

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 1704, Seventh Street SW, Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

**SUPPLEMENTARY INFORMATION:** The Federal Insurance Administrator gives notice of the final determinations for selected locations in the Township of Locust, Columbia County, Pa.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448), 42 U.S.C. 4001-4128, and 24 CFR 1917.4(a)). An opportunity for the community or individuals to appeal this determination to or through the community for a period of ninety (90) days has been provided. No appeals of the proposed base flood elevations were received from the community or from individuals within the community.

The Administrator has developed criteria for flood plain management in flood-prone areas in accordance with 24 CFR Part 1910.

The final base (100-year) flood elevations for selected locations are:

<table>
<thead>
<tr>
<th>Source of flooding</th>
<th>Location</th>
<th>Elevation in feet above national geodetic vertical datum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Susquehanna River</td>
<td>Downstream Corporate Limits</td>
<td>442</td>
</tr>
<tr>
<td></td>
<td>Pine Street (extended)</td>
<td>423</td>
</tr>
<tr>
<td></td>
<td>Confluence of Mahanoy Creek</td>
<td>426</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roaring Creek</td>
<td>State Route 42 (Upstream)</td>
<td>729</td>
</tr>
<tr>
<td></td>
<td>LR 19005 (Upstream)</td>
<td>755</td>
</tr>
<tr>
<td></td>
<td>LR 19000 (Upstream)</td>
<td>766</td>
</tr>
<tr>
<td></td>
<td>Confluence Bridge No. 27</td>
<td>778</td>
</tr>
<tr>
<td></td>
<td>Confluence Bridge No. 27</td>
<td>780</td>
</tr>
<tr>
<td></td>
<td>Confluence of Tributary No. 19 to Roaring Creek</td>
<td>916</td>
</tr>
<tr>
<td></td>
<td>Confluence of Tributary No. 19 to Roaring Creek</td>
<td>916</td>
</tr>
<tr>
<td>Mill Creek</td>
<td>Confluence with Roaring Creek</td>
<td>853</td>
</tr>
</tbody>
</table>


In accordance with Section 7(o)(4) of the Department of HUD Act, Section 324 of the Housing and Community Amendments of 1978, P.L. 95-557, 92 Stat. 2080, this rule has been granted waiver of Congressional review requirements in order to permit it to take effect on the date indicated.

Issued: January 24, 1979.

GLORIA M. JIMENEZ, Federal Insurance Administrator.
(FR Doc. 78-6803 Filed 3-8-79; 8:45 am)
PART 1917—APPEALS FROM PROPOSED FLOOD ELEVATION DETERMINATIONS

Final Flood Elevation Determination for the Township of Lower Augusta, Northumberland County, Pa.

AGENCY: Federal Insurance Administration, HUD.

ACTION: Final rule.

SUMMARY: Final base (100-year) flood elevations are listed below for selected locations in the Township of Lower Augusta, Northumberland County, Pa. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

SUPPLEMENTARY INFORMATION:

The Administrator has developed criteria for flood plain management in flood-prone areas in accordance with 24 CFR Part 1910. The final base (100-year) flood elevations for selected locations are:

SUMMARY: Final base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

SUPPLEMENTARY INFORMATION:

The Administrator has developed criteria for flood plain management in flood-prone areas in accordance with 24 CFR Part 1910. The final base (100-year) flood elevations for selected locations are:

---

### Table: Final Flood Elevations

<table>
<thead>
<tr>
<th>Location</th>
<th>Elevation (feet)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Susquehanna River</td>
<td>Downstream Corporate Limits</td>
</tr>
<tr>
<td>Confluence of Bolle Run</td>
<td>431</td>
</tr>
<tr>
<td>Confail</td>
<td>438</td>
</tr>
<tr>
<td>Susquehanna River</td>
<td>State Route 147</td>
</tr>
<tr>
<td>Legislative Route 49023</td>
<td>451</td>
</tr>
<tr>
<td>Snyder Road</td>
<td>478</td>
</tr>
<tr>
<td>Butler Road</td>
<td>486</td>
</tr>
<tr>
<td>Footbridge</td>
<td>493</td>
</tr>
<tr>
<td>Wooden Bridge</td>
<td>493</td>
</tr>
<tr>
<td>Legislative Route 40023</td>
<td>519</td>
</tr>
<tr>
<td>Township Route 290</td>
<td>559</td>
</tr>
<tr>
<td>Township Route 294</td>
<td>579</td>
</tr>
<tr>
<td>Legislative Route 40023</td>
<td>601</td>
</tr>
<tr>
<td>Township Route 294</td>
<td>616</td>
</tr>
<tr>
<td>Township Route 360</td>
<td>633</td>
</tr>
<tr>
<td>Legislative Route 40023</td>
<td>657</td>
</tr>
<tr>
<td>Township Route 360</td>
<td>692</td>
</tr>
<tr>
<td>Legislative Route 40023</td>
<td>722</td>
</tr>
<tr>
<td>Township Route 360</td>
<td>755</td>
</tr>
</tbody>
</table>

For further information contact:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
from the community or from individuals within the community.

The Administrator has developed criteria for flood plain management in flood-prone areas in accordance with 24 CFR Part 1910.

The final base (100-year) flood elevations for selected locations are:

<table>
<thead>
<tr>
<th>Source of flooding</th>
<th>Location</th>
<th>Elevation in feet, national geodetic vertical datum</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td><strong>Downstream Aber Creek Road</strong> 853</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Confluence of turtle Creek</strong> 944</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>East Thompson Run</strong> 905</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Confluence of West Thompson Run Road</strong> 905</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Frisco Run</strong> 925</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Confluence of Aber Creek Road</strong> 935</td>
</tr>
</tbody>
</table>

**RULES AND REGULATIONS**

---

**SUMMARY:** Final base (100-year) flood elevations are listed below for selected locations in the Township of Montour, Columbia County, Pa. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

**EFFECTIVE DATE:** The date of issuance of the flood insurance rate map (FIRM), showing base (100-year) flood elevations, for the Township of Montour, Columbia County, Pa.

**ADDRESS:** Maps and other information showing the detailed outlines of the flood-prone areas and the final elevations for the Township of Montour, Columbia County, Pa., are available for review at the Montour Township Municipal Building, Route 42, Rupert, Pa.

**FOR FURTHER INFORMATION CONTACT:**

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-785-5581 or toll-free line 800-424-8872.

**SUPPLEMENTARY INFORMATION:** The Federal Insurance Administrator gives notice of the final determinations of flood elevations for the Township of Montour, Columbia County, Pa.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 99, which amended section 1262 to the National Flood Insurance Act of 1968 (Title XII of the Housing and Urban Development Act of 1968) (Pub. L. 90-448), as amended (42 U.S.C. 4001-4128), and 24 CFR 1917.6(a). An opportunity for the community or individuals to appeal this determination to or through the community for a period of ninety (90) days has been provided. No appeals of the proposed base flood elevations were received from the community or from individuals within the community.

The Administrator has developed criteria for flood plain management in flood-prone areas in accordance with 24 CFR Part 1910.

The final base (100-year) flood elevations for selected locations are:

<table>
<thead>
<tr>
<th>Source of flooding</th>
<th>Location</th>
<th>Elevation in feet, national geodetic vertical datum</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td><strong>Sangreanna Road</strong> 976</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>State Route 42</strong> 476</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Unincorporated</strong> 476</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Smoketown Creek</strong> 476</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>State Route 42</strong> 476</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Hemlock Creek</strong> 476</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Legislative Route 1910</strong> 476</td>
</tr>
</tbody>
</table>

---

**FEDERAL REGISTER, VOL 44, NO. 48—FRIDAY, MARCH 9, 1979**
PART 1917—APPEALS FROM PROPOSED FLOOD ELEVATION DETERMINATIONS

Final Flood Elevation Determination for the Township of Orange, Columbia County, Pa.

AGENCY: Federal Insurance Administration, HUD.

ACTION: Final rule.

SUMMARY: Final base (100-year) flood elevations are listed below for selected locations in the Township of Orange, Columbia County, Pa. These base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the national flood insurance program (NFIP).

EFFECTIVE DATE: The date of issuance of the flood insurance rate map (FIRM), showing base (100-year) flood elevations, for the Borough of Orangeville, Columbia County, Pa., are available for review at the Orangeville Borough Building, Mills Street, Orangeville, Pa.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the final elevations for the Borough of Orangeville, Columbia County, Pa., are available for review at the residence of Mrs. Suzanne Moore, R.D. 2, Orangeville, Pa.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8972.


This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 87 Stat. 980, which added section 1363 to the National Flood Insurance Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448), 42 U.S.C. 4001-4128, and 24 CFR 1917.4(a)). An opportunity for the community or individuals to appeal this determination to or through the community for a period of ninety (90) days has been provided. No appeals of the proposed base flood elevations were received from the community or from individuals within the community.

The Administrator has developed criteria for flood plain management in flood-prone areas in accordance with 24 CFR Part 1910. The final base (100-year) flood elevations for selected locations are:

<table>
<thead>
<tr>
<th>Source of flooding</th>
<th>Location</th>
<th>Elevation in feet</th>
<th>vertical datum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fishing Creek......</td>
<td>Confluence with Stony Creek</td>
<td>538</td>
<td>National geodetic vertical datum</td>
</tr>
<tr>
<td></td>
<td>Brook...</td>
<td>558</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lick Run</td>
<td>564</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Legislative Route 19031</td>
<td>564</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Upstream).</td>
<td>583</td>
<td></td>
</tr>
<tr>
<td></td>
<td>State Route 487</td>
<td>588</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Downstream).</td>
<td>588</td>
<td></td>
</tr>
<tr>
<td></td>
<td>State Route 497</td>
<td>588</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Upstream).</td>
<td>588</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Upstream Corporate Limit.</td>
<td>613</td>
<td></td>
</tr>
<tr>
<td>Green Creek.........</td>
<td>Confluence with Fishing Creek</td>
<td>509</td>
<td>National geodetic vertical datum</td>
</tr>
<tr>
<td></td>
<td>Legislative Route 19030</td>
<td>509</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Upstream).</td>
<td>509</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Covered Bridge No. 12</td>
<td>597</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Upstream).</td>
<td>606</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Upstream Corporate Limit.</td>
<td>606</td>
<td></td>
</tr>
</tbody>
</table>


In accordance with Section 7(o)(4) of the Department of HUD Act, Section 324 of the Housing and Community Amendments of 1978, Pub. L. 95-557, 92 Stat. 2680, this rule has been granted waiver of Congressional review requirements in order to permit it to take effect on the date indicated.

Issued: January 24, 1979.

GLORIA M. JIMENEZ, Assistant Administrator, Federal Insurance Administration, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410.

[4210-01-M] (Docket No. FT-46201)

[4210-01-M] (Docket No. FT-45761)
Source of flooding Location Elevation in feet. national geodetic vertical datum
Fishing Creek Downstream Corporate 572 Limits. Upstream Corporate 577 Limits.


In accordance with Section 7(oo)(4) of the Department of HUD Act, Section 324 of the Housing and Community Amendments of 1978, P.L. 95–557, 92 Stat. 2080, this rule has been granted waiver of Congressional review requirements in order to permit it to take effect on the date indicated.

Issued: January 24, 1979.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.
(FRD Doc. 79–6808 Filed 3–6–79; 8:45 am)

[4310–HB–M.]
Title 25—Indians
CHAPTER IV—NAVAJO AND HOPI; INDIAN RELOCATION COMMISSION
PART 700—COMMISSIONS OPERATIONS AND RELOCATION PROCEDURES
Revision of Regulations Concerning Eligibility for Relocation Benefits

AGENCY: Navajo and Hopi Indian Relocation Commission.

ACTION: Final rule

SUMMARY: This rule revises the Commission's regulations regarding eligibility for relocation benefits. The rule recognizes that residency can be established by substantial recurrent contacts with an identifiable homestead when employment or other factors dictate temporary occupancy outside the area. The rule is promulgated in order to make the eligibility standards more responsive to the intent of the governing legislation within the guidelines states in Opinion of the Comptroller General, August 9, 1978.

EFFECTIVE DATE: Date of Publication.
CHAPTER III—FEDERAL PRISON INDUSTRIES, DEPARTMENT OF JUSTICE

PART 301—INMATE ACCIDENT COMPENSATION

Final Rules

Correction

In FR Doc. 79-6503, appearing at page 11759 in the issue for Friday, March 2, 1979, on page 11760 the signature should read David C. Jelinek, Acting Commissioner.

RULES AND REGULATIONS

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

On November 15, 1978, a document was published in the Federal Register (43 FR 54366) proposing to revise Chapter XII of Title 29 of the Code of Federal Regulations, by amending Part 1404 thereof. Part 1404 contains the policies and procedures of the Federal Mediation and Conciliation Service in its Arbitration Services program. The proposed revision was intended to redefine the policy of the FMCS Arbitration Services program, the standards of eligibility of arbitrators for admission to and retention on the roster, the procedures for arbitration services and proceedings, and the procedure for administrative action regarding arbitrators on the roster.

Interested persons were invited to submit comments, data, or argument on the proposed amendments and numerous comments were received. All comments with respect to the proposed revision were given full consideration by the agency.

Comments were received both supporting and opposing the language of the proposed Regulation which would exclude advocates (that is, persons who act as partisans in the labor relations process) from the roster of neutral arbitrators maintained by the Service. The final Regulations retain the exclusion. See §1404.5(c). Parties are, of course, free to choose any person acceptable to them to hear and decide their disputes. The Service believes, however, that it has a responsibility to furnish to those parties who choose to use its services arbitrators with the broadest possible acceptability and that, as a public agency, the Service is in effect certifying the neutrality and acceptability of its roster members.

To furnish to the parties panels of neutrals which contain the names of advocates both undermines the integrity of the arbitration process generally and distorts the selection process in each particular dispute by forcing a party to use its strikes to eliminate panel members who are not neutrals rather than to choose between a number of qualified neutrals. The Service has received a considerable number of complaints from parties using its services regarding the presence of advocates on its panels. The prohibition on admission of advocates will reduce those complaints.

While the Service recognizes that some individuals in some communities may be acceptable as neutrals to portions of the labor-management community despite their advocacy status, the Service has concluded that for purposes of its roster, the two roles are inconsistent. The Service recognizes, however, that some individuals on the roster who were advocates at the time of their admission and who were admitted under Regulations which did not prohibit the admission of advocates are acceptable as arbitrators in their communities. The final Regulations therefore contain a "grandfather clause" which allows such advocates to remain on the roster if otherwise qualified and acceptable.

The definition of advocacy has been changed in the final Regulations to clarify the relationships and activities covered by the prohibition.

In addition to language changes made for clarification, as a result of the comments received and after full consideration, certain other changes in the revised rules have been made. No changes have been made, however, which alter the description of significant proposed changes published in the November 15, 1978 publication.

The applicable provisions of Executive Order 12044 have been complied with. Accordingly, 29 CFR Part 1404 is revised as set forth below.

Effective date. This regulation shall become effective on April 15, 1979.

For further information please contact: David Vaughn, Associate General Counsel, Federal Mediation and Conciliation Service, Washington, D.C. 20427, 653-5305, FTS 653-5305.

Adopted by the Federal Mediation and Conciliation Service at its office in Washington, D.C., on the 26th day of February, 1979.

WAYNE L. HORVITZ,
Director.

29 CFR. Part 1404 is revised to read as follows:

Subpart A—Arbitration Policy; Administration of Roster

See, 1404.1 Scope and authority. 1404.2 Policy. 1404.3 Administrative responsibilities.

Subpart B—Roster of Arbitrators; Admission and Retention

1404.4 Roster and Status of Members. 1404.5 Listing on the Roster; Criteria for Listing and Retention. 1404.6 Freedom of Choice.

Subpart C—Procedures for Arbitration Services


FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
RULES AND REGULATIONS

1404.4 Scope and authority.

This chapter is issued by the Federal Mediation and Conciliation Service (FMCS) under Title II of the Labor Management Relations Act of 1947 (Pub. L. 80-101) as amended in 1959 (Pub. L. 86-257) and 1974 (Pub. L. 93-360). The chapter applies to all arbitrators listed on the FMCS Roster of Arbitrators, to all applicants for listing on the Roster, and to all persons or parties seeking to obtain from FMCS either names or panels of names of arbitrators listed on the Roster in connection with disputes which are to be submitted to arbitration or fact-finding.

1404.5 Adherence to Standards and Requirements. Persons listed on the Roster shall comply with the FMCS rules and regulations pertaining to arbitration and with such guidelines and procedures as may be issued by OAS pursuant to Subpart C of this part. Arbitrators are also expected to conform to the ethical standards and procedures set forth in the Code of Professional Responsibility for Arbitrators of Labor Management Disputes, as approved by the Joint Steering Committee of the National Academy of Arbitrators.

§ 1404.5(d). Status of Arbitrators. Persons who are listed on the Roster and are selected or appointed to hear arbitration matters or to serve as factfinders do not become employees of the Federal Government by virtue of their selection or appointment. Following selection or appointment, the arbitrator's relationship is solely with the parties to the dispute, except that arbitrators are subject to certain reporting requirements and to standards of conduct as set forth in this part.

1404.6 Role of FMCS. FMCS has no power to:

(1) Compel parties to arbitrate or agree to arbitrate;
(2) Enforce an agreement to arbitrate;
(3) Compel parties to agree to a particular arbitrator;
(4) Influence, alter or set aside decisions of arbitrators listed on the Roster;
(5) Compel, deny or modify payment of compensation to an arbitrator.

1404.7 Nominations and Panels. On request of the parties to an agreement to arbitrate or engage in fact-finding, OAS will provide names or panels of names without charge. Procedures for obtaining these services are contained in Subpart C of this part. Neither the submission of a nomination or panel nor the appointment of an arbitrator constitutes a determination by FMCS that an agreement to arbitrate or enter fact-finding proceedings exists; nor does such action constitute a ruling that the matter in controversy is arbitrable under any agreement.

1404.8 Rights of persons listed on the Roster. No person shall have any right to be listed or to remain listed on the Roster. FMCS reserves the authority and responsibility to assure that the needs of the parties using its facilities are served. To accomplish this purpose it may establish procedures for the submission of nominations or panels or the appointment of arbitrators which include consideration of such factors as background and experience, availability, acceptability, geographical location and the expressed preferences of the parties.

§ 1404.9 Listing on the Roster; Criteria for listing and retention.

Persons seeking to be listed on the Roster must complete and submit an application form which may be obtained from the Office of Arbitration Services. Upon receipt of an executed application form, OAS will review the application, assure that it is complete, make such inquiries as are necessary, and submit the application to the Arbitrator Review Board. The Board will review the completed applications under the criteria set forth in paragraphs (a), (b) and (c) of this section, and will forward to the Director its recommendation on each applicant. The Director makes all final decisions as to whether an applicant may be listed. Each applicant shall be notified in writing of the Director's decision and the reasons therefore.

(a) General Criteria. Applicants for the Roster must meet the following criteria:

(1) Are experienced, competent and acceptable in decision-making roles in the resolution of labor relations disputes; or
(2) Have extensive experience in relevant positions in collective bargaining; and
(3) Are capable of conducting an orderly hearing, can analyze testimony and exhibits and can prepare clear and

FEDERAL REGISTER, VOL. 44, No. 48—FRIDAY, MARCH 9, 1979
concise findings and awards within reasonable time limits.

(b) Proof of Qualification. The qualifications listed in paragraph (a) of this section are preferably demonstrated by the submission of actual arbitration awards prepared by the applicant while serving as an impartial arbitrator or by the number of times the arbitrator's name has been proposed to the parties to disputes. Equivalent experience acquired in training, internship or other development programs, or experience such as that acquired as a hearing officer or judge in labor relations controversies may also be considered by the Board.

(c) Advocacy.—(1) Definition. An advocate is a person who represents employers, labor organizations, or individuals as an employee, attorney or consultant, in matters of labor relations, including but not limited to the subjects of, union representation and recognition matters, collective bargaining, arbitration, unfair labor practices, equal employment opportunity and other areas generally recognized as constituting labor relations. The definition includes representatives of employers or employees in individual cases or controversies involving workplace compensation, occupational health or safety, minimum wage or other labor standards matters. The definition of advocate also includes a person who is directly associated with an advocate in a business or professional relationship as, for example, partners or employees of a law firm.

(2) Eligibility. Except in the case of persons listed on the Roster before November 17, 1976, no person who is an advocate, as defined above, may be listed. No person who was listed on the Roster at any time who was not an advocate when listed, or who did not divulge advocacy at the time of listing may continue to be listed after becoming an advocate or after the fact of advocacy is revealed.

(d) Duration of listing, retention. Initial listing may be for a period not to exceed three years, and may be renewed thereafter for periods not to exceed two years, provided upon review that the listing is not canceled by the Director as set forth below. Notice of cancellation may be given to the member whenever the member:

(1) No longer meets the criteria for admission;
(2) Has been repeatedly and flagrantly delinquent in submitting awards;
(3) Has refused to make reasonable and periodic reports to FMCS, as required in Subpart C of this part, concerning activities pertaining to arbitration;
(4) Has been the subject of complaints by parties who use FMCS facilities and the Director, after appropriate inquiry, concludes that just cause for cancellation has been shown.

(5) Is determined by the Director to be unacceptable to the parties who use FMCS arbitration facilities; the Director may base a determination of unacceptability on FMCS records showing the number of times the arbitrator's name has been proposed to the parties and the number of times it has been selected.

No listing may be canceled without at least sixty days notice of the reasons for the proposed removal, unless the Director determines that the FMCS or the parties will be harmed by continued listing. In such cases an arbitrator's listing may be suspended without notice or delay pending final determination in accordance with these procedures. The member in either case shall have an opportunity to submit a written response showing why the listing should not be cancelled. The Director may, at his discretion, appoint a hearing officer to conduct an inquiry into the facts of any proposed cancellation and to make recommendations to the Director.

§ 1404.6 Freedom of choice.

Nothing contained herein should be construed to limit the rights of parties who use FMCS arbitration facilities jointly to select any arbitrator or arbitration procedure acceptable to them.

Subpart C—Procedures for Arbitration Services

§ 1404.10 Procedures for requesting arbitration panels.

The Office of Arbitration Services has been delegated the responsibility for administering all requests for arbitration services under these regulations.

(a) The Service will refer a panel of arbitrators to the parties upon request. The Service prefers to act upon a joint request which should be addressed to the Federal Mediation and Conciliation Service, Washington, D.C. 20427, Attention: Office of Arbitration Services. In the event that the request is made by only one party, the Service will submit a panel; however, any submission of a panel shall not be construed as anything more than compliance with a request and does not necessarily reflect the contractual requirements of the parties.

(b) The parties are urged to use the Request for Arbitration Panel form (R-43) which has been prepared by the Service and is available in quantity at all FMCS regional offices and field stations or upon request to the Office of Arbitration Services, 2100 K Street, Washington, D.C. 20427. The form R-43 is reproduced herein for purposes of identification.
# REQUEST FOR ARBITRATION PANEL

To: Director, Arbitration Services  
Federal Mediation and Conciliation Service  
Washington, D.C. 20427

Name of Company  
Name and Address  
of Representative  
to Receive Panel  
Telephone (include area code)

Date

Name of Union and Local No.  
Name and Address  
of Representative  
to Receive Panel  
Telephone (include area code)

Site of Dispute

Type of Issue

A panel of seven (7) names is usually provided; if you desire a different number, please indicate

6. Type of Industry

- [ ] Manufacturing  
- [ ] Construction  
- [ ] Mining, Agriculture, and Finance  
- [ ] Other (Specify)

- [ ] Federal Government  
- [ ] State Government  
- [ ] Local Government  
- [ ] Retail, Wholesale and Service Industries  
- [ ] Public Utilities, Communications, Transportation (including trucking)

7. Special Requirements

- [ ] SPECIAL ARBITRATOR QUALIFICATIONS, TIME LIMITATIONS ON HEARING OR DECISION, GEOGRAPHICAL RESTRICTIONS, ETC.

8. Signatures

Although the FMCS prefers to act upon a joint request of the parties, a submission will be made based on the request of a single party. However, any submission of a panel should not be construed as anything more than compliance with a request and does not reflect on the substance or arbitrability of the issue in dispute.

Additional forms may be obtained from the Federal Mediation and Conciliation Service at any FMCS Regional Office. See 1 on reverse of Copy No. 3.

To be retained by party filing request

FEDERAL REGISTER, VOL 44, NO. 48—FRIDAY, MARCH 9, 1979
(c) A brief statement of the issues in dispute should accompany the request to enable the Service to submit the names of arbitrators qualified for the issues involved. The request should also include a current copy of the arbitration section of the collective bargaining agreement or stipulation to arbitrate.

(d) If Form R-43 is not utilized, the parties may request a panel by letter which must include the names, addresses, and phone numbers of the parties, the location of the contemplated hearing, the issue in dispute, the number of names desired on the panel, the industry involved and any special qualifications of the panel or special requirement desired.

§ 1404.11 Arbitrability.

Where either party claims that a dispute is not subject to arbitration, the Service will not decide the merit of such claim.

§ 1404.12 Nominations of arbitrators.

(a) When the parties have been unable to agree on an arbitrator, the Service will submit to the parties on request the names of seven arbitrators unless the applicable collective bargaining agreement provides for a different number, or unless the parties themselves request a different number. Together with the submission of a panel of arbitrators, the Service will furnish a biographical sketch for each member of the panel. This sketch states the background, qualifications, experience, and per diem fee established by the arbitrator. It states the existence, if any, of other fees such as cancellation, postponement, rescheduling or administrative fees.

(b) When a panel is submitted, and FMCS control case number is assigned. All future communication between the parties and the Service should refer to the case number.

(c) The Service considers many factors when selecting names for inclusion on a panel, but the agreed-upon wishes of the parties are paramount. Special qualifications of arbitrators experienced in certain issues or industries, or possessing certain backgrounds, may be identified for purposes of submitting panels to accommodate the parties. The Service may also consider such things as general acceptability, geographical location, general experience, availability, size of fee, and the need to expose new arbitrators to the selection process in preparing panels. The Service has no obligation to put an individual on any given panel, or on a minimum number of panels in any fixed period, such as a month or a year.

RULES AND REGULATIONS

(1) If at any time both parties request for valid reason, that a name or names be omitted from a panel, such name or names will be omitted, unless they are excessive in number.

(2) If at any time both parties request that a name or names be included on a panel, such name or names will be included.

(3) If only one party requests that a name or names be omitted from a panel, or that specific individuals be added to the panel, such request shall not be honored.

(4) If the issue described in the request appears to require special technical experience or qualifications, arbitrators who possess such qualifications will, where possible, be included on the panel submitted to the parties.

(5) In almost all cases, an arbitrator is chosen from one panel. However, if either party requests another panel as a result of selection for an additional panel is permissible under the terms of the agreement or the other party so agrees. Requests for more than two panels must be accompanied by a statement of explanation and will be considered on a case-by-case basis.

§ 1404.13 Selection and appointment of arbitrators.

(a) The parties should notify the OAS of their selection of an arbitrator. The arbitrator, upon notification by the parties, shall notify the OAS of his selection and willingness to serve. Upon notification of the parties' selection of an arbitrator, the Service will make a formal appointment of the arbitrator.

(b) Where the contract is silent on the manner of selecting arbitrators, the parties may wish to consider one of the following methods for selection on arbitrator from the roster:

(1) Each party alternately strikes a name from the submitted panel until one remains.

(2) Each party advises the Service of its order of preference by numbering each name on the panel and submitting the numbered list in writing to OAS. The name on the panel that has the lowest accumulated numerical number will be appointed.

(c) Informal agreement of the parties by whatever method they choose.

(d) The Service will, on joint or unilateral request of the parties, submit a panel or, when the applicable collective bargaining agreement authorizes, make a direct appointment of an arbitrator. Submission of a panel or name signifies nothing more than compliance with a request and in no way constitutes a determination by the Service that the parties are obligated to arbitrate the dispute in question. Resolution of disputes as to the propriety of such a submission or appointment rests solely with the parties.

§ 1401.14 Conduct of hearings.

All proceedings conducted by the arbitrator shall be in conformity with the contractual obligations of the parties. The arbitrator is also expected to conduct all proceedings in conformity with § 1404.12(a). The conduct of the arbitration proceeding is under the arbitrator's jurisdiction and control and the arbitrator's decision is to be based upon the evidence and testimony presented at the hearing or otherwise incorporated in the record of the proceeding. The arbitrator may, unless prohibited by law, proceed in the absence of any party who, after due notice, fails to be present or to obtain a postponement. An award rendered in an ex parte proceeding of this nature must be based upon evidence presented to the arbitrator.

§ 1404.15 Decision and award.

(a) Arbitrators are encouraged to render awards not later than 60 days from the date of the closing of the record as determined by the arbitrator, unless otherwise agreed upon by the parties or specified by law. A failure to render timely awards reflects upon the performance of an arbitrator and may lead to his removal from the FMCS roster.

(b) The parties should inform the OAS whenever a decision is unduly delayed. The arbitrator shall notify the OAS if and when the arbitrator (1) cannot schedule, hear and determine issues promptly, or (2) learns a dispute has been settled by the parties prior to the decision.

(c) After an award has been submitted to the parties, the arbitrator is required to file a copy with the OAS. The arbitrator is further required to submit a Fee and Award Statement, Form R-19, showing a breakdown of the fee and expense charges so that the Service may be in a position to review conformance with stated charges under § 1404.12(a). Filling both award and report within 15 days after rendering an award is required of all arbitrators. The reports are not used for the purpose of compelling payment of fees.

(d) While the Service encourages the publication of arbitration awards, it is the policy of the Service to not release arbitration decisions for publication without the consent of both parties. Furthermore, the Service expects the arbitrators it has nominated or appointed not to give publicity to awards.
they issue if objected to by one of the parties.

§ 1404.16 Fees and charges of arbitrators.
(a) No administrative or filing fee is charged by the Service. The current policy of the Service permits each of its nominees or appointees to charge a per diem fee and other predetermined fees for services, the amount of which has been certified in advance to the Service. Each arbitrator's maximum per diem fee and the existence of other predetermined fees, if any, are set forth on a biographical sketch which is sent to the parties when panels are submitted and are the controlling fees. The arbitrator shall not change any fee or add charges without giving at least 30 days advance notice to the Service.
(b) In cases involving unusual amounts of time and expenses relative to pre-hearing and post-hearing administration of a particular case, an administrative charge may be made by the arbitrator.
(c) All charges other than those specified by §1404.16(a) shall be divulged to and agreement obtained by the arbitrator with the parties immediately after appointment.
(d) The Service requests that it be notified of any arbitrator's deviation from the policies expressed herein. However, the Service will not attempt to resolve any fee dispute.

§ 1404.17 Reports and biographical sketches.
(a) Arbitrators listed on the Roster shall execute and return all documents, forms and reports required by the Service. They shall also keep the Service informed of changes of address, telephone number, availability, and of any business or other connection or relationship which involves labor-management relations, or which creates or gives the appearance of advocacy as defined in §1404.4(c)(1).
(b) The Service may require each arbitrator listed on the Roster to prepare at the time of initial listing, and to revise, biographical information in accordance with a format to be provided by the Service at the time of initial listing or biennial review. Arbitrators may also request revision of biographical information at other times to reflect changes in fees, the existence of additional charges, address, experience and background, or other relevant data. The Service reserves the right to decide and approve the format and content of biographical sketches.

[4510-26-M]
Title 29—Labor

CHAPTER XVII—OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR

PART 1952—APPROVED STATE PLANS FOR ENFORCEMENT OF STATE STANDARDS

South Carolina

AGENCY: Occupational Safety and Health Administration, U.S. Department of Labor.

ACTION: Denial of Petitions for withdrawal of approval of the South Carolina State Plan.

SUMMARY: The petitions by the Carolina Brown Lung Association and by the AFL-CIO, to withdraw approval of the South Carolina State Plan for the development and enforcement of State occupational safety and health standards are hereby denied by the Assistant Secretary of Labor for Occupational Safety and Health.

EFFECTIVE DATE: December 8, 1978.

FOR FURTHER INFORMATION CONTACT:
Veronica Allen, Project Officer, Office of State Programs, Occupational Safety and Health Administration, Room 149, 2100 M Street N.W., Washington, D.C. 20210, 202-653-5737.

SUPPLEMENTARY INFORMATION:

BACKGROUND:
On October 12, 1977 and March 6, 1978, the Assistant Secretary received petitions from the Carolina Brown Lung Association and the AFL-CIO, respectively, regarding the South Carolina State Plan for Occupational Safety and Health. The petitions requested that the Assistant Secretary, pursuant to 29 CFR Part 1953, withdraw approval of the South Carolina State Plan. Both petitions alleged specific performance deficiencies in enforcement of the cotton dust standard and prosecution of contested cotton dust cases and in such other areas as hazard recognition, review procedures, inspection scheduling, health referrals and response to major federal program changes. In addition, the Carolina Brown Lung Association petition alleged deficiencies in employee training and education and the AFL-CIO petition alleged legislative and regulatory deficiencies.

The Department of Labor (OSHA) investigated all allegations contained in the petitions. That investigation revealed that charges of legislative and regulatory deficiencies were unfounded. Although the South Carolina Act does not mirror the Federal Act, the South Carolina Plan, along with its implementing regulations, provide coverage and employee rights comparable to that of the Federal Act. In addition, OSHA's investigation revealed that the performance deficiencies cited have either been corrected or considerable improvement has been demonstrated by the State, especially since the filing of the petitions. Based on the foregoing, the petitions are hereby denied.

DECISION
In accordance with 29 CFR 1955.5(b)(2), both the Carolina Brown Lung Association's and the AFL-CIO's petition for the withdrawal of approval of the South Carolina State Plan are hereby denied. The denial of these petitions does not preclude future action by the Assistant Secretary on these issues or any other issues regarding the plan which may be raised by monitoring or evaluation. The denial also does not preclude the filing of future petitions by these or any other parties.

(Sec. 18, Pub. L. 91-596, 84 Stat. 1033  [29 U.S.C. 677]).

Signed at Washington, D.C. this 2d day of March, 1979.

EULA BINGHAM,
Assistant Secretary of Labor.

(FR Doc. 79-7239 Filed 3-8-79; 44 Fr. 3153)

[7710-12-M]
Title 39—Postal Service

CHAPTER I—UNITED STATES POSTAL SERVICE

PART 295—RULES OF PRACTICE BEFORE THE BOARD OF CONTRACT APPEALS

Adoption of Rules Providing for Optional Small Claims Expedited and Accelerated Procedures and Rules for Subpoenas.

AGENCY: Postal Service.

ACTION: Interim rules.

SUMMARY: The Postal Service Board of Contract Appeals rules have been modified by the Judicial Officer to add new procedures pertaining to small claims and subpoenas as required by The Contract Disputes Act of 1978, Pub. L. 95-563.

EFFECTIVE DATE: March 1, 1979.

FOR FURTHER INFORMATION CONTACT:

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
SUPPLEMENTARY INFORMATION: Effective March 1, 1979, the Contract Disputes Act of 1978, Pub. L. 95-563 provides for various changes in prior contract dispute policies and practices. The Postal Service Board of Contract Appeals has been re-established pursuant to § 8(4)(1) of that act to resolve contract appeals under the Act. The following interim rules of the Board are adopted as additions to the existing rules pending issuance by the Office of Federal Procurement Policy of final procedural guidelines under § 8(8) of Pub. L. 95-563.

To provide for new expedited and accelerated procedures for small claims and for the issuance of subpoenas, 39 CFR is amended as follows:

In part 955 revise § 955.35 and add §§ 955.36 and 955.37 to read as follows:

§ 955.35 Effective date and applicability.

(a) §§ 955.1 through 955.34 took effect on February 18, 1976. Except as otherwise directed by the Board, these rules shall apply to appeals docketed prior to their effective date.

(b) Pursuant to The Contract Disputes Act of 1978, Pub. L. 95-563, §§ 955.36 and 955.37 apply to appeals relating to contracts entered into on or after March 1, 1978. At the election of the appellant, §§ 955.36 and 955.37 shall also apply to appeals relating to contracts entered into before March 1, 1978, if the Contracting Officer’s final decision is dated March 1, 1978, or thereafter. When § 955.36 is applicable it supersedes § 955.13.

§ 955.36 Optional small claims (expedited) and accelerated procedures.

(a) These procedures are available solely at the election of the appellant.

(b) Elections to Utilize SMALL CLAIMS (EXPEDITED) and ACCELERATED Procedure.

(1) In appeals where the amount in dispute is $10,000 or less, the appellant may elect to have the appeal processed under a SMALL CLAIMS (EXPEDITED) procedure requiring decision of the appeal, whenever possible, within 180 days after the Board receives written notice of the appeal. The details of this procedure appear in paragraph (d) of this Rule.

(2) In cases proceeding under the SMALL CLAIMS (EXPEDITED) procedure or the ACCELERATED procedure, the parties are encouraged, to the extent possible, to resolve the dispute through prehearing activity will be allowed consistent with due process and the 120-day limit for a decision, at a place determined under § 955.18. If a hearing is not requested by either party within the time prescribed by this Rule, the appeal shall be deemed to have been submitted without § 955.12 without a hearing.

(3) Written decisions by the Board in cases processed under the SMALL CLAIMS (EXPEDITED) procedure will normally be short and contain only summary findings of fact and conclusions. Decisions will be rendered for the Board by a single Administrative Judge, or by a majority among these two and an additional

FEDERAL REGISTER, VOL 44, NO. 48—FRIDAY, MARCH 9, 1979
designated member in case of disagreement. Alternatively, in cases where the amount in dispute is $10,000 or less as to which the ACCELERATED procedure has been elected and in which there has been a hearing, the single Administrative Judge presiding at the hearing may, with the concurrence of the other designated member, render such decision and other orders as are necessary at the conclusion of the hearing and after entertaining such oral arguments as he deems appropriate, render on the record oral summary findings of fact, conclusions, and a decision of the appeal. Whenever such an oral decision is rendered, the Board will subsequently furnish the parties a typed copy of such oral decision for record and payment purposes and to establish the date of commencement of the period for filing a motion for reconsideration under Rule § 955.30.

(c) Motions for Reconsideration in Cases Arising Under § 955.36. Motions for reconsideration of cases decided under either the SMALL CLAIMS (EXPEDITED) procedure or the ACCELERATED procedure need not be decided within the time periods prescribed by this § 955.36 for the initial decision of the appeal, but all such motions shall be processed and decided rapidly so as to fulfill the intent of this rule.

§ 955.37 Subpoenas

(a) General—Upon written request of either party filed with the docket clerk or on his own initiative, the Administrative Judge to whom a case is assigned or who is otherwise designated by the Chairman may issue a subpoena as follows:

(1) testimony at a deposition—the depoosing of a witness in the city or county where he resides or is employed or transacts his business in person, or at another location convenient for a trip that is specifically determined by the Board;

(2) testimony at a hearing—the attendance of a witness for the purpose of taking testimony at a hearing; and

(3) production of books and papers—in addition to (1) and (2), the production by the witness at the deposition or hearing of books and papers designated in the subpoena.

(b) Voluntary Cooperation—Each party is expected (1) to cooperate and make available witnesses and evidence under its control as requested by the other party, without issuance of a subpoena, and (2) to secure voluntary attendance of desired third-party books, papers, documents, or tangible things whenever possible.

(c) Requests for Subpoenas

(1) A request for a subpoena shall normally be filed at least 15 days before a scheduled deposition where the attendance of a witness at a deposition is sought;

(2) 30 days before a scheduled hearing where the attendance of a witness at a hearing is sought;

(lii) In its discretion the Board may honor requests for subpoenas not made within these time limitations.

(2) A request for a subpoena shall state the reasonable scope and general relevance of the testimony and of any books and papers sought.

(d) Requests to Quash or Modify—Upon written request by the person subpoenaed or by a party, made within 10 days after service but in any event not later than the time specified in the subpoena, the Board may (1) quash or modify the subpoena if it is unreasonable and oppressive or for other good cause shown, or (2) require the person in whose behalf the subpoena was issued to advance the reasonable cost of producing subpoenaed books and papers. Where circumstances require, the Board may act upon such a request at any time after a copy has been served upon the opposing party.

(e) Form; Issuance

(1) Every subpoena shall state the name of the Board and the title of the appeal and the name and address of each person to whom it is directed to attend and give testimony, and if appropriate, to produce specified books and papers at a time and place therein specified. In issuing a subpoena to a requesting party, the Administrative Judge shall sign the subpoena and may in his discretion, enter the name of the witness and otherwise leave it blank. The party to whom the subpoena is issued shall complete the subpoena before service.

(2) Where the witness is located in a foreign country, a letter rogatory or similar document may be issued and served under the circumstances and in the manner provided in 28 U.S.C. 1781-1784.

(f) Service

(1) The party requesting issuance of a subpoena shall arrange for service.

(2) A subpoena requiring the attendance of a witness at a deposition or hearing may be served at any place. A subpoena may be served by a United States marshal or deputy marshal, or by any other person who is not a party and not less than 18 years of age. Service of a subpoena upon a person named therein shall be made by personally delivering a copy to that person and tendering the fees for one day's attendance and the mileage provided by 28 U.S.C. 1821 or other applicable law.

(3) The party at whose instance a subpoena is issued shall be responsible for the payment of fees and mileage of the witness and of the officer who serves to the party of the testimony and of any books and papers produced.

(g) Contumacy or Refusal to Obey a Subpoena—In case of contumacy or refusal to obey a subpoena by a person who resides, if found, or transacts business within the jurisdiction of a United States District Court, the Board will apply to the Court through the Attorney General of the United States for an order requiring the person to appear before the Board or a member thereof to give testimony or produce evidence or both. Any failure of any such person to obey the order of the Court may be punished by the Court as a contempt thereof.

(39 U.S.C. 204, 401(2).)

W. ALLEN SANDERS,
Acting Deputy General Counsel.
[FR Doc. 79-1753 Filed 3-8-79; 8:45 am]

[6560-01-M]

Title 40—Protection of the Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

[FRL 1052-61]

PART 65—DELAYED COMPLIANCE ORDERS

Approval of a Delayed Compliance Order Issued by West Virginia Air Pollution Control Commission To Brockway Glass Co., Inc.

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Administrator of EPA hereby approves a Delayed Compliance Order issued by West Virginia Air Pollution Control Commission to the Brockway Glass Co., Inc. The Order requires the company to bring air emissions from its glass furnace in Vienna into compliance with certain regulations contained in the Federal- approved Virginia State Implementation Plan (SIP). Because of the Administrator's approval, Brockway Glass Co.'s compliance with the Order will preclude suits under the Federal enforcement and citizen suit provisions of the Clean Air Act for violations of the SIP regulations covered by the Order during the period the Order is in effect.

DATES: This rule takes effect on March 9, 1979.

FOR FURTHER INFORMATION CONTACT:

Patrick McManus (3EN12), U.S. EPA, Region III, Curtis Building.
RULES AND REGULATIONS

In consideration of the foregoing, Chapter I of Title 40 of the Code of Federal Regulations is amended as follows:

PART 65—DELAYED COMPLIANCE ORDERS

1. The following entry is added to

<table>
<thead>
<tr>
<th>Source</th>
<th>Location</th>
<th>SIP Regulation involved</th>
<th>Date of FR proposal</th>
<th>Final compliance date</th>
</tr>
</thead>
</table>

[6550-01-M]

PART 65—DELAYED COMPLIANCE ORDERS

Approval of a Delayed Compliance Order Issued by West Virginia Air Pollution Control Commission to Banner Fibreboard Co.

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Administrator of EPA hereby approves a Delayed Compliance Order issued by West Virginia Air Pollution Control Commission to the Banner Fibreboard Co. The Order requires the company to bring its glass furnace in Vienna into compliance with certain regulations contained in the federally-approved West Virginia State Implementation Plan (SIP). Because of the Administrator's approval, Banner Fibreboard Co. compliance with the Order will preclude suits under the federal enforcement and citizen suit provisions of the Clean Air Act for violations of the SIP regulations covered by the Order during the period the Order is in effect.

DATES: This rule takes effect on March 9, 1979.

FOR FURTHER INFORMATION CONTACT:

ADDITIONS: A copy of the Delayed Compliance Order, any supporting material, and any comments received in response to a prior Federal Register notice proposing approval of the Order are available for public inspection and copying during normal business hours at:

SUPPLEMENTARY INFORMATION:
On September 25, 1978, the Regional Administrator of EPA's Region III Office published in the Federal Register, Vol. 43, No. 186 (43 FR 43337), a notice proposing approval of a delayed compliance order issued by West Virginia Air Pollution Control Commission to the Brockway Glass Co., Inc. The notice asked for public comments by October 25, 1978 on EPA's proposed approval of the Order.

No public comments have been received by this office; therefore, the delayed compliance order issued to Brockway Glass Co., Inc. is approved by the Administrator of EPA pursuant to the authority of Section 113(d)(2) of the Clean Air Act, 42 U.S.C. 7413(d)(2). The Order places Brockway Glass Co., Inc. on a schedule to bring its glass furnace in Vienna into compliance as expeditiously as practicable with Regulation VII, "To Prevent and Control Particulate Air Pollution From Manufacturing Process Operations", a part of the federally-approved West Virginia State Implementation Plan. If the conditions of the Order are met, it will permit Brockway Glass Co., Inc. to delay compliance with the SIP regulations covered by the Order until December 30, 1978. The company is unable to immediately comply with these regulations.

EPA has determined that its approval of the Order shall be effective March 9, 1979 because of the need to immediately place Brockway Glass Co., Inc. on a schedule which is effective under the Clean Air Act for compliance with the applicable requirements of the West Virginia State Implementation Plan.

(42 U.S.C. 7413(d), 7601.)


DOUGLAS M. COSTLE, Administrator.
March 9, 1979 because of the need to immediately place Pennzoil Co. on a schedule which is effective under the Clean Air Act for compliance with the applicable requirements of the West Virginia State Implementation Plan.

(DO C. 7413(d), 7601.)


DOUGLAS M. COSTLE,
Administrator.

In consideration of the foregoing, Chapter I of Title 40 of the Code of Federal Regulations is amended as follows:

PART 65—DELAYED COMPLIANCE ORDERS

1. The following entry is added to the table in § 65.531 to reflect approval of the following delayed compliance order:

§ 65.531 EPA Approval of State delayed compliance orders issued to major stationary sources.

(42 U.S.C. 7413(d), 7601.)

For further information contact:


Supplementary Information: On September 25, 1978, the Regional Administrator of EPA's Region III Office published in the Federal Register, Vol. 43, No. 186 (43 FR 43339), a notice proposing approval of a delayed compliance order issued by West Virginia Air Pollution Control Commission to the Pennzoil Company. The notice asked for public comments by October 25, 1978 on EPA's proposed approval of the Order.

No public comments have been received by this office; therefore, the delayed compliance order issued to Pennzoil Co. is approved by the Administrator of EPA pursuant to the authority of Section 113(d)(2) of the Clean Air Act, 42 U.S.C. 7413(d)(2). The Order places Pennzoil Co. on a schedule to bring its flare system and furnaces in Falling Rock into compliance as expeditiously as practicable with Regulation VI, "To Prevent and Control Particulate Air Pollution From Manufacturing Process Operations", a part of the federally-approved West Virginia State Implementation Plan. The Order also imposes interim requirements which meet Sections 113(d)(1)(C) and 113(d)(7) of the Act, and emission monitoring and reporting requirements. If the conditions of the Order are met, it will permit Pennzoil Co. to delay compliance with the SIP regulations covered by the Order until November 15, 1978. The company is unable to immediately comply with these regulations.

EPA has determined that its approval of the Order shall be effective March 9, 1979 because of the need to immediately place Pennzoil Co. on a schedule which is effective under the Clean Air Act for compliance with the applicable requirements of the West Virginia State Implementation Plan.


DOUGLAS M. COSTLE,
Administrator.

In consideration of the foregoing, Chapter I of Title 40 of the Code of Federal Regulations is amended as follows:

PART 65—DELAYED COMPLIANCE ORDERS

1. The following entry is added to the table in § 65.531 to reflect approval of the following delayed compliance order:

§ 65.531 EPA Approval of State delayed compliance orders issued to major stationary sources.

For further information contact:


Supplementary Information: On September 25, 1978, the Regional Administrator of EPA's Region III Office published in the Federal Register, Vol. 43, No. 186 (43 FR 43339), a notice proposing approval of a delayed compliance order issued by West Virginia Air Pollution Control Commission to the Pennzoil Company. The notice asked for public comments by October 25, 1978 on EPA's proposed approval of the Order.

No public comments have been received by this office; therefore, the delayed compliance order issued to Pennzoil Co. is approved by the Administrator of EPA pursuant to the authority of Section 113(d)(2) of the Clean Air Act, 42 U.S.C. 7413(d)(2). The Order places Pennzoil Co. on a schedule to bring its flare system and furnaces in Falling Rock into compliance as expeditiously as practicable with Regulation VI, "To Prevent and Control Particulate Air Pollution From Manufacturing Process Operations", a part of the federally-approved West Virginia State Implementation Plan. The Order also imposes interim requirements which meet Sections 113(d)(1)(C) and 113(d)(7) of the Act, and emission monitoring and reporting requirements. If the conditions of the Order are met, it will permit Pennzoil Co. to delay compliance with the SIP regulations covered by the Order until November 15, 1978. The company is unable to immediately comply with these regulations.

EPA has determined that its approval of the Order shall be effective March 9, 1979 because of the need to immediately place Pennzoil Co. on a schedule which is effective under the Clean Air Act for compliance with the applicable requirements of the West Virginia State Implementation Plan.


DOUGLAS M. COSTLE,
Administrator.

In consideration of the foregoing, Chapter I of Title 40 of the Code of Federal Regulations is amended as follows:
Approval of a Delayed Compliance Order Issued by West Virginia Air Pollution Control Commission to Pennsylvania Glass Sand Corp.

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Administrator of EPA hereby approves a Delayed Compliance Order issued by West Virginia Air Pollution Control Commission to the Pennsylvania Glass Sand Corp. The Order requires the company to bring air emissions from its coal-fired boilers in Berkeley Springs into compliance with certain regulations contained in the federally-approved West Virginia State Implementation Plan (SIP). Because of the Administrator's approval, Pennsylvania Glass Sand Corp. compliance with the Order will preclude suits under the federal enforcement and citizen suit provisions of the Clean Air Act for violations of the SIP regulations covered by the Order during the period the Order is in effect.

DATES: This rule takes effect on March 9, 1979.

FOR FURTHER INFORMATION CONTACT:


ADDRESSES: A copy of the Delayed Compliance Order, any supporting material, and any comments received in response to a prior Federal Register notice proposing approval of the Order, are available for public inspection and copying during normal business hours at:


SUPPLEMENTARY INFORMATION: On September 25, 1978, the Regional Administrator of EPA's Region III Office published in the Federal Register, Vol. 43, No. 186 (43 FR 43387), a notice proposing approval of a delayed compliance order issued by West Virginia Air Pollution Control Commission to the Pennsylvania Glass Sand Corp. The notice asked for public comments by October 25, 1978 on EPA's proposed approval of the Order.

No public comments have been received by this office; therefore, the delayed compliance order issued to Pennsylvania Glass Sand Corp. is approved by the Administrator of EPA pursuant to the authority of Section 113(d)(2) of the Clean Air Act, 42 U.S.C. 7413(d)(2). The Order places Pennsylvania Glass Sand Corp. on a schedule to bring its coal-fired boilers in Berkeley Springs into compliance with the SIP regulations covered by the Order until June 30, 1979.

The company is unable to immediately comply with these regulations.

EPA has determined that its approval of the Order shall be effective March 9, 1979 because of the need to immediately place Pennsylvania Glass Sand Corp., on a schedule which is effective under the Clean Air Act for compliance with the applicable requirements of the West Virginia State Implementation Plan. (42 U.S.C. 7413(g), 7601.)


DOUGLAS M. COSTLE,
Administrator.

In consideration of the foregoing, Chapter I of Title 40 of the Code of Federal Regulations is amended as follows:

PART 65—DELAYED COMPLIANCE ORDERS

The following entry is added to the table in § 65.531 to reflect approval of the following delayed compliance order:

§ 65.531 EPA Approval of State delayed compliance orders issued to major stationary sources.

<table>
<thead>
<tr>
<th>Source</th>
<th>Location</th>
<th>SIP regulation involved</th>
<th>Date of FR proposal</th>
<th>Final compliance date</th>
</tr>
</thead>
</table>

[6560-01-M]

PART 65—DELAYED COMPLIANCE ORDERS

Approval of a Delayed Compliance Order Issued by the State of Maryland to Glidden Pigments Group of SCM Corp.

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Administrator of EPA hereby approves a Delayed Compliance Order issued by the State of Maryland to the Glidden Pigments Group of SCM Corp. The Order requires the company to bring air emissions from its batch attack vessels and chloride processing plant in Baltimore, Maryland into compliance with certain regulations contained in the federally-approved Maryland State Implementation Plan (SIP). Because of the Administrator's approval, Glidden Pigments Group of SCM Corp. compliance with the Order will preclude suits under the federal enforcement and citizen suit provisions of the Clean Air Act for violations of the SIP regulations covered by the Order during the period the Order is in effect.

DATES: This rule takes effect on March 9, 1979.

FOR FURTHER INFORMATION CONTACT:


ADDRESSES: A copy of the Delayed Compliance Order, any supporting material, and any comments received in response to a prior Federal Register notice proposing approval of the Order are available for public inspection and copying during normal business hours at:
SUPPLEMENTARY INFORMATION: On October 27, 1976, the Regional Administrator of EPA's Region III Office published in the Federal Register, Vol. 43, No. 209, (43 FR 50221) a notice proposing approval of a delayed compliance order issued by the State of Maryland to the Glidden Pigments Group of SCM Corp. The notice asked for public comments by November 27, 1976 on EPA's proposed approval of the Order.

No public comments have been received by this office; therefore, the delayed compliance order issued to Glidden Pigments Group of SCM Corp. is approved by the Administrator of EPA pursuant to the authority of Section 113(d)(2) of the Clean Air Act, 42 U.S.C. 7413(d)(2). The Order places Glidden Pigments Group of SCM Corp., on a schedule to bring its batch attack vessels and chloride processing plant in Baltimore, Maryland into compliance as expeditiously as practicable with Regulations 10.03.38.02A and 10.03.38.03E pertaining to visible emissions and particulate matter, a part of the federally-approved Maryland State Implementation Plan. The Order also imposes interim requirements which meet Sections 113(d)(1)(C) and 113(d)(7) of the Act, and emission monitoring and reporting requirements. If the conditions of the Order are met, it will permit Glidden Pigments Group of SCM Corp. to delay compliance with the SIP regulations covered by the Order until July 1, 1979. The company is unable to immediately comply with these regulations.

EPA has determined that its approval of the Order shall be effective March 9, 1979 because of the need to immediately place Glidden Pigments Group of SCM Corp. on a schedule which is effective under the Clean Air Act for compliance with the applicable requirements of the Maryland State Implementation Plan. (42 U.S.C. 7413(d), 7601.)


DOUGLAS M. COSTELLE,
Administrator.

In consideration of the foregoing, Chapter I of Title 40 of the Code of Federal Regulations is amended as follows:

PART 65—DELAYED COMPLIANCE ORDERS

1. The following entry is added to the table in §65.251 to reflect approval of the following delayed compliance order:

<table>
<thead>
<tr>
<th>Source</th>
<th>Location</th>
<th>SIP regulations involved</th>
<th>Date of FR approval</th>
<th>Final compliance date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glidden Pigments Group of SCM Corp</td>
<td>Baltimore</td>
<td>10.03.38.02A</td>
<td>Oct. 27, 1978</td>
<td>July 1, 1979</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10.03.38.03E</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

[FR Doc. 79-7124 Filed 3-8-78; 8:45 am]

[6560-01-M]

SUBCHAPTER E—PESTICIDE PROGRAMS

PART 162—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT

Subpart A—Registration, Reregistration, and Classification Procedures

AGENCY: Environmental Protection Agency, Office of Pesticide Programs.

ACTION: Final rule.

SUMMARY: On February 7, 1979 (44 FR 7685), EPA published in the Federal Register a regulation relating to special packaging of certain toxic pesticides in child-resistant containers. This document contained certain editorial errors. Because of the importance of this regulation, EPA has decided to resole the entire document to avoid confusion and prevent inconvenience to the reader. As stated above, this rule requires the special packaging of certain toxic pesticides in child-resistant containers and sets forth the toxicity criteria to be used to determine which residential use pesticides are affected. The intent of this rule is to decrease the number of hazardous exposures of a pesticide product to children.

DATES: Effective Date: March 9, 1979

This regulation applies to products released for shipment after March 9, 1981.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION: On October 14, 1977, EPA published a proposed rule (42 FR 55235) to require certain pesticides to be specially packaged in child-resistant containers. This rule is designated §162.16 of Title 40 and is authorized under Section 25(c)(3) of the Federal Insecticide, Fungicide, and Rodenticide Act as amended (Pub. L. 92-516, 88 Stat. 983; Pub. L. 94-140, 89 Stat. 755; Pub. L. 95-556, 92 Stat. 819; 7 U.S.C. 186 et seq.; hereinafter referred to as "FIFRA").

BACKGROUND

Final rules for the registration, re-registration, and classification of pesticides (40 CFR Part 162) were published in the Federal Register on October 2, 1975, 40 FR 28242. This document reserved a section for the special packaging of pesticides. Section 25(c)(3) of amended FIFRA authorizes the Administrator of EPA to:

Establish standards (which shall be consistent with those established under the authority of the Poison Prevention Packaging Act (Pub. L. 91-601)) with respect to the package, container, or wrapper in which a pesticide or device is enclosed for use or consumption, in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated by this Act as well as to accomplish the other purposes of this Act.

Section 2(q)(1)(B) of FIFRA states that a pesticide is misbranded if "it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to Section 25(c)(3)."

Ingestion reports to the National Clearinghouse for Poison Control Centers show that pesticide ingestions for children under 5 years of age numbered over 12,000 in 1975. Pesticides have shown annual increases in the number of accidental poisonings. The number of such incidents can be substantially decreased by requiring that certain residential use products be specially packaged.

The success of special packaging of other hazardous products supports this conclusion. Within three years after the Consumer Product Safety
Commission (CPSC) required child-resistant packaging for aspirin products, the total number of accidental aspirin ingestions decreased by 41% and aspirin-induced deaths by 63 percent. Similar results were recorded after regulations were promulgated encompassing antifreeze and pesticide products. A screening study of the economic impact of special packaging determined that the cost of compliance with this regulation would not be unreasonable. The total cost to industry, for all input variables was estimated to be 2 million-5 million. This will result in an increase in cost to the consumer of 3.74 per product. Thus, with a small increase in product cost, this regulation will result in significant societal benefits.

Virtually all of the 27 comments received in response to the proposed regulations were favorable. However, many commenters, while agreeing in principle with the proposed regulations, raised questions or made suggestions that convinced the Agency that some changes from the proposed rule are warranted.

**DISCUSSION OF MAJOR COMMENTS**

**EFFECTIVE DATE**

Seventeen of twenty-seven commenters state that the proposed lead time of one year is not enough. This belief was expressed by packaging manufacturers as well as pesticide manufacturers. The majority said that a minimum of two years is necessary. Some preferred three years. The major reasons for wanting to extend the effective date include the availability of safety packaging and the conversion time required for transition from conventional to safety packaging. Many comments included detailed charts of the process and time involved for each step in a transition. Based on the inability of the packaging industry to meet the new demand and the inability of registrants to perform the required testing in one year, EPA has decided one to two years. EPA believes that this two year span will be adequate and recognizes that, in addition, the long period between the proposed and final regulation allowed time for some preliminary work. The effective date applies to all products released for shipment after that date.

In view of the significant health concern underlying this rule, EPA expects that each registrant will endeavor to convert to child-resistant packaging as soon as possible. Moreover, EPA fully anticipates that if it is not possible to convey an entire product line to child-resistant packaging before the effective date, individual products will be brought into earlier conformance with the rule. Exemptions described in the following paragraph will be granted only in extraordinary circumstances.

**FEASIBILITY**

Seven commenters believe that the technology to specially package pesticides is not currently available for all products for which special packaging is not technologically feasible, practical, and appropriate. For example, the preamble to the proposal stated that feasibility problems would be dealt with on a case-by-case basis in the registration process. To make this more clear, a new paragraph has been added to the regulations, §162.16(c)(3), which says that upon the request of a registrant or applicant, and in the discretion of the Administrator, exemptions may be granted on a case-by-case basis, for products for which special packaging is not technically feasible. The request must be accompanied by supporting data. To insure fairness, if an exemption is granted, the decision will be published in the Federal Register and will be applicable to any product in the identical situation. Some of the factors for consideration in determining whether or not a situation is identical may include the type of formulation and size and type of container. The decision may specify a time schedule for the exemption and for studying and developing a suitable package. If a request for an exemption is denied, the registrant must comply by the effective date.

**AMENDED APPLICATION/DATA SUBMISSION**

The proposed regulations would have required the registrant to submit an application for amended registration for each pesticide product for which a special packaging design is developed. The same data required to be submitted with the proposed registration application would be required to be submitted with the application for the amended registration. The registrant has an obligation to produce its own data. EPA has decided to adopt the Consumer Product Safety Commission (CPSC) testing protocol by reference in §162.16(d)(3) rather than to include it in the regulations. When doing this, any CPSC changes to the protocol will apply immediately to EPA's regulation. This will eliminate the need to amend this regulation whenever CPSC updates the protocol.

The comments included requests for clarification on several points: (1) whether a protocol test is required for each product or for each package design used; and (2) whether the registrant is required to produce its own data. Tests do not have to be run on each pesticide product, only on each special packaging design. The same protocol data on a particular special packaging design for each product or for each product or product design which would be costly and time consuming. However, in §162.16(d)(3) a requirement has been added to test each size of a closure design used. In discussions with the Consumer Product Safety Commission, EPA was advised that changing the size of a design often reduces the child-resistant effectiveness. Requiring each closure size to be tested will eliminate the possibility of an ineffective package being marketed. A complete copy of the test data, whether it is obtained from the packaging manufacturer or from the registrant's own testing, must be retained by the registrant.
Multiple uses containers are permissible if the effectiveness of the special packaging continues throughout the reasonably expected lifetime of the package. Registrants who market pesticide products in unit packages have the option of using any of specially packaging each unit or marketing the unit packaging in a child-resistant container. Special packaging will not be required for both the unit package and the retail container unless the Agency receives information which would indicate that it is necessary for a particular product for safety reasons.

NON-COMPLIING PACKAGING

Ten of twenty-seven commenters believe that non-complying packaging should be allowed in at least one size. Other commenters such as the American Academy of Pediatrics commended EPA for not allowing non-complying packaging. The Agency agrees with the Agency that the toxicity of the products to be regulated is sufficient to warrant the exclusion of a convenience package. Some commenters believe that this position discriminates against the elderly and the handicapped. The Agency assumed that a person's need for a pesticide is not normally as urgent as for a drug and the person normally could arrange for someone to take higher risks with that pesticide. Because of this, and because less toxic pesticides would be available in non-complying packaging, the Agency believed the elderly and handicapped would not be seriously inconvenienced. The Agency sent letters and copies of the proposal to a dozen organizations which represent the elderly or the handicapped, and requested their comments. Since only one reply was received and it supported the Agency position, the Agency feels that there are no serious disagreements with that position. Therefore, non-complying packaging will not be allowed for products which meet the criteria for special packaging.

TOXICITY CRITERIA

A small number of commenters suggested that the oral LD50 criterion of 1.5g/kg be lowered to 500 mg/kg so that only residential use products in Toxicity Categories I and II would be required to be specially packaged. The most commenters agreed that 1.5g/kg is an appropriate level. The calculations used to determine the acute oral LD50 criterion were based on the average weight of a small child, the amount such a child could ingest, and a safety factor of 3. The Agency does not see a sufficient reason to lower the safety factor. For further explanation see the discussion in the preamble to the Registration, Reregistration and Classification Regulations, 40 FR 28241, 28259-28261 (1975).

Explanatory language has been added to the skin effects criterion as follows: "Is corrosive to the skin (causes tissue destruction into the dermis and/or causes severe skin irritation (severe erythema or edema) at 72 hours" (§162.16(c)(2)(iv)). The additional wording does not change the value of the criterion, but it does provide a more exact description of the requirements.

While no commenters had objections to the skin irritation criterion itself, several believed that it is applied too rigidly. The Agency agreed that it is. The Registration Guidelines, many household products will not be required to be specially packaged. The Registration Guidelines are currently under revision.

The Agency has modified the eye irritation protocol recommendations of a June 1977 report prepared by the Committee for the Revision of National Academy of Sciences (NAS) Publication 1138. The Committee for the Revision of National Academy of Sciences (NAS) Publication 1138, "Principles and Procedures for Evaluating the Toxicity of Household Substances," for the Consumer Product Safety Commission under the auspices of the Committee on Toxicology of the National Research Council. This report was modified by the Agency to include the eye irritation protocol recommendations of a June 1978 report prepared by the Committee for the Revision of National Academy of Sciences (NAS) Publication 1138. The new criteria take precedence over the rabbit test that is submitted will be accepted. Until a decision is reached, any future use of human subjects for testing of pesticides. Of course, all pesticide testing involving humans must meet the stringent criteria in FIFRA Section 12(a)(2)(F) and FIFRA Section 12(a)(2)(F).

Several commenters preferred the eye irritation protocol recommendations of the NAS/NRC 1138 Committee which were also endorsed by the FIFRA Scientific Advisory Panel. The NAS/NRC 1138 Committee eye irritation protocol will also be acceptable for determining whether or not a pesticide product must be specially packaged. As stated above regarding the skin irritation protocol, until the use of this eye irritation protocol is formally adopted in the Registration Guidelines, registrants should consult with the Registration Division prior to testing to discuss the applicability of that protocol to their product.

Some of the comments included questions regarding the use of human and monkey test data. While existing human data confirmed, long-term use of monkey test data that is submitted will be accepted. EPA strongly discourages any future use of human subjects for testing of pesticides. Of course, all pesticide testing involving humans must meet the stringent criteria in FIFRA Section 12(a)(2)(F).

There are differing opinions regarding the advisability of allowing monkey test data to take precedence over the rabbit test data, and the Agency was unable to reach a decision without further review. This question has been addressed by the NAS/NRC 1138 Committee which concluded that the monkey is the second species of choice. This issue can be more appropriately treated in the Registration Guidelines and the Agency would like to specifically solicit comments on this point. Until a decision is reached, any monkey eye data that is submitted will be taken into consideration by the Agency, but will not automatically take precedence.

APPLICABILITY

This regulation applies to products intended for residential use, which meet the toxicity criteria, and which have not been classified for restricted use. The definition of residential use is...
identical to the definition of domestic use in 40 CFR 162.3(m), except that residential use does not include patient care areas of health-related institutions. This regulation does not apply to products bearing a label stating uses which are exclusively for commercial or agricultural application, since such products are not available for retail sale to the general public. Residential use is determined by whether a product has a use on the label which falls within the meaning of residential use.

FUTURE REVIEW AND REGULATION

Section 25(c)(3) of FIFRA authorizes the Administrator to establish packaging standards to protect children and adults. This special packaging regulation is designed primarily to protect children under five years of age, but it is hoped that special packaging also will protect adults and older children from accidental or negligent exposure to pesticides. The Agency strongly encourages registrants to voluntarily develop safer packaging to lessen those hazards not directly addressed by this rule to avoid the necessity of further regulation.

EPA is particularly concerned about such packaging problems as breakability and puncturability. A child-resistant closure would not necessarily avoid hazard to children if it is on a glass bottle that will break easily. A broken package could result in the contents being spilled on a person or result in the inhalation of toxic fumes. EPA will be evaluating whether to establish breakability or other standards. Information on the frequency of injuries involving skin contact and inhalation will be obtained from CPSC under a new Interagency Agreement regarding data collection. EPA would also like persons who have had accidents of this type to inform the Agency so that they can be taken into account.

The poison control statistics from the National Clearinghouse for Poison Control Centers showed a 63 percent reduction in aspirin-induced deaths of preschool children in the three year period following the promulgation of the CPSC special packaging regulations for aspirin products. EPA will make a similar review of this regulation three years after the effective date to evaluate its effectiveness.

REGULATORY ANALYSIS

The Environmental Protection Agency has determined that this document does not contain a major proposal requiring preparation of a Regulatory Analysis under Executive Order 12044.

STATUTORY REVIEW

The FIFRA Scientific Advisory Panel reviewed the final regulation in accordance with Section 25(d) of FIFRA at a meeting on October 3, 1978, and unanimously concurred with its publication. The Scientific Advisory Panel report is published in its entirety following the text of the regulation. The U.S. Department of Agriculture has reviewed the final regulation in accordance with Section 25(a) of FIFRA and concurs with its publication in the FEDERAL REGISTER without comment.

Dated: March 6, 1979.

BARBARA BLUM,
Acting Administrator.

Part 162, Chapter I, Title 40 of the Code of Federal Regulations is amended by revising §162.16, and adding a new §162.16 to read as follows:

§162.16 Pesticides requiring special packaging.

(a) General. This section implements Section 25(c)(3) of the Act, which authorizes the Administrator to establish packaging standards with respect to the package, container or wrapping in which a pesticide or device is enclosed in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated by this Act.

(b) Definitions. Terms used in this section shall have the same meaning as such terms as defined in this section.

General.

Any pesticide product that is released for shipment after March 9, 1981 shall be specially packaged if (i) its labeling allows residential use, (ii) it has not been classified for restricted use and (iii) it meets the toxicity criteria in paragraph (c)(2) of this section. Special packaging may be required on a case-by-case basis for pesticide products which are classified for restricted use, if the Administrator determines that there is a serious hazard of accidental injury or illness which special packaging could reduce.

Criteria for special packaging. Special packaging is required for a pesticide product approved for residential application if the tests conducted in accordance with Part 162 indicate that the pesticide formulation:

(i) Has an acute dermal LD<sub>50</sub> of 2000 mg/kg or less;

(ii) Has an inhalation LC<sub>50</sub> of 2 mg/liter or less;

(iii) Is corrosive to the eye (causes irreversible destruction of ocular tissue) or causes corneal involvement or irritation persisting for 21 days or more;

(iv) Is corrosive to the skin (causes tissue destruction into the dermis and/or scarring) or causes severe skin irritation (severe erythema or edema) at 72 hours;

(v) Has a acute oral LD<sub>50</sub> of 1.5 g/kg or less; or

(vi) Has such characteristics that, based upon human toxicological data, use history, accident data or such other evidence as is available, the Administrator determines that there is a serious hazard of accidental injury or illness which special packaging could reduce.

Exemptions. Upon the request of a registrant or applicant the Administrator may on a case-by-case basis, grant an exemption, based on supporting data accompanying the request.
for products for which special packaging is not technically feasible or for those pesticides for which the hazards indicated by the toxicity criteria in paragraph (a) of this section are not indicative of hazard to man. Any such decision shall be published in the Federal Register and shall be applicable to any product with identical or substantially similar composition and intended use.

(4) Unit packaging. Pesticides requiring special packaging and which use unit packaging shall either package each unit package in a special package or package the retail container which contains unit packages. Special packaging will not be required for both the outer container and the unit packages unless, on a case-by-case basis, further information shows that it is necessary for hazard reduction.

(d) Standards for special packaging. (1) General requirements. (i) The special packaging must continue to function with the same effectiveness as set forth in paragraph (c) of this section for as long as the registration is valid. These records shall be available, upon request, for inspection and copying purposes or for submission to EPA.

(ii) The applicant or registrant of a pesticide for which special packaging is required shall retain the records described in paragraphs (f)(1), (2), and (3) of this section for as long as the registration is valid. These records shall be available, upon request, for inspection and copying purposes or for submission to EPA.

(2) General requirements. (i) The special packaging must continue to function with the same effectiveness as set forth in paragraph (c) of this section for as long as the registration is valid. These records shall be available, upon request, for inspection and copying purposes or for submission to EPA.

(3) Effectiveness testing procedures. Standards for special packaging shall be evaluated for each size of a design used pursuant to the Consumer Product Safety Commission (CPSC) protocols specified in 16 CFR 1700.20 (a), (b), (c), and (d).

(e) Submission. The registrant of a registered pesticide which requires special packaging shall submit an application for amended registration under §162.6(b)(3). The application shall include a certification by the registrant that the package meets the standards of §162.16(d). An applicant for a new registration shall submit a certification statement that the package meets the standards of §162.16(d) with the application for registration.

(f) Record keeping. The applicant or registrant of a pesticide for which special packaging is required shall retain the records described in paragraphs (f)(1), (2), and (3) of this section for as long as the registration is valid. These records shall be available, upon request, for inspection and copying purposes or for submission to EPA.

(i) A full description of the package including:

(A) Its dimensions, and

(B) Its compositions; and

(ii) A full description of the closure or special package, if appropriate, including:

(A) The name of its manufacturer,

(B) The manufacturer's designation (title) for the special packaging closure or the physical working of the special packaging mechanism, and

(C) The explicit directions for proper use of the closure or special packaging and the placement of these directions on the package;

(2) A complete copy of the data resulting from the tests conducted in accordance with §162.16(d); and

(3) Data demonstrating the compatibility of the pesticide formulation with the entire package to determine that the chemical and physical characteristics of the substance will not compromise or interfere with the proper functioning of the special packaging and that the packaging will not be detrimental to the integrity of the product during storage and use.

(ii) The special packaging must continue to function with the same effectiveness as set forth in paragraph (c) of this section for as long as the registration is valid. These records shall be available, upon request, for inspection and copying purposes or for submission to EPA.

(2) Effectiveness specifications. The special packaging, when tested by the method referred to in paragraph (c) of this section, shall meet the following specifications:

(i) Child-resistant effectiveness of not less than 85 percent without a demonstration of the proper means of opening the package. In the case of unit packaging, child-resistant effectiveness of not less than 90 percent.

(2) Adult-use effectiveness of not less than 90 percent without a demonstration.

(3) Effectiveness testing procedures. Standards for special packaging shall be evaluated for each size of a design used pursuant to the Consumer Product Safety Commission (CPSC) protocols specified in 16 CFR 1700.20 (a), (b), (c), and (d).

(e) Submission. The registrant of a registered pesticide which requires special packaging shall submit an application for amended registration under §162.6(b)(3). The application shall include a certification by the registrant that the package meets the standards of §162.16(d). An applicant for a new registration shall submit a certification statement that the package meets the standards of §162.16(d) with the application for registration.

(f) Record keeping. The applicant or registrant of a pesticide for which special packaging is required shall retain the records described in paragraphs (f)(1), (2), and (3) of this section for as long as the registration is valid. These records shall be available, upon request, for inspection and copying purposes or for submission to EPA.

(i) A full description of the package including:

(A) Its dimensions, and

(B) Its compositions; and

(ii) A full description of the closure or special package, if appropriate, including:

(A) The name of its manufacturer,

(B) The manufacturer's designation (title) for the special packaging closure or the physical working of the special packaging mechanism, and

(C) The explicit directions for proper use of the closure or special packaging and the placement of these directions on the package;

(2) A complete copy of the data resulting from the tests conducted in accordance with §162.16(d); and

(3) Data demonstrating the compatibility of the pesticide formulation with the entire package to determine that the chemical and physical characteristics of the substance will not interfere with the safety and efficacy of the pesticide and the functioning of the special package.

(g) Enforcement. Failure to comply with this rule by its implementation date renders a pesticide misbranded under Section 2(g)(1)(B) of FIFRA, and is a violation of Section 12(a)(1)(E) of FIFRA. Registrants who violate these sections will be subject to civil and criminal penalties under Section 14 of FIFRA.

Title 41—Public Contracts and Property Management

CHAPTER 101—FEDERAL PROPERTY MANAGEMENT REGULATIONS

SUBCHAPTER G—TRANSPORTATION AND MOTOR VEHICLES
FOR FURTHER INFORMATION CONTACT:

Mr. Ted C. Moore, Division of Grants and Contracts, Office of Resource Management, OM, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301-443-1874).

ADDRESS: Written comments are invited as to whether PHS should make research grant awards to organizations operating or programs should be submitted for consideration and possible incorporation into a permanent regulation.

SUPPLEMENTARY INFORMATION: On August 4, 1978, the Assistant Secretary for Health, with the approval of the Secretary, published in the Federal Register (43 FR 34507) proposed miscellaneous amendments to 42 CFR Part 52 to eliminate conflicts with HEW grants administration policies, extend applicability to alcohol and drug abuse projects, and make certain other clarifying changes. Comments on the proposed regulations were invited and one comment from the Department of Justice was received.

Following is a summary of principal changes:

1. A statement is included to indicate that these regulations do not apply for the support of research training under the National Research Service Awards program. Regulations covering this program are published at 42 CFR Part 66.

2. In accordance with the Federal budgeting and appropriation process, congressional intent, and Department policy, most projects funded by grants which will require more than one year to complete must be funded on an annual basis. The PHS policy PHS: 1-85, "The Project Period System of Obligating Funds for Discretionary Project Grants," was published in December 1976. The definition of "project period" in the current regulations is in conflict with stated PHS policy.

3. Therefore, a subsection is included to revise the definition of "project period" by removing the 7-year maximum project period and permitting extension of original project periods (with or without additional grant funds), and making certain other conforming changes.

4. Other miscellaneous definitions for "Act," "Department," "grantee," "research project grant," and "project" are being added for clarification.

5. The present regulations cover section 103 of the Clean Air Act and section 503 of the Solid Waste Disposal Act. Both of these programs are administered now by other Federal agencies; and regulations covering section 305 of the Public Health Service Act are published at 42 CFR Part 67. References to these programs are therefore deleted.

Provisions making the regulations applicable to research projects supported under section 301 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, and also projects conducted under section 410 of the Drug Abuse Office and Treatment Act of 1972 have been added. In addition, the regulations are made applicable to research projects relating to radiological health and family planning which are authorized under sections 335 and 1004 of the Public Health Service Act, respectively.

The notice proposed certain changes to the sections relating to copyrights, and to patents and inventions, to conform the regulations to 45 CFR Part 74, "Administration of Grants." However, a revision published in the Federal Register (43 FR 34076) a revision of Part 74 which eliminated the need for these changes. Accordingly, the final rule contains only a simplified reference to Part 74. In addition, the regulations are made applicable to research projects relating to radiological health and family planning which are authorized under sections 355 and 1004 of the Public Health Service Act, respectively.

The Department of Justice also questioned the use of the word "man" in the expression "impairments of man" in proposed §52.1. The quoted expression derives verbatim from the statutory provision upon which it is based, namely, section 301 of the Public Health Service Act (42 USC 241) and, in context, it is clear that Congress intended "mankind" or humanity as a class, as opposed to other species. The words "human life" have been substituted, however, to clarify the intended meaning.

7. In addition, §§52.1 and 52.10 are combined into one simplified provision, "Title IX of the Education Amendments of 1975 applies to all federally assisted "education programs and activities." The provision has been incorporated into the new, simplified §52.27 without the stated limitations.

8. The Department of Justice also questioned the use of the word "man" in the expression "impairments of man" in proposed §52.1. The quoted expression derives verbatim from the statutory provision upon which it is based, namely, section 301 of the Public Health Service Act (42 USC 241) and, in context, it is clear that Congress intended "mankind" or humanity as a class, as opposed to other species. The words "human life" have been substituted, however, to clarify the intended meaning.

9. In addition, §§52.1 and 52.10 are combined into one simplified provision, "Title IX of the Education Amendments of 1975 applies to all federally assisted "education programs and activities." The provision has been incorporated into the new, simplified §52.27 without the stated limitations.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
Accordingly, Part 52 of Title 42, Code of Federal Regulations, is amended as set forth below.

Your attention is directed to §52.11(a)(3) which sets forth eligibility requirements which specifically excludes profitmaking organizations from receiving a grant award.OMB, in providing its final guidance in implementing the Federal Grant and Cooperative Agreement Act of 1977, states that subject to the requirements of the Act, assistance awards may be made to for-profit organizations when deemed by the agency to be consistent with legislative intent and program purposes. PHS is presently undertaking a review of its assistance programs to determine if profitmaking organizations may be eligible to apply for assistance from those programs where the legislation permits.

To assist us in this review, we are requesting public comments as to whether PHS should make research-grant awards to organizations operated for profit and what administrative policies should apply. Should the PHS review and public comments indicate that research grant awards can and should apply. Should the legislation permits.

The project period as authorized under section 1004 of title 42, U.S.C., as amended, is deleted.

(d) "Act" means the Public Health Service Act (42 U.S.C. 201 et seq.).

(e) "Department" means the Department of Health, Education, and Welfare.

(f) "Grantee" means the institution, organization, individual or other person designated in the grant award document as the responsible legal entity to whom a grant is awarded under this part.

(g) "Research project grant" means the award by the Secretary of funds to a grantee to assist in meeting the costs of conducting for the benefit of the public health an identified project which is intended and designed to establish, discover, develop, elucidate or confirm information or the underlying mechanisms relating to a program set forth in §52.1.

(h) "Project" means the particular activity within the scope of one or more of the programs set forth in §52.1 which is supported by a grant awarded under this part.

§52.10 [Deleted]

5. Section 52.10 is deleted.

6. Section 52.11 is amended by revising the heading, and by changing the heading of paragraph (b) "Projects Eligible" to read "Permissible activity," (b) These regulations do not apply to general research grants authorized for the construction of research facilities (see Part 57 of this chapter), for the construction of hospital or other medical facilities (see Part 53 of this chapter), or the award of fellowships (see Part 61 of this chapter), traineeships (see Part 65 of this chapter), training grants (see Part 64 of this chapter), or to the support of research training under the National Research Service Awards program (see Part 66 of this chapter).

4. Section 52.2 of Subpart A is amended by amending paragraph (b) and adding new definitions (d), (e), (f), (g), and (h) as follows:

§52.2 Definitions.

* * * * *

(b) "Project period" means the period of time which the Secretary finds is reasonably required to initiate and conduct a research project within the scope of §52.1, including the initial period of support determined under §52.13 and any extension of that period (with or without the award of additional funds) as authorized by §52.20(e). The project period may include the time required for initial staffing and acquisition of facilities and for the preparation and publication of the results of the project.

* * * * *

(d) "Act" means the Public Health Service Act (42 U.S.C. 201 et seq.).

(e) "Department" means the Department of Health, Education, and Welfare.

(f) "Grantee" means the institution, organization, individual or other person designated in the grant award document as the responsible legal entity to whom a grant is awarded under this part.

(g) "Research project grant" means the award by the Secretary of funds to a grantee to assist in meeting the costs of conducting for the benefit of the public health an identified project which is intended and designed to establish, discover, develop, elucidate or confirm information or the underlying mechanisms relating to a program set forth in §52.1.

(h) "Project" means the particular activity within the scope of one or more of the programs set forth in §52.1 which is supported by a grant awarded under this part.

§52.10 [Deleted]

5. Section 52.10 is deleted.

6. Section 52.11 is amended by revising the heading, and by changing the heading of paragraph (b) "Projects Eligible" to read "Permissible activity,"
ties within projects." As amended § 52.11 reads as follows:

§ 52.11 Who is eligible to apply for a grant?

(a) Persons eligible. Except where otherwise prohibited by law, any individual, corporation, public or private institution or agency, or other legal entity found by the Secretary to be authorized and qualified by scientific or other relevant competence to carry out a proposed research project in accordance with the regulations of this part shall be eligible for a grant award except:

(1) Federal agencies or institutions not specifically authorized by law to receive such a grant;

(2) Any corporation, institution, agency or other such person, other than an individual, that is organized or operated for profit; and

(3) Any individual, corporation, institution, agency or other entity that, having previously received a grant award, has failed willfully and materially in the judgment of the Secretary to comply with accounting or other requirements applicable to that prior award.

(b) Permissible activities within projects. Any project found by the Secretary to be a research project within the meaning of § 52.1 shall be eligible for a grant award. Eligible projects may consist of laboratory, clinical, population, field, statistical, basic, applied or other types of investigations, studies or experiments, or combinations thereof, and may either be limited to one, or a particular aspect of a problem or subject, or may consist of two or more related problems or subjects for concurrent or consecutive investigation involving multiple disciplines, facilities and resources.

7. Section 52.12 is amended to read as follows:

§ 52.12 How to apply for a grant.

(a) A grant application must include the following information:

(1) Nature, project period, purpose and plan of the project;

(2) Name and qualifications of the principal investigator and any key personnel;

(3) Qualifications of the principal staff members to be responsible for the project;

(4) The total facilities and resources that will be available;

(5) Justification of the amount of grant funds requested; and

(6) Other pertinent information the Secretary may require to evaluate the proposed project.

(b) The application must be signed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of any award, including the regulations of this Part. Interested persons are invited to submit grant applications in conformity with this Part.

8. Paragraph (b) of § 52.13 is amended to read as follows:

§ 52.13 Evaluation and disposition of applications.

(1) Disposition. On the basis of the application’s evaluation of the project in accordance with paragraph (a) of this section and subject to approvals, recommendations or consultations by the appropriate National Advisory Council or other body as may be “granted” for the Secretary will (1) approve, (2) defer because of either lack of funds or a need for further evaluation, or (3) disapprove support of the proposed project in whole or in part.

With respect to approved projects, the Secretary will determine the project period (subject to extension as provided in § 52.20(c)) during which the project may be supported. Any deferral and disapproval of an application will not preclude its reconsideration or a reapplication.

§ 52.14 [Amended]

9. Section 52.14 is amended by changing the reference to § 52.10 in the first sentence of paragraph (a) to § 52.1 by substituting the word “the Secretary” for the word “he” in the first sentence of paragraphs (d) and (f); by deleting the first sentence of paragraph (e) and by substituting the word “such” for the word “grant” in the second sentence of paragraph (e). Section 52.20 is amended to read as follows:

§ 52.20 Use of funds; changes.

(a) Delegation of fiscal responsibility. The grantee may not in whole or in part delegate or transfer to another person responsibility for the use or expenditure of grant funds.

(b) Changes in project. The permissible changes by the principal investigator in the approved project shall be limited to changes in methodology approach or other aspects of the project to expedite achievement of the project's research objectives, including changes that grow out of the approved project and serve the best scientific strategy. If the grantee and the principal investigator are uncertain whether a change complies with this provision, the question must be referred to the Secretary for a final determination.

(c) Changes in project period. The project period determined pursuant to § 52.15(c) may be extended by the Secretary, with or without additional grant support, for such an additional period as the Secretary determines may be required to complete, or fulfill the purposes of, the approved project.

§§ 52.22, 52.23 and 52.25 [Reserved]

11. Sections 52.22, 52.23 and 52.25 are deleted. These sections are reserved for future regulations.

12. Section 52.24, previously reserved, is amended to read as follows:

§ 52.24 Animal Welfare.

The provisions in the Department Grants Administration Manual (Chapter 4-53) are applicable to applications for grants under this part.

13. A new § 52.27 is added immediately after § 52.26, as follows:

§ 52.27 Other HEW regulations that apply.

Several other HEW regulations apply to grants under this Part.

These include:

42 CFR Part 59, Subpart PHS grant appeals procedure.

45 CFR Parts 6 and 8—Public health and safety; grants and contracts.

45 CFR Part 16—Department grants appeals process.


45 CFR Part 74—Administration of grants to individuals.

45 CFR Part 75—Uniform grant appeals procedures (indirect costs rates and other cost allocations).

45 CFR Part 83—Nondiscrimination under public授予 programs receiving Federal assistance through the Executive Office of the President—Protection of Title VI of the Civil Rights Act of 1964.


45 CFR Part 84—Nondiscrimination on the basis of handicap in programs receiving Federal assistance.

45 CFR Part 85—Nondiscrimination on the basis of sex in programs receiving Federal assistance.

§ 52.33 [Amended]

14. Section 52.33 is amended by deleting the term "Surgeon General" in the second sentence of paragraph (c) and inserting “Secretary” in lieu thereof.

Subpart E [Deleted]

15. Subpart E, relating to grantee accountability, is now fully covered by 45 CFR Part 74 (particularly Subparts F, M and O) setting forth general administrative requirements, and Subpart E is therefore deleted in its entirety.

Subpart F [Deleted]

16. Subpart F, setting forth the applicability of 45 CFR Part 74, is now covered in a new, simplified § 52.27 which cross-references in one conve-
Title 45—Public Welfare
SUBTITLE A—DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, GENERAL ADMINISTRATION
PART 25—HEARING EXAMINERS—SUPPLEMENTAL SECURITY INCOME
Revocation of Part 25

AGENCY: Office of the Secretary, HEW.

ACTION: Final rule.

SUMMARY: These regulations revoke 45 CFR Part 25. 45 CFR Part 25 contains the personnel rules for the Supplemental Security Income hearing examiner position. Since this position no longer exists, these provisions are obsolete.

EFFECTIVE DATE: March 9, 1979.

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION: 45 CFR Part 25 was issued to implement a provision in title XVI of the Social Security Act for the supplemental security income (SSI) program. This provision (section 1631(d)(2) of the Act as originally enacted) authorized the Secretary to appoint as hearing examiners in SSI hearings, qualified persons who do not meet the prescribed standards for hearing examiners under the Administrative Procedure Act. 45 CFR Part 25 contains the administrative provisions for the SSI hearing examiner position such as qualifications, appointment, pay, and separation.

Public Law 94-202, enacted on January 2, 1976, made changes concerning the SSI hearing examiner position. Section 2 of Pub. L. 94-202 terminated the Secretary's authority to appoint SSI hearing examiners. Section 3 of Pub. L. 94-202 authorized SSI hearing examiners to conduct hearings under titles II, XVI, and XVIII of the Social Security Act as if they were appointed under the Administrative Procedure Act, and provided for terminating the appointments of all SSI hearing examiners by December 31, 1978.


Since the SSI hearing examiner position no longer exists, the 45 CFR Part 25 provisions are obsolete. We are revoking these provisions to comply with the Operation Common Sense objectives of removing outdated material from Title 45.

Since this amendment only revokes unnecessary and obsolete material, the Secretary of Health, Education, and Welfare finds that publication with Notice of Proposed Rulemaking is unnecessary.

[PART 25—RESERVED]

Accordingly, 45 CFR Part 25 is revoked and reserved.


(Catalog of Federal Domestic Assistance Program No. 13.807, Supplemental Security Income Program.)


JOSEPH A. CALIFANO, Jr., Secretary of Health, Education, and Welfare.

[FR Doc. 79-7235 Filed 3-8-79; 8:45 am]

Title 49—Transportation
CHAPTER II—FEDERAL RAILROAD ADMINISTRATION, DEPARTMENT OF TRANSPORTATION
[Docket No. RP-1, Notice No. 3]
PART 211—RULES OF PRACTICE

Interim Procedures for the Administrative Review of Emergency Orders

AGENCY: Federal Railroad Administration (FRA), Department of Transportation.

ACTION: Issuance of interim rules.

SUMMARY: This document issues interim procedures for the review of orders issued under the emergency powers provision of the Federal Railroad Safety Act of 1970 (45 U.S.C. 432). That provision authorizes the FRA to take emergency action to abate conditions which affect the safety of railroad operations. Subsequent review of an emergency order is provided in the form of an on-the-record administrative hearing. Issuance of interim procedures at this time is necessary to facilitate the conduct of a review proceeding currently pending before the FRA.

EFFECTIVE DATE: These procedures are effective on date of issuance by the Administrator.

FOR FURTHER INFORMATION CONTACT:
Principal Legal Drafter, Grady C. Cothen, Jr., Office of Chief Counsel, Federal Railroad Administration, 400 Seventh Street, S.W., Washington, D.C. 20590, 202-426-8220.

SUPPLEMENTARY INFORMATION: Section 203 of the Federal Railroad Safety Act of 1970 (45 U.S.C. 432) reads as follows:

If through testing, inspection, investigation, or research carried out pursuant to this title, the Secretary determines that any facility or piece of equipment is in unsafe condition and thereby creates an emergency situation involving a hazard of death or injury to persons affected by it, the Secretary may immediately issue an order, without regard to the provisions of section 202(b) of this title, prohibiting the further use of such facility or equipment until the unsafe condition is corrected. Subsequent to the issuance of such order, opportunity for review shall be provided in accordance with section 554 of title 5 of the United States Code.

The Secretary of Transportation's powers under that provision have been delegated to the Federal Railroad Administrator (49 CFR §1.49(n)).

The FRA currently has before it a petition for review of an emergency order. Because this is the first such petition filed with the FRA, and because prior revisions of the FRA Rules of Practice did not contain sufficiently specific language to facilitate the governance of review proceedings, FRA has decided to issue interim procedures in the form of a new Subpart F to Part 211.

The interim procedures incorporate by reference and leave undisturbed section 211.47 of the Rules of Practice, under which the pending petition for review was filed. The new procedures merely supplement existing rules, conferring broad discretion on the presiding officer to provide for the conduct of the hearing.

Section 211.71 sets forth a general description of the nature of the new subpart and defines the term “Administrator” to mean the statutory head of an agency or his deputy.

Section 211.73 deals with the identity of the presiding officer and the powers conferred on the presiding officer. Paragraph (a) identifies the presiding officer as the Administrator or an administrative law judge appointed under Office of Personnel Management regulations.

Paragraph (b) delegates to the presiding officer the power to regulate the proceeding. FRA has considered and rejected the possibility of adopting detailed practice rules at this time. Because the subject matter of an

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
emergency order may be very specific or rather extensive, FRA believes the presiding officer should be able to provide for the orderly conduct of a proceeding by adapting procedural techniques utilized by the Federal Courts and by other administrative agencies. Under this general delegation, the presiding officer enjoys the powers referred to in subsection 556(c) of Title 5, United States Code, as well as the general powers specified by subsection 208(a) of the Federal Railroad Safety Act of 1970 (45 U.S.C. 437(a)), insofar as those latter powers relate to the conduct of administrative hearings.

It should be noted that the delegation to the presiding officer is directed at the conduct of the administrative record on all material issues, both legal and factual. It is not intended that a presiding officer cut short a review proceeding because of any perceived lack of statutory authority. That is an issue which will have been decided at the threshold level by the head of agency and the chief legal counsel to the agency prior to issuance of the order. During the period administrative review is in progress, the Administrator retains jurisdiction over requests for the stay or modification of the emergency order. By the same token, the presiding officer is free to hear arguments on the question of statutory authority and to enter conclusions on that issue in the final decision, providing such analysis as may be appropriate.

Paragraph (e) relates to the findings and conclusions of the presiding officer, delegating to the presiding officer the power to set aside, modify or affirm the emergency order based on the entire administrative record developed through the hearing process. It is intended that the administrative law judge exercise discretion to alter or adapt procedural techniques utilized by United States Courts and Magistrates to the conduct of emergency orders. These procedural rules are made effective on issuance in order to facilitate the prompt disposition of a proceeding currently before the FRA.

In consideration of the foregoing, Part 211 of Title 49, Code of Federal Regulations, is amended—

1. By adding the following at the end of the table of contents:

Subpart F—Interim Procedures for the Review of Emergency Orders

211.71 General.
211.73 Presiding officer; powers.
211.75 Evidence.
211.77 Appeal to the Administrator.

2. By adding at the end of authority citation the following:

Subpart F is also issued under secs. 203 and 209(a), 46 Stat. 972, 974-975 (45 U.S.C. 432, 436) and 974.975 (45 U.S.C. 434.975). See § 211.54-559.

3. By adding at the end thereof a new subpart to read as follows:

Subpart F—Interim Procedures for the Review of Emergency Orders

§ 211.71 General.

(a) This subpart consists of interim procedures for the review of emergency orders issued under section 203 of the Federal Railroad Safety Act of 1970, supplementing § 211.47 of this part.

(b) Proceedings under this subpart are subject to the requirements of 5 U.S.C. 554-559.

(c) Notwithstanding § 211.1 of this part, as used in this subpart “Administrator” means the Federal Railroad Administrator or Deputy Administrator.

§ 211.73 Presiding officers; powers.

(a) An administrative hearing for the review of an emergency order is presided over by the Administrator or by an administrative law judge designated at the request of FRA pursuant to 5 CFR 390.213.

(b) The presiding officer may exercise the powers of the FRA to regulate the conduct of the hearing and associated proceedings for the purpose of achieving a prompt and fair determination of all material issues in controversy.

(c) The final decision of the presiding officer shall set forth findings and conclusions based on the administrative record. That decision may set aside, modify or affirm the requirements of the emergency order under review.

(d) Except as provided in § 211.77, the decision of the presiding officer is administratively final.

§ 211.75 Evidence.

(a) The Federal Rules of Evidence for United States Courts and Magistrates shall be employed as general guidelines for the introduction of evidence in proceedings under this subpart, except as provided in paragraph (b) of this section, all relevant and probative evidence offered by a party shall be received in evidence.

(b) The presiding officer may deny the admission of evidence which is determined to be—

(1) Unduly repetitious; or

(2) So extensive and lacking in relevance or probative effect that its admission would impair the prompt, orderly, and fair resolution of the proceeding.

§ 211.77 Appeal to the Administrator.

(a) Any party aggrieved by the final decision of a presiding officer (other than the Administrator) may appeal to the Administrator. The appeal must be filed within twenty (20) days from issuance of the presiding officer's decision and must set forth the specific exceptions of the party to the decision, making reference to the portions of the administrative record which are believed to support the exceptions. The notice of appeal and any supporting papers shall be accompanied by a certificate stating that they have been served on all parties to the proceeding.


John M. Sullivan, Administrator.
SUMMARY: The purpose of this document is to give notice that requests to inspect records not considered public under 5 U.S.C. 552 (Part 1001.4) should be addressed to the Freedom of Information Officer. Accordingly, all references to Secretary in said Part 1001.4 are herewith amended to read Freedom of Information Officer.

DATES: This final rule becomes effective upon publication in the Federal Register.

FOR FURTHER INFORMATION CONTACT:
S. Arnold Smith, Freedom of Information Officer, 202-275-1717.

SUPPLEMENTARY INFORMATION: In order to achieve more effective management and control of the processing of information requests under the Freedom of Information and Privacy Acts, the Commission has consolidated such functions under one officer assigned to the Managing Director's Office. Therefore, the Secretary's Office, which previously processed Freedom of Information requests, will no longer be involved with this particular activity, and all references thereto in Part 1001.4 should be deleted and Freedom of Information Officer substituted in its stead. Because this is an administrative rule change only, public comments are not solicited with respect thereto.

§ 1001.4 [Amended]
Section 1001.4 is amended by substituting "Freedom of Information Officer" for "Secretary" wherever that word appears.

Decided March 2, 1979.
By the Commission, Chairman O'Neal.
H. G. Homme, Jr.,
Secretary.

[FR Doc. 79-7126 Filed 3-8-79; 8:45 am]

[7035-01-M]
[Service Order No. 1365]

PART 1033—CAR SERVICE
The Baltimore and Ohio Railroad Co. Authorized To Transport Shipments of Less Than 6,370 Tons

AGENCY: Interstate Commerce Commission.

ACTION: Emergency Order, Service Order No. 1365.

SUMMARY: There is a flood at Delhi, Ohio, which is preventing Indiana Grain Co-op from loading the complete set of 65 cars of a unit-grain train movement. Service Order No. 1365 authorizes Baltimore and Ohio to forward the 45 cars now loaded with soybeans. The remaining 20 covered hopper cars will be loaded and forwarded to destination when the flood conditions permit.


FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION: The Order is printed in full below.

Decided: March 1, 1979.

Traffic Executive Association—Eastern Railroad Tariff 4043, I.C.C. T.E.A. 4043 requires a minimum of 6,370 tons of soybeans to be loaded into 65 cars from Delhi, Ohio, to Locust Point, Baltimore, Maryland. Indiana Grain Co-op at Delhi has loaded forty-five (45) carloads of soybeans. Because of a flood, Indiana Grain is unable to load the other twenty (20) cars in order to comply with tariff requirements. The Baltimore and Ohio Railroad Company (BO) has requested authority to waive the 6,370 tons, 65 car provisions of this tariff, and to forward 45 cars immediately with the remaining 20 cars to be forwarded when the flood conditions permit loading of the cars. Better utilization of covered hopper cars will be effected by authorizing the loaded cars to be forwarded.

It is the opinion of the Commission that an emergency exists and that there is good cause to authorize BO to transport shipments of less than 6,370 tons. The Commission finds 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,
§ 1033.1365 (S.O. 1365).
(a) The Baltimore and Ohio Railroad Company authorized to transport shipments of less than 6,370 tons. The Baltimore and Ohio Railroad Company (BO) is authorized to waive the sixty-five (65) car, 6,370 tons requirement provided in Item 370 of Traffic Executive Association—Eastern Railroad Tariff 4043, I.C.C. T.E.A. 4043, and is authorized to transport forty-five (45) cars of soybeans from Delhi, Ohio, to Locust Point, Baltimore, Maryland, on a one trip basis. The remaining twenty (20) cars of soybeans will be operated together in the final movement in order to comply with the tariff minimum weight requirement. Detention rules will be treated as if each of the movements is a complete movement in itself.
(b) Other tariff provisions. All tariff provisions not specifically modified by this order shall remain in effect.
(c) Application. The provisions of this order shall apply to intrastate, interstate and foreign commerce.
(d) Minimum weights. The minimum weights required to be transported as provided in the applicable tariff shall remain fully in effect.
(e) Billing to be endorsed. The bills of lading and the waybills covering a partial shipment authorized by this order to be forwarded shall bear the following endorsement:
"Unit-grain-train of ( ) cars. Partial shipment of ( ) cars forwarded under authority ICC Service Order No. 1365. ( ) additional cars to follow.
(f) Consent of shipper required. The shipper shall consent before the cars are forwarded as authorized in Section (a) of this order.
(g) Effective date. This order shall become effective at 9:00 a.m., March 1, 1979.

(h) Expiration date. The provisions of this order shall expire at 11:59 p.m., March 15, 1979, unless otherwise modified, changed or suspended by order of this Commission.

[49 U.S.C. (10304-10305 and 11121-11129)]

This order shall be served upon the Association of American Railroads, Car Service Division, as agent of all 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. Member Robert S. Turkington not participating.

H. G. Homme, Jr.,
Secretary.

[FR Doc. 79-7238 Filed 3-8-79; 8:45 am]

[7035-01-M]

SUBCHAPTER B—PRACTICE AND PROCEDURE

[Ex Parte No. 293, Sub-No. 2]

PART 1125—STANDARDS FOR DETERMINING RAIL SERVICE CONTINUATION SUBSIDIES

Decision

AGENCY: Rail Service Planning Office, Interstate Commerce Commission.
ACTION: Denial of request to reopen rulemaking.

SUMMARY: RSPO reasserts that the Congressional intent regarding the reasonable return concept was implemented in the original drafting of the Regional Subsidy Standards in 1975. The "reasonable return on the value" of rail properties contained in 49 CFR 1125.9 is determined by using "net liquidation value" and the rate of return on U.S. Treasury Notes and Bonds. The fact that recent inflation has resulted in dramatic increases in interest rates does not negate the "reasonable return" concept or criteria.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION: On February 6, 1979, the Ohio Rail Transportation Authority, on behalf of the states in the Northeast and Midwest Region, requested the Rail Services Planning Office (RSPO) to reopen the Regional Subsidy Standards (49 CFR 1125) to address the issues of "market price" valuation, Treasury Bond rates of return, and a price escalator provision.

TREASURY BOND RATES OF RETURN

The crux of the request to reopen is the recent increase in interest rates. The states which subsidize services in the Region agreed to use the Treasury Bond rate of return during the third subsidy year. At that time, it was 7.2 percent. In January 1979, the Penn Central Corporation submitted to the states its estimated costs for the fourth year use of its rail properties. The projected earnings return was at the estimated Treasury Bond rate of 10.5 percent, resulting in a 46 percent increase in lease costs due solely to increased interest rates. The states currently leasing Penn Central's rail lines argue that they accepted the Treasury Bill rate last year because it is (1) easily verifiable; (2) a publicly accessible measure; (3) lower than the prime rate; and (4) reasonably stable. They further contend that "the increase in the T-Bill rate in the last twelve months belies the factor of stability.

First, RSPO would like to clarify that the rate used in the Standards is that for U.S. Treasury Bonds or Notes, which differ from Treasury Bills. The T-Bills' life is usually less than one year, while the use of bonds-and notes provides the flexibility to use periods of one year or more. While it is true that Treasury Bond and Note rates have risen dramatically in the past year, this does not demonstrate a case of instability or unreasonableness when considered within the context of all interest rates. On February 15, 1979, the Treasury Bond and Note rate was 9.9 percent. This shows a less rapid increase than the prime rate did over the same period, the prime rate has risen from 8 percent in April, 1978, to 11.75 percent today.

It is a general increase in the entire money market which places the parties in their current position. This economic fact of life does not renounce the concept of reasonableness as intended by Congress or as defined in the Standards. If Penn Central were able to liquidate the leased properties and invest the proceeds prudently and conservatively, it could very easily receive a return of approximately 10 percent in today's money market.

Interest rates have fluctuated over the past 10 years and it is within the realm of possibility that the rates could drop to 8 percent by next year.

Although this would give the subsidizers the advantage of lower lease costs, we would not expect Penn Central to petition for the retention of the 10 percent rate. When RSPO issued its Standards on January 8, 1978, we determined that the world market (i.e., Treasury Bonds) would provide the greatest degree of fairness to all parties. Nothing has been presented in ORTA's arguments to change that opinion.

MARKET PRICE VALUATION

ORTA stated that it, and the other states, assumed last year that the net liquidation value (NLV) was established as Penn Central's "book price" in 1978, and that the 1978 value would be used during the entire subsidy period. In its fourth year estimates, Penn Central increased NLV by using a price index. RSPO agrees that the 1978 NLV should be used during the entire subsidy period. However, the subsidy period in question is only a one-year period. Therefore, when negotiating a new lease for the fourth year, the parties will have to use the current value at which the owners could liquidate the properties. There is no intent in the legislation or in the Standards to "freeze" the value of the properties at the NLV on April 1, 1978, or any other date.

RSPO believes that the properties should be valued at the current level, but does not agree that the prior year's value should be increased across-the-board by use of an arbitrary index. We believe that it would be beneficial to the parties if the individual elements of the property, such as scrap rail, relay rail, ties, and land, were analyzed separately and valued individually rather than collectively.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979

RULES AND REGULATIONS

ORTA recommends that RSPO establish a price escalator for leasing rail properties by using the President's Price Guidelines of 8.5 percent as the multiplier for establishing lease value. The underlying principle of the Subsidy Standards is to compensate the owner and operator for expenses incurred in the continuation of rail service. The intent of the law is clear that those owners and operators should not suffer unreimbursed losses in the provision of this service. Thus, if fuel costs rise 100 percent (as they did in 1973-1974), the subsidizer must compensate the operator for these increased costs. This is true of any of the costs incurred during the subsidy agreement period. The subsidizer must, in effect, make the operator/owner whole for any costs incurred in the provision of the subsidized service. To compensate the owner of the properties at a rate less than that available on the money market (i.e., Treasury Bonds) would be a failure to satisfy the minimum constitutional standards of sufficiency. Finally, the President's Price Guidelines specifically exempt interest rates. Thus, the arguments for establishing a price escalator which is not tied to the money market are inappropriate.

This is not a major federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969.

Issued March 5, 1979 by Alexander L. Morton, Director, Rail Services Planning Office.

By the Commission.

H. G. Holm, Jr.,
Secretary.

[FR Doc. 79-7242 Filed 3-9-79; 6:45 am]

[4310-55-M]

Title 50—Wildlife and Fisheries

CHAPTER I—U.S. FISH AND WILDLIFE SERVICE, DEPARTMENT OF THE INTERIOR

PART 26—PUBLIC ENTRY AND USE

Special Regulations for Continued Opening of Izembek National Wildlife Refuge, Alaska, to Public Access, Use, and Recreation

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Special regulations.
SUMMARY: The director has determined that the opening to public access, use, and recreation of Izembek National Wildlife Refuge and the Unimak Island portion of the Aleutian Islands National Wildlife Refuge in accordance with applicable State and Federal Regulations as set forth in Title 50 Code of Federal Regulations, Part 26, and with certain restrictions as delineated below under Supplementary Information, is compatible with the objectives for which the areas were established, and will provide recreational opportunity to the public.

EFFECTIVE DATES: These regulations are effective from March 9, 1979 through April 15, 1980.

FOR FURTHER INFORMATION CONTACT:

John Sarvis, Refuge Manager Izembek National Wildlife Refuge, Pouch No. 2, Cold Bay, Alaska 99571, (907) 532-2445.

SUPPLEMENTARY INFORMATION:
The primary author of this document is John Sarvis.

§ 26.34 Special regulations concerning public access, use, and recreation for individual national wildlife refuges.

UNIMAK ISLAND PORTION OF THE ALEUTIAN ISLANDS NATIONAL WILDLIFE REFUGE AND IZEMBEK NATIONAL WILDLIFE RANGE

(a) The landing of aircraft is permitted only at the airstrips at False Pass and Cape Sarichef and on lakes, bays, lagoons and adjacent beaches on Unimak Island. The landing of aircraft is prohibited on Izembek National Wildlife Refuge, except in the event of emergency.

(b) Overflights by aircraft of less than 1000 feet above ground level are prohibited except as required by Federal Aviation Regulations governing landing approaches to the Cold Bay Airport.

(c) The use of motorized vehicles is restricted to the established road system.

(d) The use of boats driven by air thrust, commonly known as air boats and jet boats, is prohibited.

(e) Permission to enter or use those refuge headquarters, Office of the Area Manager (addresses listed above). The Refuge Recreation Act of 1962 (16 U.S.C. 460k) authorized the Secretary of the Interior to administer such areas for public recreation as an appropriate incidental or secondary use only to the extent that it is practicable and not inconsistent with the primary objectives for which the area was established. In addition, the Refuge Recreation Act requires that before any area of the refuge system is used for forms of recreation not directly related to the primary purposes and functions of the area, the Secretary must find that: (1) Such recreational use will not interfere with the primary purposes for which the area was established; and (2) funds are available for the development, operation, and maintenance of the permitted forms of recreation. The recreational use authorized by these regulations will not interfere with the primary purposes for which these refuges were established. Funds are available for the administration of the recreational activities permitted by these regulations.

The provisions of these special regulations supplement the regulations which govern public use on wildlife refuge areas generally as set forth in Title 50 Code of Federal Regulations, Part 26, and appropriate State regulations. The public is invited to offer suggestions and comments at any time.


LeRoy W. Sowel,
Alaska Area Director,
U.S. Fish and Wildlife Service.

[F R Doc. 79-7234 Filed 3-8-79; 8:45 am]

portions of Izembek and Unimak National Wildlife Refuge selected by the Native villages of False Pass, King Cove, and Pauloff Harbor under ANCSA should be obtained from the False Pass, King Cove, or Pauloff Harbor Village corporations respectively. Public access, use, and recreation on portions of the described refuges shall be in accordance with applicable State and Federal Regulations, subject to additional special regulations and conditions as indicated. Special conditions applying to individual refuges and maps are available at.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
DEPARTMENT OF AGRICULTURE
Agricultural Marketing Service
[7 CFR Part 1062]
(Docket No. A9-10-A53)
MILK IN THE ST. LOUIS-OZARKS MARKETING AREA

Decision and Order To Terminate Proceeding on Proposed Amendments to Marketing Agreement and to Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of termination of the opportunity to file written exceptions.

SUMMARY: This final decision denies the milk industry proposal to change the pooling standards for supply plants. The proposal was considered at a public hearing held June 21–22, 1978. The proposal would have allowed a pool supply plant to meet its shipping requirements through transfers and diversions of milk from the supply plant to pool distributing plants, rather than just through transfers. The order accompanying the decision terminates the proceeding in this matter.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTAL INFORMATION:

Prior documents in this proceeding:


PRELIMINARY STATEMENT

A public hearing was held upon proposed amendments to the marketing agreement and the order regulating the handling of milk in the St. Louis-Ozarks marketing area. The hearing was held, pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), and the applicable rules of practice (7 CFR Part 900), at Bridge- ton, Mo., on June 21–22, 1978, pursuant to a notice thereof issued on May 31, 1978 (43 FR 24540).

Upon the basis of the evidence introduced at the hearing and the record thereof, the Deputy Administrator, Marketing Program Operations, on November 17, 1978 (43 FR 54642), filed with the Hearing Clerk, United States Department of Agriculture, his recommended decision containing notice of the opportunity to file written exceptions thereto.

This decision deals only with Issue 2. The findings and conclusions and rulings of the recommended decision with respect to Issue 2 are hereby approved and adopted and are set forth in full herein, subject to the addition of 4 new paragraphs at the end of the discussion under the heading "2. Pooling standards for supply plants."

The material issues on the record relate to:

1. Regulation of a distributing plant that qualifies as a pool plant under more than one order.
2. Pooling standards for supply plants.
3. Limitations on the diversion of producer milk.
5. Funding rate for the Advertising and Promotion program.
6. Assessment for order administration.

This decision deals only with Issue 2. Issues 1, 3, 4, 5, and 6 were dealt with in a prior decision.

FINDINGS AND CONCLUSIONS

The following findings and conclusions on the material issues are based on evidence presented at the hearing and the record thereof:

2. Pooling standards for supply plants. A proposal that would allow a supply plant operator to move milk directly from producers' farms to pool distributing plants and have such deliveries count as though they were shipments from his supply plant for purposes of meeting the supply plant shipping requirements should not be adopted on the basis of this record.

Presently, the order requires that a supply plant must ship 50 percent of its Grade A receipts to pool distributing plants during the month to qualify as a pool plant. A plant that has made the required shipments during each of the months of September through February is eligible for automatic pooling status during the following months of March through August.

Kraft, Inc., proposed that deliveries of milk from producers' farms to pool distributing plants by a supply plant operator be allowed to count as qualifying shipments from the supply plant. Kraft's spokesman testified that his company operates a pool distributing plant located at St. Louis and nonpool manufacturing plants located at Springfield, Missouri, and Bentonville and Berryville, Arkansas. In addition, he said that Kraft had under construction a supply plant at Springfield which it planned to qualify as a pool plant under the St. Louis-Ozarks order in September 1978.

Kraft's witness stated that the company planned to qualify its Springfield supply plant on the basis of deliveries to a pool distributing plant at Fayetteville, Arkansas. He testified that 70 percent of the milk that Kraft intends to pool through its Springfield supply plant is located in the Springfield area, 20 percent is in the Bentonville area, and 5 percent is in the Berryville area. The witness stated that Kraft intended to supply the Fayetteville distributing plant primarily with milk from farms located in the Bentonville and Berryville areas. Any additional quantities of milk needed by the Fayetteville plant would be obtained from milk supplies associated with Kraft's Springfield plant. The witness indicated that when milk in the Bentonville and Berryville area was not needed at the Fayetteville pool distributing plant, it would be delivered directly from the farm to Kraft's nonpool plants at Bentonville and Berryville. Likewise, whenever milk from the Springfield area was not needed at the Fayetteville plant, the milk would be diverted to Kraft's nonpool plant at Springfield.

Kraft's spokesman indicated that under the present order provisions it would be extremely inefficient for Kraft to supply the Fayetteville plant with milk from the Bentonville-Berryville area and still qualify the Springfield plant as a pool supply plant. Kraft would have to ship the milk to its Springfield supply plant, unload it there, and then reload it onto a tank truck and ship it to Fayetteville. The

FEDERAL REGISTER, VOL. 44, NO. 49—FRIDAY, MARCH 9, 1979
spokesman said that if milk in the Bentonville area had to move through the Springfield supply plant for delivery to Fayetteville, it would take at least 220 miles. Similarly, he said, the milk would have to be shipped 25 miles, a savings of 194 miles. Similarly, the spokesman said, the milk from the Bentonville area would have to be shipped 195 miles if it were delivered via the Springfield plant compared to 60 miles if it were permitted to go directly from producers' farms to Fayetteville.

The witness also stated that, in addition to the savings in transportation involved, the quality of the milk would be better if the milk were shipped directly from farms in the Bentonville-Berryville area to Fayetteville. He indicated that the quality of the milk deteriorates every time it is pumped, such as at reloading facilities.

Mid-Am's proposal to allow shipments directly from producers' farms to pool distributing plants to count as qualifying shipments for pooling a supply plant. A Mid-Am spokesman held that the present supply plant shipping requirements are reasonable and that the adoption of Kraft's proposal would make it possible for pool handlers to attach excessive milk supplies to the St. Louis-Ozarks market. Thus, he said, would reduce the uniform price in an already deficit market, thus making it more difficult to attract milk from surplus-producing regions.

The witness for the cooperative stated that there is a provision in the order now that allows a plant operated by a cooperative association to qualify on the basis of direct shipments from producers' farms "if the major function of the marketing association is to attract milk from surplus-producing regions." It was his position that under Kraft's proposal a proprietary plant operator should be required to furnish a supply of milk for the fluid needs of the market to the same extent as a cooperative. He held, therefore, that if Kraft's proposal is adopted, the shipping requirements for a supply plant should be increased to 70 percent of the plant's producer receipts, which approximates the average proportion of the milk of its members on the market that Mid-Am delivers to pool distributing plants.

A spokesman representing the Kroger Company testified that his company is opposed to letting milk be associated with the fluid market without some requirement that the milk be available when needed for fluid use. He contended that there is a growing need for increasing the present performance requirements of pool plants. He held that with the marketwide

**PROPOSED RULES**

Class I utilization running 65 percent in May and with declining production in the grain belt, it is getting more and more difficult for farmers to attract a supply of milk for fluid use. These extra costs, he stated, must be passed on to consumers. He claimed that if consumers then reduce their consumption of milk because of the extra costs, the dairy farmer will ultimately receive a lower price for his milk.

Kraft's proposal was presented as a means of facilitating the efficient handling of milk of producers who are associated with a pool supply plant. Kraft's representative contended that if producers are located closer to a distributing plant that is buying milk from a supply plant than they are to the supply plant, the milk should be permitted to move directly from their farms to the distributing plant rather than to the supply plant for reloading and transshipment. However, the efficient handling of milk that Kraft wanted to accomplish is associated with milk that normally might be associated with its proposed pool supply plant at Springfield. Instead, Kraft's proposed modification of the pool supply plant definition was designed to accommodate primarily the pooling of milk at farms located near Kraft's nonpool plants at Berryville and Bentonville rather than milk located in the proximity of the Springfield plant.

Kraft's witness indicated that the company had no intention of physically associating milk in the Bentonville area with its proposed pool supply plant at Springfield. He stated, in response to a question concerning the Springfield supply plant, that the company had no plans to deliver milk from the Bentonville area to its plants in Springfield. He indicated that when the hearing was held, Kraft's Springfield supply plant was not in operation.

Because the proposed Springfield supply plant has not in existence, there has been no operational experience to demonstrate whether or not the producers in the Bentonville-Berryville area would in fact ever have their milk physically associated with the plant. However, it is reasonable to assume from this record that none of this milk which might move directly from farms to pool distributing plants would ever be received at the Springfield supply plant. In this case, there would be little resemblance between this type of supply plant operation and the usual operation of a supply plant where milk of producers associated with the plant is physically received at the plant. Actually, the proposed operation could be likened somewhat to the operation of a cooperative that qualifies its balancing plant on the basis of milk deliveries from farms to distributing plants, as was contended by Mid-Am. This raises the question of whether the current period under Kraft's proposal for pool supply plants (i.e., level of shipments by the plant operator) would be equal to appropriate under the different operational arrangements. A change in the level of performance was not contemplated under Kraft's proposal.

It is conceivable that some accommodation for diversions from a supply plant to distributing plants could be warranted in those cases where the producers involved might otherwise not have their milk received at the supply plant. This type of situation was not portrayed on the record. It is recognized that the record evidence upon which this decision is based may not be representative of Kraft's actual marketing experience in operating its pool supply plant. As previously noted, Kraft's supply plant was under construction at the time of the hearing. Consequently, testimony was limited to the projected operation of the plant on September 1, 1978, and thereafter. No basis exists, therefore, for determining whether the marketing conditions that Kraft anticipated would exist on and after that date are representative of the actual marketing conditions. Actual operating experience might well suggest a different approach to dealing with the marketing situation.

Kraft, Inc., expected to the Department's tentative denial of its proposal to allow a supply plant to count as qualifying shipments for pooling purposes milk that is diverted from such supply plant to pool distributing plants. While exception was agreed with the Department's tentative conclusion that a supply plant should not be permitted to qualify as a pool plant solely on the basis of diversions from the Springfield supply plant to a pool distributing plant, Kraft excepted to the continued use of the present standards. As an alternative, Kraft proposed in its exceptions to the recommended decision that a handler be permitted to meet up to one-half of the total required shipments for pool supply plant qualification from diversions from the Springfield supply plant to pool distributing plants.

Kraft's support for the company's modified proposal at this stage of the proceeding is due to a change in the company's earlier marketing plans. When the hearing was held, Kraft's Springfield supply plant at Springfield, Missouri, was under construction. At that time, Kraft intended to divert milk from the Springfield supply plant to a pool distributing plant located at Fayetteville, Arkansas. Kraft now indicates that it was unable to put that plan into operation. Instead, on September 1, 1978, Kraft started delivering milk from its
supply plant to two pool distributing plants located in the St. Louis area. Since September, the pool supply plant has been regulated under the St. Louis-Ozarks order.

In view of the changed marketing conditions, Kraft now supports a modified version of its earlier proposal. The company indicates that the proposed revision would accommodate the pooling of a group of producers who are located between the Springfield, Missouri pool supply plant and distributing plants which receive the milk of such producers. Proponent also indicates that the revised amendment is identical to the order amendment that the Department has recommended for adoption in the Tennessee Valley milk order (44 FR 4696). The marketing conditions upon which proponent’s request is based occurred after the close of the hearing and, therefore, are not a part of the record evidence upon which this decision must be based. Furthermore, adoption of the requested change at this stage of the proceeding would not permit interested parties an opportunity to comment on the proposed change. For these reasons, proponent’s request must be and is hereby denied.

RULINGS ON PROPOSED FINDINGS AND CONCLUSIONS

Briefs and proposed findings and conclusions were filed on behalf of certain interested parties. These briefs, proposed findings and conclusions, and the evidence in the record were considered in making the findings and conclusions set forth above. To the extent that the suggested findings and conclusions filed by interested parties are inconsistent with the findings and conclusions set forth herein, the requests to make such findings or reach such conclusions are denied for the reasons previously stated in this decision.

RULINGS ON EXCEPTIONS

In arriving at the findings and conclusions, and the regulatory provisions of this decision, each of the exceptions received was carefully and fully considered in conjunction with the record evidence. To the extent that the findings and conclusions, and the regulatory provisions of this decision are at variance with any of the exceptions, such exceptions are hereby overruled for the reasons previously stated in this decision.

TERMINATION ORDER

In view of the foregoing, it is hereby determined that the proceeding with respect to the proposed amendment to the tentative marketing agreement and to the order should be and is hereby terminated.

PROPOSED RULES

(This decision constitutes the Department’s final Impact Analysis Statement for this proceeding.)

Signed at Washington, D.C., on March 6, 1979.

P.R. “Booey” Surratt,
Assistant Secretary for Marketing and Transportation Services.

(FR Doc. 79-7162 Filed 3-8-78; 8:45 am)

[6210-01-M]

FEDERAL RESERVE SYSTEM

[12 CFR Part 215]

LOANS TO EXECUTIVE OFFICERS, DIRECTORS AND PRINCIPAL SHAREHOLDERS

FEDERAL DEPOSIT INSURANCE CORPORATION

[12 CFR Parts 334, 349]

(Docket No. R-0210)

FORMS, INSTRUCTIONS, AND REPORTS LOANS BY CORRESPONDENT BANKS

AGENCIES: Board of Governors of the Federal Reserve System; Comptroller of the Currency, and Federal Deposit Insurance Corporation.

ACTION: Proposed regulations.

SUMMARY: The agencies listed above are considering methods and procedures to implement Title VIII (Correspondent Accounts) and Title IX (Disclosure of Material Facts) of the Financial Institutions Regulatory and Interest Rate Control Act of 1978, Pub. L. 95-630 (“FIRA”). Title VIII and IX of FIRA take effect on March 10, 1979.

Title VIII prohibits banks that maintain a correspondent account relationship with each other from extending credit on preferential terms to each other’s executive officers, directors or principal shareholders. It also prohibits the opening of a correspondent account relationship between banks where there is a preferential extension of credit from one bank to an executive officer, director or principal shareholder of the other bank. In addition, Titles VIII and IX require insured banks and the executive officers and principal stockholders of record of insured banks to file certain reports.

DATE: Comments must be received by April 20, 1979.

ADDRESS: Interested persons are invited to submit comments regarding the proposed regulations. National banks should address their comments to the Secretary, Board of Governors, of the Federal Reserve System, Washington, D.C. 20551, with a copy to John E. Sederberg, Chief Counsel, Office of the Comptroller of the Currency, 490 L’Enfant Plaza East, S.W., Washington, D.C. 20219. State banks that are members of the Federal Reserve System should send their comments to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551. Insured banks that are not members of the Federal Reserve System should address their comments to the Office of the Executive Secretary, Federal Deposit Insurance Corporation, 550 17th Street, N.W., Washington, D.C. 20429.

All other interested persons should address their comments to the Board of Governors of the Federal Reserve System, with a copy to any other appropriate agency. All material submitted should refer to F.R.B. Docket No. R-0210. All comments received will be made available for public inspection.

FOR FURTHER INFORMATION CONTACT:

Board of Governors of the Federal Reserve System: Bronwen Mason, Senior Attorney, Legal Division (202/452-3564), or Michael Bleler, Senior Attorney, Legal Division (202/452-3721); Federal Deposit Insurance Corporation: Alan J. Kaplan, Senior Attorney, Legal Division (202/389-4433); Comptroller of the Currency: William H. Rivoir, Attorney, Enforcement and Compliance Division (202/447-1989).

SUPPLEMENTARY INFORMATION:

a. Title VIII—Effective March 10, 1979, Title VII of FIRA, which amends section 106 of the Bank Holding Company Act Amendments of 1970, prohibits banks that maintain a correspondent account relationship with each other from extending credit to each other’s executive officers, directors or principal shareholders unless the extension of credit is (1) made on substantially the same terms as those prevailing at the time for comparable transactions with other persons and (2) does not involve more than the normal risk of repayment or present other unfavorable features. The agencies propose to interpret the term “other persons” to mean other persons not associated with, or employed by, the bank.

Title VIII also prohibits the opening of a correspondent account relationship between banks where there is a preferential extension of credit from one of the banks to an executive officer, director, or principal shareholder of the other bank.

Persons covered by these prohibitions include any individual or company that directly or indirectly owns or controls more than ten percent of any class of voting shares of a bank. In the proposed rule, a principal shareholder includes a person who controls a principal shareholder, and such person is a member of a bank holding company. In addition, shares owned by an indi-
vidual's immediate family, as defined in the Federal Reserve Board's Regulation O, are deemed to be owned by the individual.

The proposed rule defines a correspondent account as an account that is maintained by a bank for the deposit or placement of funds. The agencies are considering exclusions from the definition of correspondent account such as time deposit accounts at prevailing interest rates and accounts maintained solely for the purpose of effecting correspondent transactions or loan participations. The agencies request comment on this definition as well as suggestions for other possible inclusions or exclusions. Such suggestions should be justified in light of the purposes of the Act.

In addition to its prohibitions, Title VIII imposes reporting requirements upon executive officers and principal stockholders of record. The proposed regulations define the principal stockholder of record as a person that, directly or indirectly, owns, controls, or has the power to vote more than ten percent of any class of voting securities of an insured bank.

For the purposes of these requirements, the term insured bank includes a branch of a foreign bank, the deposits of which are insured by the FDIC. If a foreign bank maintains a non-insured branch or an agency or a commercial lending company in the United States, the branch, agency or company would qualify as a bank for purposes of the prohibitions of Title VIII, but would not be subject to Title VIII's reporting requirements.

Executive officers and principal stockholders of record of insured banks are required to provide the board of directors of their bank with a report regarding any extension of credit made to them and to each of their related interests by each of their bank's correspondent banks during a calendar year. A correspondent bank is defined as a bank that maintains a correspondent account with the insured bank, and to which the insured bank forwards or calls funds.

The agencies propose to define the term "maximum amount of indebtedness" as the highest amount that was owed during the year. As an alternative, the agencies are considering defining "maximum amount of indebtedness" as the sum of all extensions of credit. While the alternative method of calculation appears less burdensome, it yields a higher figure that may not accurately reflect the extent of correspondent borrowing by a bank's executive officers and principal stockholders. Comment is specifically requested on this point.

Title VIII requires each insured bank to compile the reports submitted to it by its executive officers and principal stockholders of record and to forward them to the appropriate Federal banking agency upon request. The proposed regulations incorporate the definitions in the Federal Reserve Board's Regulation O for the terms "executive officer," "extension of credit," "immediate family," and "control of a bank or company.

The prohibitions against preferential lending in Title VIII are prospective only. Preferential loans that are outstanding as of March 10, 1979, are not specifically addressed in the statute or the proposed regulations. If a bank makes a preferential loan that is not specifically addressed in the statute or the proposed regulations, it is not subject to the prohibitions in Title VIII. However, banks should eliminate the preferential terms on such loans as soon as practicable. If such preferential terms are not eliminated, they may be subject to criticism by the agencies. This policy applies particularly to demand loans that are within the power of the bank to call and renegotiate at any time.

It is emphasized that, although these are proposals and not final regulations, the actual statute takes effect on March 10, 1979, and all banks are expected to comply with the law beginning on that date. Title VIII is expected to specify the terms contained in the proposed regulations (in particular, the definitions of terms contained in the proposed regulations).
The agencies are considering whether it is necessary to provide forms on which the statements and reports required under Titles VIII and IX must be filed. Any such forms, and accompanying instructions, would be published at a later date. The first reports under Titles VIII and IX are due to be filed by executive officers and principal stockholders of record on January 31, 1980, and by insured banks by January 31, 1980. The period covered by such reports will be from March 10, 1979 (the effective date of the Rate Control Act of 1978) through December 31, 1979. However, the agencies may consider limiting the first reporting period to July 1, 1979 to December 31, 1979, in order to provide for the orderly implementation of the Act's reporting requirements. Also, comment is requested on whether the January 31 filing date for insured banks should be extended to a later date.

Accordingly, the Board of Governors of the Federal Reserve System hereby proposes to amend the title to the Board's Regulation O (12 CFR Part 215) to read “Part 215—Loans to Executive Officers, Directors, and Principal Shareholders,” to add a new paragraph (b) to section 215.9 of Regulation O, to include sections 215.1 through 215.10 of Regulation O in Subpart A titled “Loans by Member Banks,” and to add a new Subpart B to Regulation O to read as set forth below, and the Board of Directors of the Federal Deposit Insurance Corporation hereby proposes to amend 12 CFR by adding thereto a new Part 349 and a new section 304.4 to read as set forth below.

### Federal Reserve System

1. The Title to Part 215 is revised, and paragraph (b) is added to §215.9 as follows:

**PART 215—LOANS TO EXECUTIVE OFFICERS, DIRECTORS, AND PRINCIPAL SHAREHOLDERS**

**Subpart A—Loans by Member Banks**

- §215.9 Reports by member banks.
  - (b) On or before January 31 of each year, each member bank shall file with the appropriate Federal Reserve Bank or the Comptroller of the Currency, as the case may be, a report that shall include the following information with respect to the preceding calendar year:
    1. A list by name of each executive officer of the member bank and a list

**Subpart B—Loans by Correspondent Banks**

- §215.20 Authority, purpose, and scope.
  - (a) Authority. This Subpart is issued pursuant to Title VIII of the Financial Institutions Regulatory and Interest Rate Control Act of 1978 ("FIRA") (P.L. 95-630), and under authority of sections 11(i) and 22(h)(7) of the Federal Reserve Act (12 U.S.C. 245(i) and 375b(7) and 12 U.S.C. 1817(k)(1)). Title VIII amends section 106(b) of the Bank Holding Company Act Amendments of 1970 (12 U.S.C. 1972).
  - (b) Purpose and Scope. The purpose of this Subpart is to implement the provisions of Title VIII of FIRA. It prohibits (1) preferential lending by a bank to executive officers, directors and principal shareholders of another bank when there is a correspondent account relationship between the banks, and (2) the opening of a correspondent account relationship between banks when there is a preferential account relationship between the banks having a correspondent account relationship. A bank does not have a correspondent account relationship with another bank simply because it has an account with another bank.
§215.22 Prohibited transactions.

(a)(1) No bank that maintains a correspondent account for another bank shall make an extension of credit to an executive officer, director, or principal shareholder of such other bank unless the extension of credit is not preferential.

(2) No bank shall open a correspondent account at another bank that has outstanding an extension of credit to an executive officer, director, or principal shareholder of the bank desiring to open the account unless the extension of credit is not preferential.

(3) No bank that maintains a correspondent account at another bank shall make an extension of credit to an executive officer, director or principal shareholder of such other bank unless the extension of credit is not preferential.

(b) For the purposes of this section, an extension of credit is not preferential if (1) it is made on substantially the same terms, including interest rates and collateral, as those prevailing at the time for comparable transactions with other persons that are not covered by this Subpart and who are not employed by the bank, and (2) it does not involve more than the normal risk of repayment or present other unfavorable features.

§215.23 Reports by executive officers and principal stockholders of record.

(a) If during any calendar year an executive officer or principal stockholder of record of a member bank had outstanding an extension of credit from a depository bank(s) of the member bank, the executive officer or stockholder shall, on or before January 10 of the following year, make a written report to the board of directors of the member bank.

(b) The report required by this section shall include the following information:

1. The "maximum amount of indebtedness" of the executive officer or principal stockholder of record and of each of the person's related interests to each depository bank;

2. The amount of indebtedness of the executive officer or principal stockholder of record and of each of that person's related interests outstanding as of December 31 of the calendar year for which the report is made to each depository bank;

3. The range of interest rates charged on the indebtedness reported in paragraphs (b)(1) and (b)(2) of this section; and

4. A general description of the terms and conditions of the indebtedness reported in paragraphs (b)(1) and (b)(2) of this section.

(c) For the purposes of this Subpart, "maximum amount of indebtedness" shall mean the highest amount owed during the calendar year for which the report is made.

(d) The report required by this section must be filed by a person who was an executive officer or a principal stockholder of record of a member bank at any time during the reporting year and who received an extension of credit during that year from a depository bank of the member bank.

§215.24 Reports by member banks.

(a) On or before January 31 of each year, each member bank shall compile the reports filed under section 215.23(a) above, and shall forward a compilation of such reports to the Comptroller of the Currency, in the case of a national bank, or the appropriate Federal Reserve Bank, in the case of a State member bank. The reports required by section 215.23(a) above, shall be retained at the member bank for a period of five years. The appropriate Federal banking agency may require these reports to be retained by the bank for an additional period of time.

(b) Each member bank shall include in the report required under section 215.2(b) of Subpart A the following information:

1. A list by name of each person who files a report under section 215.23(a) above; and

2. The aggregate amount, or sum, of all the maximum amounts of indebtedness reported under section 215.23(b)(1) above.

§215.25 Civil penalties.

As specified in subsection 106(c)(2)(F) of the Bank Holding

Company Act Amendments of 1970 (12 U.S.C. 1972(b)(2)(F)), any bank, or any officer, director, employee, agent, or other person participating in the conduct of the affairs of the bank, that violates any provision of this Subpart shall forfeit and pay a civil penalty of not more than $1,000 per day for each day during which the violation continues.

By Order of the Board of Governors of the Federal Reserve System March 6, 1979.

FEDERAL DEPOSIT INSURANCE CORPORATION

THEODORE E. ALLISON,
Secretary of the Board.

4. Section 304.4 is added to read as follows:

PART 304-FORMS, INSTRUCTIONS, AND REPORTS

§304.4 Report of loans to executive officers and principal stockholders of record.

(a) On or before January 31 of each year, each insured nonmember bank shall file with the Corporation the report required by section 7(k)(1) of the Federal Deposit Insurance Act (12 U.S.C. 1817(k)(1)). The report shall include the following information with respect to the preceding calendar year:

1. A list by name of each executive officer of the insured nonmember bank and a list by name of each principal stockholder of record of the insured nonmember bank;

2. The aggregate amounts of all extensions of credit made by the insured nonmember bank to its executive officers and principal stockholders of record and their related interests; and

3. The information required to be included under section 349.5(b) of the Corporation's rules and regulations (12 CFR 349.5(b)).

(b) For the purposes of this subsection, "aggregate amount of all extensions of credit" shall mean the sum of the highest amounts of indebtedness owed to the insured nonmember bank during the year by each executive officer or principal stockholder of record and each of the reporting person's related interests, and the terms "executive officer," "extension of credit," "principal stockholder of record," and "related interest" shall have the meanings provided in Federal Reserve Board Regulation O (12 CFR Part 215), except that the term "member bank" in Regulation O shall be deemed to refer to an insured nonmember bank for the purposes of this subsection.

5. A new Part 349 is added to read as follows:

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979

1. The definition of related interest in this Subpart differs from that in Subpart A. The definition in Subpart A excludes insured banks.

2. Persons reporting under this section are not required to include information on extensions of credit that are fully described in a report by a person they control or a person that controls them, provided they identify their relationships with such other person.
sections 349.4 and 349.5.

§ 349.2 Definitions.

(a) "Bank" has the meaning given in 12 U.S.C. §1841(c). The term includes a branch of a foreign bank, or a commercial lending company that is controlled by a foreign bank, or by a company that controls a foreign bank, where the branch or agency is maintained in a State of the United States or in the District of Columbia or the commercial lending company is organized under State law.1

(b) "Company" means any person, estate, trust, partnership, corporation, association, or similar organization. The term does not include any corporation the majority of the shares of which are owned by the United States or by any State.3

(c) "Control of a company or a bank," "executive officer," "extension of credit," and "immediate family" shall have the meanings provided in Subpart A of Federal Reserve Board Regulation O (12 C.F.R. Part 215), except that the term "member bank" in Regulation O shall be deemed to refer to an insured nonmember bank for the purposes of this Part 349.

(d) "Correspondent account" is an account that is maintained by a bank with another bank for the deposit or placement of funds.

(e) "Depository bank" means a bank that maintains a correspondent account(s) for an insured nonmember bank in an amount aggregating more than $100,000 at any time during the reporting year.

(f) "Person" means an individual or a company.

(g) "Principal shareholder" means any person that directly or indirectly, acting alone or in concert with one or more persons, owns, controls, or has the power to vote more than 10 percent of any class of voting securities of a bank or a company. The term includes a person that controls a principal shareholder (e.g., a person that controls a bank holding company). Shares owned or controlled by a member of an individual’s immediate family are considered to be owned or controlled by the individual.

(h) "Principal stockholder of record" means a person that directly or indirectly owns, controls, or has the power to vote more than 10 percent of any class of voting securities of an insured bank. The term includes a person that controls a principal stockholder of record.

(i) "Related interest" means any company controlled by a person and any political or campaign committee, the funds or services of which will benefit a person or that is controlled by a person.3

§ 349.3 Prohibited transactions.

(a)(1) No bank that maintains a correspondent account for another bank shall make an extension of credit to an executive officer, director, or principal shareholder of such other bank unless the extension of credit is not preferential.

(b) For the purposes of this section, an extension of credit is not preferential if (1) it is made on substantially the same terms, including interest rates and collateral, as those prevailing at the time for comparable transactions with other persons that are not employed by this bank, and (2) does not involve more than the normal risk of repayment or present other unfavorable features.
ness reported in paragraphs (b)(1) and 
(b)(2) of this section.

(c) For the purposes of this part, “maximum amount of Indebtedness” shall mean the highest amount owed during the calendar year for which the report is made.

(d) The report required by this section must be filed by a person who was an executive officer or a principal stockholder of record of an insured nonmember bank at any time during the reporting year and who received an extension of credit during that year from a depository bank of the insured nonmember bank.

§ 349.5 Reports by insured nonmember banks

(a) On or before January 31 of each year, each insured nonmember bank shall compile the reports filed under section 349.4(a) above and shall forward a compilation of such reports to the FDIC. The reports required by section 349.4(a) above shall be retained at the insured nonmember bank for a period of five years. The FDIC may require these reports to be retained by the bank for an additional period of time.

(b) Each insured nonmember bank shall include in the report required under section 7(c)(1) of the Federal Deposit Insurance Act (12 U.S.C. § 1817(c)(1)) and section 304.4 of the FDIC rules and regulations (12 CFR § 304.4) the following information:

(1) A list by name of each person who files a report under section 349.4(a) above; and

(2) The aggregate amount, or sum, of all the maximum amounts of indebtedness reported under section 349.4(a) above.

§ 349.6 Civil penalties.

As specified in subsection 106(b)(2)(CF) of the Bank Holding Company Act Amendments of 1970 (12 U.S.C. 1972(b)(2)(CF)), any bank, or any officer, director, employee, agent, or other person participating in the conduct of the affairs of the bank, that violates any provision of this Part shall forfeit and pay a civil penalty of not more than $1,000 per day for each day during which the violation continues.

By order of the Board of Directors, dated March 6, 1979.

HOYLE L. ROBINSON, 
Acting Executive Secretary.

(FR Doc. 79-7309 Filed 3-8-79; 8:45 am)

[6355-01-M] 

PROPOSED RULES

CONSUMER PRODUCT SAFETY COMMISSION

[16 CFR Part 1208]

MINIATURE CHRISTMAS TREE LIGHTS

Extension of Time to Publish Final Standard

AGENCY: Consumer Product Safety Commission.

ACTION: Extension of time.

SUMMARY: The Commission extends the time in which it must publish a final safety standard or withdraw its proposed standard for miniature Christmas tree lights until March 15, 1981. The rule was proposed to address the risks of fire and electric shock associated with these products. The reason for the extension is to allow the Commission time to monitor industry's upgrading of and conformity with voluntary standards before making any decision whether to issue a final mandatory standard.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

For more than five years, the Commission has been investigating the need for a mandatory standard to address risks of injury from shock and fire hazards associated with miniature Christmas tree lights. (See 41 FR 17154, March 31, 1979; 43 FR 19136, May 3, 1978.)

In the course of these investigations, the Commission tried to encourage improvements in the voluntary standards affecting these lights, but without sufficient success. As a result, CPSC proposed a mandatory standard in May 1978 (43 FR 19136, May 3, 1978.)

In response to the Commission's work, Underwriters Laboratories (UL) has revised its existing standard to include virtually all of the requirements in the Commission's proposed standard. Also, since the proposed standard was published, the government of Taiwan, a major exporter of miniature Christmas tree lights, has confirmed its intent to require all such lights to be UL approved. Most miniature Christmas tree light sets are imported into the United States. Approximately 60 percent of the miniature Christmas tree light sets imported into the United States last season were certified as meeting the UL standard. The Commission believes that this development is especially encouraging and hopes that it will continue in the future.

In addition, the National Ornament and Electric Lights Christmas Association (NOEL), a trade association of many importers and manufacturers of miniature Christmas tree lights, has indicated it will amend the NOEL standard to include the provisions of the standard recommended to the Commission by the National Consumers League, the offeror in the Commission's standard development proceeding. NOEL also stated that the association would undertake a survey of its membership to determine the extent of the adoption of the upgraded NOEL standard and advise the Commission of the results.

EXTENSION OF TIME TO PUBLISH A FINAL STANDARD

As a result of these developments, the Commission believes that a mandatory standard may not be necessary at this time in order to protect consumers from the risk of injury from fire and shock associated with miniature Christmas tree lights and similar miniature decorative lights.

In the May 1978 Federal Register notice proposing the standard, the Commission extended, until March 15, 1979, the period of time by which it must either publish a final mandatory standard or withdraw the notice of proceeding. However, as a result of the developments discussed above, the Commission believes that an additional period of time should be provided to allow the Commission to monitor industry's upgrading and conformance with voluntary standards, before making any decision that a mandatory standard is not necessary to protect the public.

The Commission believes that a two year extension, until March 15, 1981, will provide sufficient time to monitor industry's upgrading and conformance with voluntary standards, over two production seasons, and will allow the Commission sufficient time to decide whether to issue a mandatory standard. During the two year period, the Commission staff will provide the Commission with periodic reports that assess industry's progress. The Commission expects continued satisfactory progress in upgrading voluntary standards. If satisfactory progress in upgrading voluntary standards does not continue, or if the Commission observes that industry members are falling to conform with the voluntary standards, then at any time in the next two years the Commission may decide that a mandatory standard is necessary and prepare to issue a final standard.

CONCLUSION

Accordingly, pursuant to provisions of the Consumer Product Safety Act (Section 9(a)(1), Pub. L. 92-575, 86 Stat. 1215, 15 U.S.C. 2058(a)(1)), the Commission extends, from March 15, 1979 until March 15, 1981, the date on
which it must either publish a consumer product safety rule addressing the risk of injury from fire and shock associated with miniature Christmas tree lights or withdraw by rule the applicable notice of proceeding. This period may be further extended for good cause shown.

Dated: March 6, 1979.

SADIE E. DUNN, Secretary, Consumer Product Safety Commission.

[FR Doc. 79-1152 Filed 3-6-79; 8:45 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 333]

Docket No. 75N-0183

TOPICAL ANTIMICROBIAL PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Reopening of the Administrative Record

AGENCY: Food and Drug Administration.

ACTION: Reopening of record on proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is reopening the administrative record of the proposed monograph establishing conditions for the safety, effectiveness, and labeling of over-the-counter (OTC) topical antimicrobial drug products for human use, e.g., antibacterial soaps, surgical scrubs, skin cleanser, and first-aid preparations. By this action, the agency is granting 6 petitions that requested reopening this record and is deferring action on 11 requests for an oral hearing.

DATES: New or additional data, information, and comments by June 7, 1979. Reply comments by July 9, 1979.

ADDRESS: Written data, information, comments, and reply comments to the Hearing Clerk (HPA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

William E. Gilbertson, Bureau of Drugs (BPD-510), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION:

In the Federal Register of September 13, 1974 (39 FR 32100), FDA issued a proposal, 21 CFR Part 333, to establish a monograph for OTC topical antimicrobial drug products for repeated daily human use, together with the report of the Advisory Review Panel on OTC Topical Antimicrobial (1) Drug Products. Interested persons were invited to submit comments on the proposal within 60 days—on or before November 12, 1974. Reply comments in response to comments filed during the initial 60-day period were allowed until December 12, 1974. In response to numerous requests, the agency published a notice in the Federal Register of October 17, 1974 (39 FR 37066) granting an extension of the deadlines for comments until December 12, 1974 and for reply comments until January 13, 1975.

In response to the proposal of September 13, 1974, 86 comments and reply comments were received, several of which contained extensive additional data. After an extensive and time-consuming review of the Panel's report, the proposed monograph, and all comments and reply comments, FDA issued in the Federal Register of January 6, 1978 (43 FR 1210) a tentative final monograph on OTC topical antimicrobial products.

Interested persons were invited to submit objections or requests for an oral hearing on or before February 6, 1978. In response to numerous requests to extend the time period for submitting objections or requests for oral hearing, the agency issued a notice in the Federal Register of February 3, 1978 (43 FR 4637) granting an extension of the deadline to March 6, 1978.

During the period permitted for submitting objections or requests for an oral hearing, FDA received the following six petitions to reopen the administrative record. The Proctor & Gamble Co., Cincinnati, OH 45217 (CP 0003) submitted new data on the safety and effectiveness of triclosan as an active antimicrobial ingredient. Ciba-Geigy Corp., Ardsley, NY 10502 (CP 0001) submitted new data bearing on the proliferation of use of triclosan. This problem was first discussed in the tentative final order; it was never considered by the Panel. The Soap and Detergent Association, New York, NY 10016 (SUP 0001) submitted new data on the safety of antimicrobial soaps in infants. Significant amounts of new and previously unconsidered data were submitted with each of the above petitions. The Colgate-Palmolive Co., New York, NY 10022 (LET 0002) petitioned the agency to evaluate previously submitted data on the safety and effectiveness of a combination deodorant bar soap containing triclosan and triclocarban. These data were not addressed in the January 6, 1978 tentative final order. A petition was also submitted by the Upjohn Co., Kalamazoo, MI 49001 (HEB 0001) to consider previously submitted data (OTC Volume 020005) on the safety and effectiveness of secondary amyliertroes and ortho-hydroxyphenylmercuric chloride as active antimicrobial ingredients. No new data were submitted with this petition.

The Xytobin Laboratories, Chicago, IL 60609 (CP 0003) requested the agency to consider data on chlorhexidine gluconate, a new ingredient not previously reviewed or included in the tentative final order. Copies of all of these petitions are on file in the office of the Hearing Clerk, FDA.

Eleven requests for a hearing and many comments containing new data have also been received in response to the tentative final order. Much new data have been generated over the 4-year period since the original Panel report was published. These new data may materially affect and alter some of the agency's decisions presented in the January 6, 1978 tentative final order. In addition, some of the data upon which the original Panel report was based have been called into question as a result of the agency's current investigation of certain testing laboratories.

Thus, FDA has determined that it is in the public interest to defer action on the requests for a hearing, and to grant the six petitions to reopen the administrative record to allow interested persons to submit comments, reply comments, and any new or additional data. FDA will publish an updated tentative final order and monograph based on the review and evaluation of these submissions, and on a reevaluation of existing data. Persons who requested a hearing or submitted a petition will be notified by letter that FDA has reopened the administrative record. Data, information, and comments submitted in response to the September 13, 1974 or January 6, 1978 publications need not be resubmitted.

Interested persons are invited to submit their comments in writing (preferably four copies identified with the Hearing Clerk document number found in brackets in the heading of this document) on or before June 7, 1979. Such comments should be addressed to the office of the Hearing Clerk (HPA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be accompanied by a supporting memorandum or brief. Additional comments replying to any comment so filed may also be submitted on or before July 9, 1979. Received comments may be seen in the above office during working hours, Monday through Friday.

FEDERAL REGISTER, VOL 44, NO. 48—FRIDAY, MARCH 9, 1979

WILLIAM F. RANDOLPH, 
Acting Associate Commissioner 
for Regulatory Affairs.

[FR Doc. 79-7674 Filed 3-8-79; 8:45 am]

[4310-02-M] 
DEPARTMENT OF INTERIOR 
Bureau of Indian Affairs 
(25 CFR Part 273) 
EDUCATION CONTRACTS UNDER JOHNSON-
OMALLEY ACT 
Distribution Formula 

AGENCY: Bureau of Indian Affairs, Department of the Interior.

ACTION: Proposed Rule.

SUMMARY: Notice is hereby given that it is proposed to revise 25 CFR 273.31, distribution formula. Pub. L. 95-561, Section 1102(a) requires that the Secretary of Interior to develop and publish alternative methods for the equitable distribution of supplemental program funds. The intended effect of the action is to determine a formula for the purpose of distribution of funds appropriated.

DATES: Comments must be received on or before May 7, 1979.

ADDRESS: Send comments to U.S. Department of the Interior, Office of the Assistant Secretary for Indian Affairs: Attention: Deputy Assistant Secretary Lavis, 18th & C Streets NW., Room 6352, Washington, D.C. 20240.

FOR FURTHER INFORMATION CONTACT:

Jon C. Wade, Division of Education-
al Assistance, Office of Indian Edu-
cation Programs, Post Office Box 1788, Albuquerque, New Mexico 87103, Area Code 505-766-2427.

SUPPLEMENTARY INFORMATION: This notice is published in exercise of authority delegated by the Secretary of Interior to the Assistant Secretary—Indian Affairs by 230 DM 2.

It is the policy of the Department of Interior, whenever practicable, to afford the public an opportunity to participate in the rulemaking process. Accordingly, interested persons may submit written comments, suggestions or objections regarding the proposed rule to the U.S. Department of the Interior, Office of the Assistant Secretary for Indian Affairs: Attention: Deputy Assistant Secretary Lavis, 18th & C Streets NW., Washington, D.C. 20240.

The current distribution formula is not a part of regulation. It is required by law that it be incorporated into reg-
ulation. Pub. L. 95-561, Sec. 1102(a) directs the Secretary to develop alter-
native methods for the equitable dis-
tribution of any supplemental pro-
gram funds; provided and to publish them in the FEDERAL REGISTER by March 1, 1979 for the purpose to allow for eligible tribes to comment by May 1, 1979. During this time, the Secretary of Interior will conduct field hearings for the purpose of collecting further comments. Approximately two days of field hearings will be scheduled during the period of March 26, 1979 through April 15, 1979 in Anchorage, Alaska; Minneapolis, Minnesota; Ft. Hall, Idaho; Albuquerque, New Mexico; Sulphur, Oklahoma; Nashville, Tennessee; and San Diego, California.

After May 7, 1979, the Secretary will revise, in accordance with all comments, such formula alternatives and submit them to a vote of the tribes.

Pub. L. 95-561, Section 1102(b) requires that the formula which receives 75 percent of the above vote will be published as a final rule in the FEDERAL REGISTER by July 1, 1979. This vote will be taken during the period of May 7, 1979 to June 7, 1979 and will be certified by the Secretary. It must be also understood that the numbers as defined in 25 CFR, Part 273.3(g) will have one (1) vote each.

Section 273.31, Distribution formula, provides for the apportionment among contractors within each State so that each contractor will receive approximately the same amount for each eligible Indian student to be served under the contract. The formula receiving a majority of votes will be made a part of § 273.31 and will be used for computing the distribution.

The following distribution formulas have been developed and are published for the purpose to allow eligible tribes to comment by May 1, 1979:

(1) Option “A”: Based on the number of eligible Indian students for whom funds are sought, multiplied by a national average per-pupil expenditure and a weighting factor which is intended to take into account the differences, in education costs among the States. The weighting factor is the quotient obtained by dividing every State’s cost of delivering educational services by the lowest State’s cost; except that, for every State whose cost is below the national average, the national average will be used as that State’s cost. (This method is the current distribution formula).

(2) Option “B”: The weighting factor for this option is the quotient obtained by dividing every State’s cost of delivering educational services by the lowest State’s cost; except that, in considering a State’s cost of delivering educational services, no State will be considered at a level less than 80 percent and more than 120 percent of the national average.

(3) Option “C”: Each eligible student will receive 25 percent of their State’s or the national average per-pupil cost, whichever is greater.

(4) Option “D”: Every eligible student will receive the same amount.

(5) Option “E”: Seventy-five percent (75 percent) of the appropriated funds will be distributed equally, with each eligible student receiving a per capita share. Twenty-five percent (25 percent) of the appropriated funds will be distributed in accordance with Option “A”.

(6) Option “F”: Seventy-five percent (75 percent) of the appropriated funds will be distributed equally, with each eligible student receiving a per capita share. Twenty-five percent (25 percent) of the appropriated funds will be distributed in accordance with Option “B” above.

Tribes may recommend and comment on their own proposed formula as well.

The Department of Interior has determined that this document is not a major Federal action within the scope of the National Environmental Policy Act of 1969, 42 U.S.C. 4321 et seq.

The primary authors of this document are Bill Riefenbary, Task Force Member, Bureau of Indian Affairs, Western Washington Agency, telephone number (FTS) 8-392-9320, Commercial (206) 258-2651 and Steering Committee Members Maxine Edmo, Bureau of Indian Affairs, Fort Hall, Idaho, telephone number (208) 237-0450, and Benny Atencio, Santo Domingo Pueblo, Santo Domingo Pueblo, New Mexico, telephone number (505) 465-2240.

It is proposed to amend Part 273, § 273.31, Subchapter Y of Chapter 1 of Title 25 of the Code of Federal Regulations to read as follows:

§ 273.31 Distribution formula.

(a) Reserved for formula.

(b) The Commissioner may make ex-
ceptions to the provisions of Para-
graph (a) of this section based upon

the special cultural, linguistic, social or educational needs of the communi-
ties involved.


FORREST J. GERARD, 
Assistant Secretary, 
Indian Affairs.

[FR Doc. 79-7673 Filed 3-8-79; 8:45 am]
Each speaker will be limited to 10 minutes for an oral presentation exclusive of the time consumed by questions from the panel for the Government and answers to these questions. Because of controlled access restrictions, attendees cannot be admitted beyond the lobby of the Internal Revenue Building until 9:30 a.m.

An agenda showing the scheduling of the speakers will be made after outlines are received from the speakers. Copies of the agenda will be available free of charge at the hearing.

This document does not meet the criteria for significant regulations set forth in paragraph 8 of the Treasury Directive appearing in the Federal Register for Wednesday, November 8, 1978.

By direction of the Commissioner of Internal Revenue:

**DEPARTMENT OF THE TREASURY**

Internal Revenue Service

[26 CFR Part 56]

**[LR-2-77]**

**EFFECTIVE DATES OF GENERATION-SKIPPING TRANSFER TAX**

Public Hearing on Proposed Regulations

AGENCY: Internal Revenue Service, Treasury.

ACTION: Public hearing on proposed regulations.

SUMMARY: This document provides notice of a public hearing on proposed regulations relating to the application of the effective dates provisions of a new tax on generation-skipping transfers which was added by the Tax Reform Act of 1976.

DATES: The public hearing will be held on April 10, 1979, beginning at 10:00 a.m. Outlines of oral comments must be delivered or mailed by March 27, 1979.

ADDRESS: The public hearing will be held in the IRS Auditorium, Seventh Floor, 7400 Corridor, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, D.C. The outlines should be submitted to the Commissioner of Internal Revenue, Attn: CC:LR:T (LM-2-771, Washington, D.C. 20224).

FOR FURTHER INFORMATION CONTACT:


**SUPPLEMENTARY INFORMATION:**

The subject of the public hearing is proposed regulations under section 2601 of the Internal Revenue Code of 1954. The proposed regulations appeared in the Federal Register for Friday, December 22, 1978, at page 59849 (FR 59849).

The rules of § 601.601(a)(X) of the "Statement of Procedural Rules" (26 CFR Part 601) shall apply with respect to the public hearing. Persons who have submitted written comments within the time prescribed in the notice of proposed rulemaking and also desire to present oral comments at the hearing on the proposed regulations should submit an outline of the comments to be presented at the hearing and the time they wish to devote to each subject by March 27, 1979.

Each speaker will be limited to 10 minutes for an oral presentation exclusive of time consumed by questions from the panel for the Government and answers to these questions. Because of controlled access restrictions, attendees cannot be admitted beyond the lobby of the Internal Revenue Building until 9:30 a.m.

An agenda showing the scheduling of the speakers will be made after outlines are received from the speakers. Copies of the agenda will be available free of charge at the hearing.

This document does not meet the criteria for significant regulations set forth in paragraph 8 of the Treasury Directive appearing in the Federal Register for Wednesday, November 8, 1978.

By direction of the Commissioner of Internal Revenue:

**PROPOSED RULES**

**David E. Dickinson,**

Assistant Director, Legislation and Regulations Division.

(PR Doc. 79-1139 Filed 3-8-79; 8:45 a.m.)

**[6560-01-M]**

**ENVIRONMENTAL PROTECTION AGENCY**

[40 CFR Part 56]

**FRL 1018-5**

**REGIONAL CONSISTENCY**

AGENCY: Environmental Protection Agency.

ACTION: Proposed rulemaking.

SUMMARY: This notice proposes regulations to provide for consistent implementation of the Clean Air Act by the various EPA Regional Offices. EPA is required to promulgate regulations for this purpose under Section 301(a)(2) of the Clean Air Act. The intended effect of this action is to provide a system for assuring fair and consistent application of rules, regulations, and policy throughout the country by assuring that the actions of each of the individual EPA Regional Offices are consistent with one another and national policy.

DATES: Comments must be received on or before May 8, 1979.

EPA will hold a public hearing on this proposal in about a month and a half in Washington, D.C. EPA will publish notice of that hearing shortly in the Federal Register.

ADDRESSES: Persons may submit written comments on this proposal to: Mr. Darryl D. Tyler, Chief, Standards Implementation Branch (MD-15), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, N.C. 27711. EPA will consider all comments received on or before May 8, 1979. All comments will be placed in the public docket upon receipt, and will be available for inspection during normal business hours at: EPA's Control Docket Section, Room 935B, Watertown Mall, 401 M Street SW, Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT:

Mr. Joseph Sableski, Chief, Plans Guidelines Section, Control Programs Development Division (MD-15), U.S. Environmental Protection Agency, Research Triangle Park, N.C. 27711 (919-541-5457).

**SUPPLEMENTARY INFORMATION:**

**AVAILABILITY OF RELATED INFORMATION**

Docket No. OAQPS 79-11 containing all supporting information used by EPA in developing the proposed standards, is available for public inspection and copying between 8 a.m. and 4 p.m., Monday through Friday, at EPA's Central Docket Section. The docket contains an organized and complete file of all the information submitted to or otherwise considered by EPA in the development of this proposed rulemaking. The docketing system is intended to allow members of the public and industries involved to readily identify and locate documents so that they can intelligently and effectively participate in the rulemaking process. Along with the statement of basis and purpose of the promulgated rule and EPA responses to significant comments, the contents of the docket will serve as the record in case if judicial review (Section 301(d)(A)).

**BACKGROUND**

Under Section 301(a)(2) of the Clean Air Act, enacted on August 7, 1977, EPA is required to promulgate regulations concerning consistency among EPA Regional Offices and States in implementing and enforcing the Act. Section 301(a)(2) reads as follows:

(2) Not later than one year after the date of enactment of this paragraph, the Administrator shall promulgate regulations establishing general applicable procedures and policies for regional offices and employees (including the Regional Administrator) to follow in carrying out a delegation under paragraph (1), if any. Such regulations shall be designed—

(A) to assure fairness and uniformity in the criteria, procedures, and policies, applied by the various regions in implementing and enforcing the Act;

(B) to assure at least an adequate quality audit of each State's performance and adherence to the requirements of this Act in implementing and enforcing the Act, particularly in the review of new sources and in enforcement of the Act; and

(C) to provide a mechanism for identifying and standardizing inconsistent
or varying criteria, procedures, and policies being employed by such officers and employees in implementing and enforcing the Act.

On February 6, 1978, EPA published an advanced notice of proposed rulemaking (ANPRM) to initiate regulated activities under this provision of the Act. EPA solicited written comments and invited all interested persons to participate in public workshops that were held to discuss the development of the regulation. EPA held workshops in Denver, Colo., on February 17, 1978; in Atlanta, Ga., on March 17, 1978; in Dallas, Tex., on April 13 and 14, 1978; and in Boston, Mass., on May 18 and 19, 1978. The workshops were well attended by representatives from industry, State and local governments, and public interest groups. The regulation proposed below was developed largely from the suggestions developed at these public workshops.

**Description of Proposal**

The regulation proposed below would appear as a new Part 56 of Title 40, Chapter I, Subchapter C, which concerns air programs. The regulation's main features are as follows:

1. A provision requiring EPA to include rules, regulations, and program directives in the Federal Register. This provision would apply to rules, regulations, and program directives that EPA issued after August 6, 1977.

2. A provision requiring the Regional Offices to follow these mechanisms.

3. A provision requiring the Regional Offices to obtain Headquarters concurrence on significant interpretations of the Act or rules, regulations, or program directives.

4. Revised procedures for timely and more comprehensive distribution of policy and guidance.

5. Provisions for annual audits of the performance of EPA Regional Offices and State and local agencies in implementing and enforcing the Act.

Regarding the first two features, the regulation proposed below defines a mechanism as "an administrative procedure, guideline, manual, or written statement." A mechanism would be included and explained in the preamble to a regulation or in the body of a guideline or program directive.

EPA's regulations for prevention of significant deterioration, which EPA published in the Federal Register on June 19, 1978 (43 FR 26338), provide an example of a mechanism for assuring consistency of application. The regulation requires major stationary sources to apply best available control technology (BACT) as a condition for receiving a permit to construct. The determination of what constitutes BACT, however, will be made on a case-by-case basis by the reviewing authority, taking into account several factors, including cost, energy consumption, and technical feasibility. One mechanism for assuring regional consistency in applying the provisions to the PSD regulations is the establishment of an Advisory Committee on Stationary Point Source Emission Standards (LAER) and EPA Regional Offices in making determinations of BACT. For instance, EPA will develop a guidance document to assist reviewing authorities in implementing the BACT requirement.

In addition, EPA will establish a national clearinghouse for distributing BACT determinations. The clearinghouse will advise reviewing authorities of each other's determinations and thereby promote a consistent basis of experience.

Similarly, EPA expects to establish a clearinghouse for determinations of what constitutes "lowest achievable emission rates" (LAER). The requirements under Part D of Title I of the Clean Air Act that apply to nonattainment area major stationary sources to apply LAER would be made on a case-by-case basis.

For written program directives issued by EPA Headquarters, a mechanism for assuring Regional Office consistency in following the program directive would be generally a statement in the directive that adherence to the directive would be a condition for receiving a permit to construct.

For written program directives issued by Regional Offices, a mechanism for assuring Regional Office consistency in following the program directive would be generally a statement in the directive that adherence to the directive would be a condition for receiving a permit to construct.

Similarly, EPA expects to establish a clearinghouse for determinations of what constitutes "lowest achievable emission rates" (LAER). The requirements under Part D of Title I of the Clean Air Act that apply to nonattainment area major stationary sources to apply LAER would be made on a case-by-case basis.

For written program directives issued by EPA Headquarters, a mechanism for assuring Regional Office consistency in following the program directive would be generally a statement in the directive that adherence to the directive would be a condition for receiving a permit to construct.

For written program directives issued by Regional Offices, a mechanism for assuring Regional Office consistency in following the program directive would be generally a statement in the directive that adherence to the directive would be a condition for receiving a permit to construct.

**Issues Raised During Development of Proposal**

A number of issues were raised by persons who attended the four public workshops and who sent written comments on the concepts outlined in the advanced notice of proposed rulemaking. The following summarizes the major issues raised and discusses the manner in which EPA has addressed them in this proposed regulation.

1. Issue: EPA's organization at both Regional and Headquarters levels splits responsibility for various parts of the air program and other programs among several offices, making communication, information dissemination, and oversight activity more difficult.

Response: The Agency has established a task force to review both Regional and Headquarters organization and feels this approach is more appropriate than attempting to address this issue in the regulation. The proposed regulation, however, does provide a means for improved communication and coordination within the existing organizational structure and the technique would be applicable to any alternative organization that might eventually be adopted.

2. Issue: Several participants expressed concern about the general level of knowledge, training, and resources in Federal, State, and local air pollution control programs and pointed out a number of cases when inadequate staff led to inconsistent decision making.

Response: EPA recognizes its responsibility to provide adequate funds for air pollution control efforts and training of air pollution control staff. The proposed regulation requires responsible Headquarters officials to carry out a guidance program at the initiation of any new major program under the Clean Air Act. Also, the regulation provides for distribution of a monthly compilation of interpretations of policy made by Regional Offices with Headquarters concurrence. This monthly compilation will keep each of the Regions abreast of the most recent national policy and regional applications.

3. Issue: Many participants commented that persons who are not EPA employees be made an integral part of policy development, Regional Office and State audits, and advisory committees.

Response: EPA feels that its existing public participation process provides an adequate opportunity for involvement in policy and regulatory development.

EPA is not proposing to include persons who are not EPA employees on the audit teams that would be established by this regulation because it feels that the legislation places this responsibility upon the Agency. The regulation does provide opportunity for public knowledge of the audit process and results. First, the regulation requires publication and opportunity for public comment on the criteria to be used in audits. Second, this regulation would require the audit results to be available to the public, and that public notice be given of such availability.

4. Issue: A number of workshop participants urged that this regulation specifically address areas where flexibility should be provided and suggested that this regulation include criteria by which such flexibility be provided. Conversely, other participants recommended that the regulations substantially reduce the number of activities...
where individual Regional Office discretion is allowed.

Response: EPA interprets § 301(a)(2) of the Act as a mandate to assure greater consistency among the Regional Offices in implementing the Act, certainly not as a license to institutionalize the kind of inconsistencies that prompted Congress to enact this provision. Furthermore, the Act does not specifically refer to criteria for providing flexibility. The regulations proposed below incorporate features that EPA believes will ensure consistency in implementation of the Act.

5. Issue: There were a number of comments that EPA should consider allowing flexibility in its actions to provide consideration of economic factors.

Response: EPA feels its authority to consider economics is clearly addressed in the Clean Air Act as amended. EPA, in setting source performance standards under Section 111 of the Act and in providing guidance for implementing a plan for designated pollutants and facilities under Section 111, the Act also considers cost in reviewing determinations of best and reasonably available control technologies. Furthermore, EPA considers the economic impact of State implementation plans that must promulgate. EPA may not consider economics, however, in establishing national ambient air quality standards under Section 109 of the Act.

6. Issue: There was much discussion as to the direction this regulation should take, i.e., whether to specifically address identified programmatic areas of concern or to establish a process within which EPA would address consistency.

Response: EPA feels that changing information and technology would make any effort to write one all-encompassing regulation too unwieldy. The proposed regulation would establish a process whereby program officials would identify the need for consistency and measures to assure consistency.

7. Issue: Several individuals gave examples of non-uniformity that results from overlapping jurisdictional boundaries. A single air quality control region may have different control requirements imposed by two adjacent local governments, States, or EPA Regional Offices.

Response: The proposed regulation would require the audits of Regional Offices and State agencies to address the consistency of air pollution control regulation between adjacent States or local and regional governmental jurisdictions. It should be noted that the Clean Air Act provides States with the authority to develop their own control strategies to attain and maintain standards. Section 126 of the Act, as amended, provides a mechanism for resolving conflicts concerning interstate pollution.

8. Issue: A number of individuals asked that the regulations provide an opportunity for a review of certain Regional Office decisions that appear inconsistent and suggested establishment of an appeals board that includes persons who are not EPA employees to accomplish this purpose.

Response: EPA feels that establishment of an appeals board would create another level of bureaucracy and would be less efficient than the proposed scheme in minimizing inconsistencies among the Regional Offices.

9. Issue: Several persons suggested that EPA expand its public participation efforts to include policy making as well as the formal regulatory development process.

Response: EPA is currently reviewing its total public participation program.

10. Issue: Many commenters indicated serious concern over the lack of timely dissemination of Agency policy and precedent-establishing decisions.

Response: The proposed regulation addresses this problem by providing for the publication of a compilation of air program policy and guidance directive, an index to the compilation, a monthly summary of interpretations and determinations, availability of videotapes of EPA policy seminars, and EPA workshops on new regulations and policies.

11. Issue: Several attendees indicated that a basic reason for inconsistencies was that the Act allowed States to establish standards more stringent than the national ambient air quality standards.

Response: Though this may be a potential problem, the Act does allow this State discretion, and this non-uniformity is a conscious decision on the part of the State and is therefore not a problem created by inadequate program implementation.

12. Issue: A number of participants commented on the need for a requirement for consistency in the data bases used in determining the applicability of various air programs.

Response: Through its activities over the past several years, EPA's Standing Air Monitoring Group (SAMWG) has addressed many issues concerning air quality data. In 1977, SAMWG published recommendations for improving the quality of the data and avoiding duplication of effort. EPA has proposed regulations that incorporate those recommendations (43 FR 34892, published August 7, 1978). Since these regulations will apply nationally, they will provide for further consistency in the air quality data bases used in implementing the Clean Air Act.

13. Issue: The public advantage of the opportunity afforded by the public workshops to provide a number of specific examples of the lack of consistency in individual air programs, such as approval and revision of SIPs, monitoring, and discrepancies between air program and enforcement requirements.

Response: The regulations proposed below require each air program component to identify within one year after promulgation which program elements that have been issued since August 6, 1971, already have adequate mechanisms for consistency and which do not. For those that do not, the regulations would require establishment of mechanisms within 18 months after promulgation. Any new rule, regulation, or program directive would have to contain a section specifically dealing with consistency of application. Furthermore, public comment on consistency mechanisms would be solicited for each regulation and certain program directives.

14. Issue: Several participants commented on the fact that the Act allows the States to select the mix of control strategies in the SIP and that this may result in inconsistent control requirements.

Response: Though nonuniformity can result within the framework of the Act, regulations generally apply throughout an AGCR. In addition, States can obtain uniformity, if desired, in their selection of control strategies. This topic is discussed further under Issue 7 above.

15. Issue: A number of questions were raised concerning the scope and criteria to be used in an audit of State performance.

Response: The regulations address the scope of such audits by limiting the areas to be reviewed to certain activities which have the potential for inconsistency. The regulations require the development of audit manuals, which would have to identify the criteria upon which the State agency will be evaluated.

The criteria to be used to assure uniform review of State agency performance is required to be developed by the Agency with six months. EPA will publish notice of availability of the criteria in the Federal Register.

Environmental, Economic, and Energy Impact Assessments

EPA has classified the regulation proposed below as a "significant-routine" action. Therefore, EPA has prepared no environmental, economic, or energy impact assessments. The regulations should result in more consistent application throughout the country of air pollution control require-
§ 56.1 Definitions.

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

“Act” means the Clean Air Act as amended (42 USC 7401 et seq.).

“Administrator,” “Deputy Administrator,” “Assistant Administrator,” “Deputy Assistant Administrator,” “Regional Administrator,” “Regional Office,” “Headquarters,” “Staff Office,” and “Regional Office” are described in Part 1 of this Title.

“Mechanism” means an administrative procedure, guideline, manual, or written statement.

“Program directive” means any written statement by the Administrator, the Deputy Administrator, an Assistant Administrator, a Deputy Assistant Administrator or a Staff Office Director that is intended to guide or direct Regional Offices in the implementation of provisions of the Act; the term does not include an interpretation or clarification of existing rules, regulations, or other program directives.

“Responsible official” means the EPA Administrator or any EPA employee who is directly accountable to the Administrator for carrying out a power or duty delegated under Section 301(a)(1) of the Act, or is accountable in accordance with EPA’s formal organization for a particular program or function as described in Part 1 of this Title.

§ 56.2 Scope.

This part covers actions taken by—

(a) Employees in EPA Regional Offices, including Regional Administrators, in carrying out powers and duties delegated by the Administrator under Section 301(a)(1) of the Act.

(b) EPA employees in Headquarters to the extent that they are responsible for developing the procedures to be employed or policies to be followed by Regional Offices in implementing and enforcing the Act.

§ 56.3 Policy.

It is EPA's policy to—

(a) Assure fair and uniform application by all Regional Offices of the criteria, procedures, and policies employed in implementing and enforcing the Act;

(b) Provide a mechanism for identifying and correcting inconsistencies by standardizing criteria, procedures, and policies being employed by Regional Office employees in implementing and enforcing the Act; and

(c) Insure an adequate quality audit for each State's performance in implementing and enforcing the Act.

§ 56.4 Mechanisms for fairness and uniformity—Responsibilities of Headquarters employees.

(a)(1) The Administrator shall include with any rule or regulation that implements the requirement of the Act, a mechanism to assure that the rule or regulation is implemented and enforced fairly and consistently by the Regional Offices.

(2) The EPA responsible official in Headquarters shall include with any program directive that implements the requirements of the Act a mechanism to assure that the program directive is implemented and enforced fairly and consistently by the Regional Offices.

(b)(1) The following rules, regulations, and program directives must include at the time of proposal or first public appearance in draft form a proposed mechanism to assure fair and consistent application by all Regional Offices:

(i) Those rulemakings required by the Administrative Procedure Act to be published in proposed form before final promulgation.

(ii) Those that, in conformity with EPA practice appear first in draft form before final adoption by EPA.

(2) The appropriate responsible official shall solicit public comment concerning the mechanism proposed and consider any comments before issuance of the final rule, regulation, or program directive.

(c)(1) Within one year after promulgation of this part, each EPA Headquarters office with air pollution control responsibility shall review and evaluate all significant currently applicable rules, regulations, and program directives (including guidelines) issued after August 6, 1977, under the Act for the purpose of determining if appropriate mechanisms exist for assuring fairness and consistency in application among the Regional Offices. The Administrator will publish notice in the Federal Register of the availability of the evaluations.

(2)(i) Within 18 months after promulgation of this part, each EPA Headquarters office that identified rules, regulations, or program directives that do not have mechanisms for insuring fairness and consistency in application among the Regional Offices shall, where appropriate, develop mechanisms.

(ii) In the case of rules and regulations, the mechanisms must be proposed in the Federal Register within 18 months after promulgation of this part. The mechanism must then be promulgated after adequate public comment and internal review.

(iii) In the case of program directives, the mechanisms must be available for public information within 18 months after promulgation of this part and included in the comprehen-
sive air programs policy and guideline system required under § 56.6(a)(1).
(d) This section applies only where the EPA responsible official in Head¬
quarters deems reasonable and appropriate the inclusion of the mecha¬
nisms under this section with the rule, regulation, or program directive. The determination that a mechanism is un¬
necessary shall be explained in writing by the appropriate responsible official in Headquarters and must accompany the relevant rule, regulation, or pro¬
gram directive when it is issued or published.

§ 56.5 Mechanisms for fairness and uniformity—Responsibilities of Regional Office employees.
(a) Each responsible official in a Re¬
gional Office, including the Regional Administrator, shall assure that ac¬
tions taken under the Act are carried out fairly and in a manner that is con¬
sistent with the activities of other Re¬
gional Offices and shall—
(1) Comply with the mechanisms de¬
developed under § 56.4 of this part, and
(2) Implement recommendations made by the Regional Office Audit Committee under § 56.7 of this part.
(b) A responsible official in a Re¬
gional Office shall seek and obtain written concurrence of the appropri¬
ate EPA Headquarters program office on any interpretation of the Act, or rule, regulation, or program directive when such interpretation may result in inconsistent application among the Regional Offices of the Act or rule, regulation, or program directive.

§ 56.6 Dissemination of policy and guid¬
ance.
(a) The Assistant Administrator for Air, Noise, and Radiation shall estab¬
lish as expeditiously as practicable but no later than one year after promulga¬
tion of this part the programs listed in this section for the dissemination of policy and guidance. He or she shall distribute material developed under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(i) A comprehensive air programs policy and guideline system containing the following:
(A) A compilation of all relevant EPA program directives and guidance, except for rules and regulations, con¬
cerning the requirements under the Act.
(B) A procedure whereby each Head¬
quarters office with air pollution con¬
trol responsibility will enter new and revised guidance into the compilation.
(C) A topical index of all material in the compilation and procedures for continually updating the index. The index is to serve as a manual for find¬
ing all current air program policy and guidance.
(iv) An annotated bibliography of all the material in the compilation and procedures for continually updating the bibliography.
(v) A monthly summary of interpre¬
tations of the Act, rules, regulations, or program directives made under § 56.5(b) of this part.
(b) The Assistant Administrator for Air, Noise, and Radiation shall seek and obtain written concurrence of the responsible Headquarters program office on any interpretation of the Act, or rule, regulation, or program directive when it is issued or published.

§ 56.7 Regional Office audits.
(a) (1) Within three months after promulgation of this part, the Admin¬
istrator shall form a Regional Office Audit Committee comprising repre¬
sentatives of EPA Headquarters offices, including staff offices, and se¬
lected Regional Office personnel with air pollution control responsibilities. The Assistant Administrator for Air, Noise, and Radiation or his or her des¬
ignee shall chair the Committee.
(2) The Administrator shall annually review the control systems of the Region¬
al Office Audit Committee and make any changes that he or she deems ap¬
propriate.
(b) The Administrator shall consult with Headquarters Offices with air pollution control responsibilities, together with Regional Office personnel with air pollution control responsibilities, concerning the development of criteria for use in auditing Regional Office programs for performance in implementing and enforcing the Clean Air Act. The criteria shall provide for consultation with affected State and local agencies in the development of the criteria.

§ 56.8 State and local agency performance audits.
(a) (1) Within one year after promulga¬
tion of this part, the Administrator shall develop criteria for use in auditing Regional Office programs for performance in implementing and enforcing the Clean Air Act. The criteria shall provide for consultation with affected State and local agencies in the development of the criteria.

§ 56.9 Regional Office Audit Committee.
(a) (1) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(b) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(c) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(d) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.

§ 56.10 Regional Office Audit Committee.
(a) (1) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(b) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(c) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(d) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.

§ 56.11 Regional Office Audit Committee.
(a) (1) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(b) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(c) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(d) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.

§ 56.12 Regional Office Audit Committee.
(a) (1) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(b) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(c) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(d) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.

§ 56.13 Regional Office Audit Committee.
(a) (1) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(b) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(c) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(d) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.

§ 56.14 Regional Office Audit Committee.
(a) (1) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(b) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(c) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(d) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.

§ 56.15 Regional Office Audit Committee.
(a) (1) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(b) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(c) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(d) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.

§ 56.16 Regional Office Audit Committee.
(a) (1) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(b) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(c) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(d) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.

§ 56.17 Regional Office Audit Committee.
(a) (1) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(b) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(c) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(d) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.

§ 56.18 Regional Office Audit Committee.
(a) (1) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(b) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(c) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(d) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.

§ 56.19 Regional Office Audit Committee.
(a) (1) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(b) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(c) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(d) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.

§ 56.20 Regional Office Audit Committee.
(a) (1) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(b) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(c) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
(d) The Regional Office Audit Committee shall provide for the inclusion of the mechanisms under this section with the rule, regulation, or program directive, concerning the requirements under the Act.
ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Commissioner of Education proposes regulations governing grants under the Environmental Education Act of 1978. Grants assist educational projects that improve public understanding of environmental issues as they relate to the quality of life.

The proposed regulations incorporate an amendment to the previous authority governing the program. This amendment permits multi-year funding of projects. The proposed regulations also simplify the current regulations.

DATES: Comments on these proposed regulations must be received on or before April 23, 1979. Written comments are preferred.

ADDRESSES: Comments should be addressed to Ms. Sylvia Wright, Program Officer, Office of Environmental Education, Room 205F, 400 Maryland Avenue, SW., Washington, D.C. 20020.

FOR FURTHER INFORMATION CONTACT: Ms. Sylvia Wright, (202) 245-9231.

SUPPLEMENTARY INFORMATION: The Environmental Education Program provides grants to public and private nonprofit organizations, agencies, and institutions. These grants support developmental, demonstration, and mini-grant projects that improve education about environmental issues and alternative resolutions of those issues.

The Environmental Education Act (Pub. L. 91-516, as amended by Pub. L. 93-278) has been reauthorized by the Education Amendments of 1978, Pub. L. 95-561, Section 301, with only technical amendments. This reauthorization places the Environmental Education Act in Part II of Title III of the Elementary and Secondary Education Act. As a consequence, it is now one of a number of programs grouped under Title III—"Special Projects." All of these programs are being placed together in the Code of Federal Regulations. Accordingly, the Environmental Education Regulations become Part 161h of Title 45 of the Code of Federal Regulations. Because of the inclusion of the Environmental Education Act in Title III of the Elementary and Secondary Education Act: (1) Local educational agencies must afford the public an opportunity to comment on the subject matter of their applications; and (2) local educational agencies and State educational agencies must meet the requirements of Title III of the Elementary and Secondary Education Act for involvement of private schools. The proposed regulations simplify existing regulations. They create a new rule for the award of multi-year grants. Under the multi-year grant provision, projects may be funded on a non-competitive basis after the first year. These grants may support comprehensive projects that have the potential for achieving national demonstration status.

National public and private educational organizations and other interested groups that attended a public meeting held by the Bureau of Elementary and Secondary Education on September 14, 1978 were informed that new regulations for the Environmental Education Program would be developed. Since there were only technical amendments involved, no issues had been identified and no comments have been received.

Since 1973 each Office of Education grant program has been governed by two sets of regulations: the specific program regulations and the OE General Provisions Regulations in 45 CFR Parts 100 through 106d.

As a part of Operation Common Sense, the Department is developing a revision of the OE General Provisions Regulations that will update and clarify administrative and fiscal requirements and will consolidate or eliminate overlapping, duplicative, or inconsistent program regulations. These new consolidated regulations will apply to programs in the entire Education Division and will cover a number of subjects not covered in the General Provisions Regulations.

The new regulations will adopt HEW's general grant regulations (45 CFR Part 74) by reference, rather than repeating them verbatim as is currently done in the General Provisions Regulations.

By eliminating duplicative program regulations, EDGAR is expected to achieve substantial contribution to the further simplification of Education Division Regulations. EDGAR will provide consolidated regulations on:

(1) How to apply for a grant;
(2) How the Education Division makes grants;
(3) Conditions that a grantee must meet;
(4) The administrative responsibilities of a grantee; and
(5) The compliance procedures of the Education Division.

However, since EDGAR has not yet been published, no cross-references to EDGAR are included in this document. Some matters that may eventually be included in EDGAR are published in this document either in the text or as an appendix. When EDGAR is issued as final regulations, any overlapping provisions will be removed from these regulations.
§ 161h.1 What is the Environmental Education Program?

The Environmental Education Program assists educational projects that improve public understanding of environmental issues as they relate to the quality of life. Under this program, the Commissioner may award direct grants to public or nonprofit private institutions, agencies, or organizations for developmental, demonstration or mini-grant projects.

(20 U.S.C. 3011-3018)

§ 161h.2 [Reserved]

§ 161h.3 What are the definitions that apply specifically to this program?

(a) As used in these regulations—

"Act" means the Environmental Education Act of 1978;

"Consortium" means a group consisting of representatives of various areas of expertise in environmental education, such as State and regional planning, economics, social policy, environmental protection, public interest, business, higher education, secondary education, and community education;

"Environmental area of study" means the study of the relation of various aspects of the natural and man-made environment to the total human environment. These aspects include the relation of energy, population, resource allocation and depletion, conservation, transportation, technology, economic impact, and urban and rural planning to the total human environment. The term also encompasses specific environmental issues.

"Resources" means materials, personnel, methods, or information;

"Target group" means the group to benefit from or to participate in, a project.

(b) The term "environmental education" is defined in the Act.

(20 U.S.C. 3011-3018)

§ 161h.4 Who is eligible to receive grants?

(a) The following are eligible to receive grants:

(1) Public and private institutions of higher education and other nonprofit private organizations. Each of these applicants shall have been in existence for one year or more.

(2) State educational agencies, local educational agencies, and other public agencies and organizations.

(b) State educational agencies and local educational agencies must meet the requirements for the involvement of private schools in Sec. 302(b), Title III, Elementary and Secondary Education Act of 1965.

(20 U.S.C. 3013(b)(1) and 3018)

§ 161h.10 What are the purposes of the projects?

In order to be considered for a grant, an applicant shall propose a project that—

(a) Includes the study of the policy, social, cultural, and economic aspects of the environmental area of study or issues to be addressed; and

(b) Provides an objective and balanced treatment of different views on environmental issues and resolutions of those issues.

(20 U.S.C. 3011)

§ 161h.11 What categories of projects are supported?

Basic categories. Funds may be awarded for three types of projects:

(a) Comprehensive multi-year projects.

(b) General projects.

(c) Mini-grant projects.

(20 U.S.C. 3013, 3016)

§ 161h.12 What is a comprehensive multi-year project?

(a) A comprehensive multi-year project is a developmental or a demonstration project that involves a number of activities in environmental education and has more than one target group.

(b) A comprehensive multi-year project is intended to demonstrate effective methods for—

(1) Improving, over the long term, individual and institutional capabilities in environmental education;

(2) Adapting new knowledge about the environment as it becomes available;

(3) Identifying and using, in an appropriate and effective way, a broad range of local and regional resources;
§ 161h.13 What is a general project?
(a) A general project is a developmental project that focuses on a single activity in environmental education.
(b) A general project is intended to result in a new or refined resource for the project's target group.
(c) A general project requires no more than 12 months to achieve its objectives.
(20 U.S.C. 3013)

§ 161h.14 What is a mini-grant project?
(a) A mini-grant project is one or more community workshops, seminars, symposiums, or conferences on a community or local environmental problem.
(b) A mini-grant project is intended to assist adults—including members of community organizations other than the grantee organization—in understanding—
(1) The causes and effects of an environmental problem;
(2) Local policies, practices, and issues associated with the problem; and
(3) The options for resolving the problem.
(c) In addition to the primary activity, a mini-grant project may include a variety of preparatory and follow-up activities as needed to assure the project's success.
(d) A mini-grant project usually requires fewer than 12 months to achieve its objectives.
(20 U.S.C. 3013)

§ 161h.15 Will priorities for funding be established?
(a) The Commissioner may establish priorities among projects to be funded in any given year. The Commissioner announces these priorities in the Federal Register.
(b) In addition—
(1) In awarding grants for comprehensive multi-year projects, the Commissioner gives priority to consortia of eligible applicants; and
(2) In awarding grants for mini-grant projects, the Commissioner gives priority to nonprofit citizens' groups and volunteer organizations.
(20 U.S.C. 3013, 3016)

Subpart C—How Does One Apply for a Grant?
§ 161h.20 [Reserved]
§ 161h.21 To whom must an applicant submit its application for comment?
Before submitting an application to the Commissioner, a local educational agency shall submit a copy of its application to its State educational agency for review and comment.
(20 U.S.C. 3014(b))

Subpart D—How is a Grant Made?
§ 161h.30 What selection criteria does the Commissioner use?
(a) The Commissioner evaluates an application on the basis of the selection criteria in this section and in the Appendix to this part.
(b) The selection criteria in the Appendix constitute 70 possible points. The maximum possible point score for each criterion indicates the relative importance assigned to that criterion by the Commissioner, as follows:
(1) The extent to which the proposed project—
(i) Organizes into a meaningful relation to one another the policy, social, economic, cultural, technological, biophysical, and human health aspects of the environmental area of study of issues(s) to be addressed; (25 points)
(ii) Reflects current knowledge of the environmental area of study or issue(s) to be addressed; (10 points)
(iii) Communicates the knowledge in a manner that is appropriate to the project's objective(s) and target group(s); (10 points)
(2) The extent to which the project will enhance the ability of its target group(s) to participate in environmental decision-making by improving the ability of the group(s) to—
(i) Contribute to the identification of environmental issues and alternative resolutions of those issues;
(ii) Assess short- and long-term risks, benefits, costs, and acceptability of alternative resolutions; and
(iii) understand the need for practicable resolutions embodying differing points of view. (15 points)
(3) The extent to which the project demonstrates—under one of the following categories—potential for improving the quality of environmental education:
(i) If the proposed project is a comprehensive multi-year project, the extent to which it has the potential for being a national demonstration project or
(ii) If the proposed project is a general project, the extent to which its results can be adapted for environmental education in other areas of the country; or
(iii) If the proposed project is a mini-grant project, the extent to which it is likely to improve the ability of its target group(s) to understand local environmental issues in a broader context. (10 points)
(20 U.S.C. 3013, 2016)

Subpart E—What Conditions Must a Grantee Meet?
§ 161h.40 Must a grantee help defray part of its project's cost?
(a) If the project is a national-level curriculum development, evaluation, dissemination, or demonstration project, the grant may cover 100 percent of the cost.
(b) If the project is a mini-grant project, the grant may cover 100 percent of the cost up to $10,000.
(c) For other types of projects, grants may not exceed 80 percent of the approved project cost for the first year. In the second and third years, grants may not exceed an amount equal to 60 percent and 40 percent, respectively, of the approved first-year project cost.
(20 U.S.C. 3014(a))

§ 161h.41 Are there restrictions on the type of costs a grant may support?
(a) Funds may not be used for construction, repair, remodeling, or alteration of facilities or sites. (b) Funds may not be used for subgrants.
(20 U.S.C. 3013, 3016)

§ 161h.42 What other restrictions apply to the use of grants?
Grants may be used to supplement or increase funds made available by the applicant for the project. Grants may not be used to supplant these funds.
(20 U.S.C. 3014(a)(4))

APPENDIX TO PART 161h

SELECTION CRITERION—PLAN OF OPERATION
(a) The Commissioner reviews each application for information that shows the quality of the plan of operation for the project.
(b) The Commissioner looks for information that shows—
(1) High quality in the design of the project;
(2) An effective plan of management that insures proper and efficient administration of the project;
(3) A clear description of how the objectives of the project relate to the purpose of the program; and
(4) Achieving significant interaction between formal education and community education; and
(5) Facilitating local or regional adoption of the project's activities and the continuation of these activities after the project period ends.

(c) A comprehensive multi-year project requires more than 12 months to achieve its objectives and may be supported for up to three years. Grants may be provided for an initial 12-month budget period and for 12-month continuation budget periods. The budget periods for these projects must be clearly related to the time necessary for each stage of the project, e.g., planning, design, implementation, demonstration, and local adoption.
(20 U.S.C. 3013)

(a) In awarding grants for comprehensive multi-year projects, the Commissioner gives priority to consortia of eligible applicants; and
(b) In awarding grants for mini-grant projects, the Commissioner gives priority to nonprofit citizens' groups and volunteer organizations.
PROPOSED RULES

1. The facilities that the applicant plans to use are adequate; and
2. The equipment and supplies that the applicant plans to use are adequate. (3 points)

[FR Doc. 79-7157 Filed 3-8-79; 8:45 am]

[6712-01-M]

FEDERAL COMMUNICATIONS COMMISSION

[47 CFR Parts 31, 33, 42 and 43]

[CC Docket No. 78-196]

REVISION OF UNIFORM SYSTEM OF ACCOUNTS AND FINANCIAL REPORTING REQUIREMENTS FOR TELEPHONE COMPANIES

Notice Establishing Service List

AGENCY: Federal Communications Commission.

ACTION: Notice Establishing Service List.

SUMMARY: This Notice establishes a service list to be used in future rounds of comments in the proceeding involving a proposed revision of the Uniform System of Accounts and Financial Reporting Requirements and provides a procedure for other interested persons to be included on the list.

DATES: Non-Applicable.


FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

Released: March 9, 1979.

In the matter of revision of the uniform system of accounts and financial reporting requirements for telephone companies (Parts 31, 33, 42 and 43 of the FCC’s rules, CC Docket No. 78-196, See 43 FR 40886, September 13, 1978.

1. On July 21, 1978, the Commission adopted a notice of proposed rulemaking, FCC 78-453, 43 FR 33560 (1978), in the above captioned proceeding. Initial comments were due January 15, 1979. To date, more than seventy parties have filed comments exceeding a total of 1700 pages. A list of the names and addresses of the commenting parties is appended as Attachment A.

2. To expedite the exchange of comments among the parties in future rounds of comments in this docket, we are establishing this list as the service list for the docket. Parties to this proceeding should serve a copy of all pleadings in this proceeding on those parties listed in Attachment A. At least one copy per party should be served on those firms representing more than one party. Others interested in participating in the proceeding and receiving copies of the comments may be included on the service list by notifying the Commission in writing of their desire to be included on the service list herein. Anyone interested only in receiving copies of Commission actions may do so by contacting the Dockets Branch by telephone at 202-632-7535 or by writing the Dockets Branch at the Federal Communications Commission, Washington, D.C. 20554. All communications must specify the docket number. Copies of all comments filed and Commission actions taken will be available for public inspection in the Commission’s Public Reference Room at 1919 M Street, NW, Washington, D.C.

FEDERAL COMMUNICATIONS COMMISSION,

Chief, Common Carrier Bureau.

ATTACHMENT A

Jon W. Owens, General Manager, Ace Telephone Association, 207 East Cedar Street, House Springs, Missouri 63054.


Richard W. Braun, Donald W. Auten, Arthur Young & Company, 515 Olive Street, St. Louis, Missouri 63101.

Ray J. Smith, Manager, Blackfoot Telephone Cooperative Inc., 1112 North Russell Street, Missoula, Montana 59801.


Duane L. Day, President, Cascade Utilities, P.O. Box 158, Estacada, Oregon 97023.

Eugene H. Imlinger, Vice President and Counsel, Central Telephone & Utilities Corporation, O’Hare Plaza, 3725 East River Road, Chicago, Illinois 60613.

Robert McColl, President, Chillicothe Telephone Company, Chillicothe, Ohio 45601.
PROPOSED RULES

S. S. Carpenter, Personnel Director, Clifton Forge-Waynesboro Telephone Company, Executive Office, P.O. Box 2008, Staunton, Virginia 24401.

Earl P. Phifer, Executive Manager, Coastal Utilities, Inc., P.O. Box 558-100 Ryon Avenue, Hinesville, Georgia 31313.

Gary R. MacCormack, Secretary-Treasurer, Colorado Telephone Association, PO. Box 48, Colorado City, Colorado 81019.

Laurence Singer, Esq., Fager & Singer, Suite 800, 1737 DeSales Street, N.W., Washington, D.C. 20009, Counsel for Consumer Federation of America.

Richard A. Gonnelli, Coopers & Lybrand, 1251 Avenue of the Americas, New York, New York 10020.

Helen E. Foulke, President, Cooperstown Telephone Company, 120 Second Street, Cooperstown, Pennsylvania 16210.


Jack L. Bentley, General Manager, Delta County Telephone Company, 122 Grand Avenue, P.O. Box 730, Paonia, Colorado 81428.

Dean E. Anderson, Manager, Deutel Telephone Cooperative Association, Clear Lake, South Dakota 57226.

W. R. Buchanan, President, Eastern Missouri Telephone Company, 215 West Church, Bowling Green, Missouri 42101.

Edward J. Neckvatal, Jr., General Manager, Farmers Telephone, 129 East Maple Street, Lancaster, Wisconsin 53815.

David L. Smith, Executive Director, Floridais Public Service Commission, Fletcher Building, 101 East Gaines Street, Tallahassee, Florida 32304.

Lawrence C. Ware, General Manager, Garden Valley Telephone Company, Erin, Minnesota 55345.

E. A. Gordon, President, Garrett Telephone Company, Inc., 112 East Keyser Street, Garrett, Indiana 46738.

B. B. Knowles, Director, Utilities Financial Analysis, Georgia Public Service Commission, 244 Washington Street, S.W., Atlanta, Georgia 3034.


Charles H. Lindsey, Executive Vice President, Georgia Telephone Association, 1900 Century Boulevard, Suite S, Atlanta, Georgia 30044.

Howard Ellis, President & Manager, Haviland Telephone Co., Inc., Haviland, Kansas 67549.

Irene M. Baldwin, Vice-President, Home Telephone Company, Inc., Galva, Kansas 67443.

Illinois Telephone Cooperative Association, P.O. Box 299, Louisiville, Illinois 62228.


J. Gordon, Walter, Esq., Donald G. Cherry, Esq., International Business Machines Corporation, 360 Madison Avenue, New York, New York 10016.

James R. Maret, Esq., Iowa State Commerce Commission, 324 Fourtir Street, Des Moines, Iowa 50301.

J. Kent Jerome, Secretary-Treasurer, Iowa Telephone Association, 1601 22nd Street, P.O. Box 3026, Des Moines, Iowa 50302.


Alana S. Johnson, Certified Public Accountant, Box 343, Fergus Falls, Minnesota 56547.

John LaBry, Jr., Accountant, Kaplan Telephone Company, P.O. Box 369, Kaplan, Louisiana 70548.

Leon McDowell, President, Lathrop Telephone Company, Administrative Office, Mendon, Missouri 64660.


F. E. Harrell, Jr., Secretary-Treasurer, Madison Telephone Company, Inc., Madison, Kansas 66860.

Elton M. Snowden, General Manager, McComb Telephone Cooperative, Inc., P.O. Box 359, Colchester, Illinois 61924.

W. S. Howard, President, Millington Telephone Company, Inc., 4880 Navy Road, Millington, Tennessee 38053.

C. J. McCurry, Executive Vice President, Missouri Telephone Association, Box 783, Jefferson City, Missouri 65101.

R. S. McClelland, Jr., Executive Vice President, Missouri Telephone Company, Executive Offices, 200 East Walnut Building, P.O. Box 65201, Kansas City, Missouri 64195.

Ivo Bauman, Vice President—Manager, Mt. Angel Telephone Company, P.O. Box 406, Mt. Angel, Oregon 97362.

Eric A. Leighton, Chairman of Task Force to Study Proposed PUC Uniform System of Accounts, Fred C. Huebner, Chairman, Staff Committee on Accounting, National Association of Regulatory Utility Commissioners, 1102 Interstate Commerce Commission Building, Constitution Avenue and Twelfth Street, N.W., Post Office Box 684, Washington, D.C. 20444.


E. W. Olson, Vice President, Navajo Communications Co., Inc., P.O. Box 707, Window Rock, Arizona 86515.

Howard S. Smith, Vice President—General Manager, Nevada Telephone Telegraph Company, 120 Joyce Lake, Drawer E, Incline Village, Nevada 89450.

George H. Barbour, President, Joseph C. O'Hara, Chief, Bureau of Accounts, New Jersey Board of Public Utilities, Department of Energy, 101 Commerce Street, Newark, New Jersey 07102.

Peter H. Schiff, Esq., General Counsel, New York Department of Public Service, The City of New York, 100 Church Street, Post Office Box 309, New York, New York 10222.

Peter Varr Kampen, Executive Vice President, New York State Telephone Association, Inc., 111 Madison Avenue, Albany, New York 12210.

Leroy H. Hemingway, Deputy Commissioner, Director, Utility Program, Public Utility Commission of Oregon, Labor & Industries Building, Salem, Oregon 97310.

Nicholas P. Miller, Esq., Preston, Thorgrinson, Ellis, Holman & Fletcher, 1725 F Street, N.W., Washington, D.C. 20006, Counsel for the Organization for the Protection and Advancement of Small Telephone Companies.

Howard W. Hall, Jr., Vice President, Plant Telephone & Power Company, Inc., P.O. Box 187, Tifton, Georgia 31794.

Robert O. Karr, President, The Pleasanton Telephone Company, P.O. Box 435, Pleasanton, Kansas 66705.

Hazel L. Parker, President, Pymatuning Independent Telephone Company, 1800 West Maple Street, New Town Plaza, Rochester, New York 64144.

Robert W. Fargen, Administrator, Rural Electrification Administration, Washington, D.C. 20250.


James Smith, Manager, SL Croix Telephone Co., 154 2nd Street, New Richmond, Wisconsin 54017.


Robert T. McWilliams, Executive Director, General Telephone Company, Old Orchard Road, Des Plaines, Illinois 60016.

James Best, Controller, Telephone Utilities, Inc., P.O. Box E, Ilwaco, Washington 98624.

Eugene L. Andrus, Manager, Three Rivers Telephone Cooperative, Fairfield, Montana.

John G. Foster, President, Twin Valley Telephone, Inc., Miltonvale, Kansas 67468.


Federal Procurement Policy, Administrator for Regulations, Office of to William W. Thybony, Assistant regulation from and submit comments

DATE:

SUMMARY: The Office of Federal Procurement Policy is making available upon request for public and Government agency review and comment segments of the Federal Acquisition Regulation. The following subparts of the draft Federal Acquisition Regulation are available for public and Government agency review and comment:

PART 3—Ethics

3.1 Standards of conduct.

This subpart prescribes strict standards of conduct for all Government personnel responsible in any way for conducting Government business with industry. Rules are set which require complete impartiality and avoidance of any appearance of a conflict of interest in Government contractor relationships. Further, all Government employees are prohibited from soliciting or accepting, directly or indirectly, for themselves or anyone else, any gratuity, gift, favor, entertainment, loan or any other thing of monetary value from any person, firm or group seeking to obtain Government contracts or other business or financial relationship with their agency. A Gratuities clause is provided for in contracts and will be published in Part 52 of the completed FAR. The clause provides for contract default action against contractors found in violation of the gratuities clause of the draft Acquisition Regulation (FAR) regarding Ethics, Contractor Recordation, Publicizing Contract Actions, Labor Surplus Area Concerns, Foreign Acquisitions, and Bonds, and Sureties. Availability of additional segments for comment will be announced on later dates. This regulation is being developed to replace the current system of procurement regulations. It will be a single uniform acquisition regulation for use by all Federal executive agencies in the acquisition of supplies and services with appropriated funds. Disciplinary action will be taken against Government employees for violation of the standards in accordance with the agency's regulations issued under Title 5, Part 735.107, Code of Federal Regulations. 

3.2 Contractor gratuities to Government personnel.

This subpart implements 10 U.S.C. 2207 for the Department of Defense and, as a matter of policy, is extended to all executive agencies except for the assessment of exemplary damages. It provides that the cognizant Board of Contract Appeals, after notice and hearing, shall determine if a violation of the gratuities clause of a contract has occurred. The gratuities clause is also provided for by regulations issued under Title 5, Part 735.107, Code of Federal Regulations.

3.3 Reports of suspected antitrust violations and other noncompetitive practices.

This subpart provides that agency personnel shall report all suspected noncompetitive practices through the contracting officer for referral to the Attorney General of the United States and the appropriate Federal, state, or local agencies. Reports will be made where antitrust violation, collusive bidding, follow-the-leader pricing, kickbacks, rotated low bids, subcontractor kickbacks, or other similar practices are suspected. Reporting requirements of the Attorney General have been shortened and simplified to reduce the paperwork burden.

3.4 Contingent fees.

This subpart prescribes policies and procedures that restrict contingent fee arrangements for soliciting or obtaining Government contracts to those permitted by 10 U.S.C. 2506(b) and 41 U.S.C. 254(a). These statutes require a warrant by the contractor against contingent fees in every negotiated contract. They permit, as an exception to the warranty, contingent fee arrangements between contractors and bona fide employees or agencies. They also provide that, for breach or violation of the warranty by the contractor, the Government may annul the contract without liability, deduct from the contract price, or otherwise recover the full amount of the contingent fee. The subpart includes guidance for contracting officer review of contingent fee representation and agreement. Also included from Part 52 are the required solicitation provision and contract clause.

3.5 Buying-in.

This subpart requires that the contracting officer take appropriate action to ensure buying-in losses are not recovered by the contractor through the pricing of change orders or follow-on contracts subject to cost analysis. It provides that the Government should minimize the opportunity for buying-in by seeking a price commitment for the entire program by using multi-year contracting or priced options.

4.7 Contractor records retention.

This subpart provides policies and procedures for retention of records by contractors and subcontractors to meet the records review requirements of the Government. The purpose of this subpart is to relieve the burden on
contractors of excessive records retention requirements while ensuring that the records review requirements of the Comptroller General and contracting officers maintain a reasonable number of copies of solicitations publicized in the Commerce Business Daily to be available to those not initially solicited and to enable small business concerns and others interested in sub-contracting to contact prospective prime contractors early in the acquisition process.

5.3 Symposes of contract awards.

This subpart requires the sympos on the CBD of all sole source awards exceeding $10,000 and, for sub-contracting opportunities, all other awards exceeding $25,000. It also requires public announcement and Congressional notification on the date of award of all contracts exceeding $1,000,000.

5.4 Release of information.

This subpart provides that contracting offices may make maximum information in the acquisition process available to the public, subject to the level of business security must be maintained in order to preserve the integrity of the acquisition process. When it is necessary to obtain information from potential contractors and others outside the Government for use in preparing Government estimates, contracting offices shall ensure that the estimates are not publicized or discussed with prospective contractors. This subpart also provides procedures for release of long-range acquisition estimates to assist industry planning.

5.5 Paid advertisements.

Although it will be moved to another part of the FAR this subpart currently contains policies and procedures for the acquisition of paid advertisements.

PART 20—LABOR SURPLUS AREA CONCERNS

20.1 General.

This subpart prescribes definitions, the basic Labor Surplus Area (LSA) policy, effect of the Buy American Act; and designation of depressed industries by the Federal Preparedness Agency.

20.2 Set-asides.

This subpart includes policies and procedures for total LSA set-asides and with stated exceptions for Defense Department partial set-asides.

20.3 Labor surplus area subcontracting program.

This subpart requires that in contracts from $10,000 to $500,000, contractors are required to use their best efforts to subcontract with LSA concerns and in contracts exceeding $500,000, contractors are required to take affirmative actions to subcontract with LSA concerns. The contract clauses for both thresholds are included for review and comment.

PART 25—FOREIGN ACQUISITION

25.1 Buy American Act—Supplies.

This subpart implements the Buy American Act (41 U.S.C. 10) and Executive Order 10582, December 17, 1954 (as amended). It requires contractors to supply contracts and to contracts for services that involve the furnishing of supplies. It defines domestic end product and requires, with certain exceptions, that only domestic end products shall be acquired for public use. One such exception is if the cost of the domestic product is unreasonable. To make this determination 6% is added to the foreign offer if the domestic offer is from a large business that is not a labor surplus area concern and 12% if the domestic offer is from a small business or any labor surplus area concern. The Department of Defense use of 50% differential is not extended to all agencies by FAR.


This subpart applies to contracts for the construction, alteration, or repair of any public building or public work in the United States. The Act requires that, with certain exceptions, only domestic construction materials be used in construction in the United States. It provides that, for evaluation purposes, 6% be added to each foreign construction material offered and requires offers proposing to use foreign materials to provide adequate data for such evaluation and permits alternative offers for comparable domestic materials at stated prices.

25.3 Balance of payments program.

This subpart provides policies and procedures applicable to contracting for supplies, services, or construction for use outside the United States, and provides for the use of excess or near-excess foreign currency. In order to reduce dollar expenditures overseas, and thus improve the United States balance of payments position, solicitations for supplies and services for use outside the United States shall, with certain exceptions stated in the subpart, be restricted to domestic end products and services. Acquisitions paid for in excess or near-excess foreign currencies are an exception to the balance of payments restrictions. Excess and near-excess foreign currencies shall be used whenever feasible in payment of contracts valued at $1,000,000 or more that are performed in whole or in part in any of the countries listed in the subpart. The $1,000,000 threshold has been newly established because the reduced amount of both the amount of U.S. owned foreign currency and the number of countries involved make detailed procedures for using such currency inappropriate.

25.4 Payment in local foreign currency.

This subpart requires payment in local currency when contracts are entered into and performed outside the U.S. with local foreign firms.

25.5 Customs and duties.

This subpart provides policies and procedures for exempting from import duties certain supplies purchased under Government contracts. It requires that agencies use such exemptions whenever the anticipated savings will outweigh the administrative costs associated with processing the required documentation.

25.6 Restrictions on certain foreign purchases.

This subpart requires, with certain exceptions, that agencies and their contractors and subcontractors shall not acquire supplies or services originating from sources within Rhodesia or the Communist areas of North Korea, Vietnam, Cambodia or Cuba.
25.7 *International agreements and coordination.*

This subpart requires that the contracting officer determine the existence and applicability of any international agreements and ensure compliance when placing contracts with contractors outside the U.S. for performance outside the U.S.

25.8 *Omission of the examination of records clause.*

This subpart provides that the Examination of Records by Comptroller General clause shall be included in contracts with foreign contractors whenever possible. Omission of the clause can be approved only after the contracting agency has made all reasonable efforts to include the clause.

**PART 28—BONDS AND INSURANCE**

28.1 *Bonds.*

This subpart prescribes requirements and procedures for use of bonds and all types of bid guarantees. It provides that the use of bid guarantees is permissible only when a performance bond or a performance and payment bond is required and that annual bid bonds are not acceptable for construction contracts. It covers the amount of bid guarantee required, noncompliance with bid guarantee requirements, performance and payment bonds for construction and non-construction contracts, advance payment bonds and fidelity and forgery bonds.

28.2 *Sureties.*

This subpart prescribes procedures for the use of sureties to protect the Government from financial losses. It defines acceptable corporate and individual sureties and requires that solicitations shall not preclude offerors from utilizing the types of surety or security permitted by this subpart, unless prohibited by law or regulation. This subpart provides for options in lieu of sureties such as U.S. bonds or notes, certified or cashier's checks, bank drafts, money orders, or currency. Although located in Parts 52 and 53, applicable clauses and forms are included here for review and comment.

Dated: March 5, 1979.

LESTER A. FEITIG,
Administrator.

[F.R. Doc. 79-7171 Filed 3-8-79; 8:45 am]
[3410–16–M]
DEPARTMENT OF AGRICULTURE
Soil Conservation Service
CROOKED LAKE BAYOU WATERSHED, ARKANSAS

Intent Not To File an Environmental Impact Statement for Deauthorization of Federal Funding of the Crooked Lake Bayou Watershed

Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR 1500); and the Soil Conservation Service Guidelines (7 CFR 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for deauthorization of Federal funds for the Crooked Lake Bayou Watershed, Mississippi County, Arkansas.

The environmental assessment of this action indicates that the measure plan will not cause significant adverse local, regional, or national impacts on the environment. As a result of these findings, Mr. M. J. Spears, State Conservationist, has determined that the preparation and review of an environmental impact statement is not needed for this project.

The project concerns a plan for the purpose of watershed protection, flood prevention, and agricultural water management on a 31,920-acre watershed. The project plan provides funding for accelerated technical assistance for application of land treatment measures on 16,000 acres of cropland and the installation of about 37.7 miles of drainage mains and laterals, a pumping plant, a levee, and two water control structures.

The notice of intent not to prepare an environmental impact statement has been forwarded to the Environmental Protection Agency.

The basic data developed during the environmental assessment are on file and may be reviewed by contacting Mr. M. J. Spears, State Conservationist, Soil Conservation Service, Federal Office Building, 700 West Capitol Avenue, Little Rock, Arkansas 72203; (501-378-5445). An environmental impact appraisal has been prepared and sent to various Federal, State, and local agencies and interested parties. A limited number of copies of the environmental impact appraisal are available to fill single copy requests at the above address.

No administrative action on implementation of the proposal will be taken until May 8, 1979.


Dated: February 27, 1979.

VICTOR H. BARRY, JR., Deputy Administrator for Programs.

[FR Doc. 79-7219 Filed 3-8-79; 8:45 am]

[3410–16–M]
GARRETT BRIDGE WATERSHED, ARKANSAS

Intent Not To File an Environmental Impact Statement for Deauthorization of Federal Funding of the Garrett Bridge Watershed

Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR 1500); and the Soil Conservation Service Guidelines (7 CFR 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for deauthorization of Federal funds for the Garrett Bridge Watershed, Lincoln County, Arkansas.

The environmental assessment of this action indicates that the measure plan will not cause significant adverse local, regional, or national impacts on the environment. As a result of these findings, Mr. M. J. Spears, State Conservationist, has determined that the preparation and review of an environmental impact statement is not needed for this project.

The project concerns a plan for the purpose of watershed protection, flood prevention, and agricultural water management on a 18,700-acre watershed. The project plan provides funding for accelerated technical assistance for application of land treatment measures on 16,000 acres of cropland and the installation of about 37.7 miles of drainage mains and laterals, a pumping plant, a levee, and two water control structures.

The notice of intent not to prepare an environmental impact statement has been forwarded to the Environmental Protection Agency.

The basic data developed during the environmental assessment are on file and may be reviewed by contacting Mr. M. J. Spears, State Conservationist, Soil Conservation Service, Federal Office Building, 700 West Capitol Avenue, Little Rock, Arkansas 72203; (501-378-5445). An environmental impact appraisal has been prepared and sent to various Federal, State, and local agencies and interested parties. A limited number of copies of the environmental impact appraisal are available to fill single copy requests at the above address.

No administrative action on implementation of the proposal will be taken until May 8, 1979.


Dated: February 27, 1979.

VICTOR H. BARRY, JR., Deputy Administrator for Programs.

[FR Doc. 79-7224 Filed 3-8-79; 8:45 am]

[3410–16–M]
RICHLAND CREEK WATERSHED PROJECT, SOUTH DAKOTA

Intent Not To Prepare an Environmental Impact Statement for Deauthorization of Funding of the Richland Creek Watershed

Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR 1500); and the Soil Conservation Service Guidelines (7 CFR 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the deauthorization of funding of the Richland Creek Watershed Project, Union County, South Dakota.

The environmental assessment of this action indicates that deauthorization of funding of the project will not cause significant adverse local, regional, or national impacts on the environment. As a result of these findings, Mr. Robert D. Swenson, State Conservationist, has determined that the preparation and review of an environmental impact statement is not needed for this action.

The project being deauthorized concerns a plan for watershed protection.
NOTICES

and flood prevention. The planned works of improvement include one single purpose floodwater retarding structure, and 3.5 miles of single purpose channel improvement for flood prevention.

The basic data developed during the environmental assessment are on file and may be reviewed by interested parties at the Soil Conservation Service office, 200 Fourth Street, S.W., Huron, South Dakota 57359.

An environmental impact appraisal has been prepared and sent to various Federal, State, and local agencies, and interested parties. A limited number of copies of the environmental impact appraisal is available to fill single copy requests at the above address.

No administrative action on implementation of the proposal will be taken until May 8, 1979.


DATED: February 27, 1979.

VICTOR H. BARRY, Jr.,
Deputy Administrator
for Programs.

(F.R. Doc. 79-7218 Filed 3-8-79; 8:45 am)

[3410-16-M]

TOWN OF RAMSEUR PUBLIC WATER-BASED RECREATION RC&D MEASURE, NORTH CAROLINA

Intent Not To Prepare an Environmental Impact Statement

Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR 1500); and the Soil Conservation Service Guidelines (7 CFR 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the Town of Ramseur Public Water-Based Recreation RC&D Measure, Randolph County, North Carolina.

The environmental assessment of this federally assisted action indicates that the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Mr. Jesse L. Hicks, State Conservationist, determined that the preparation and review of an environmental impact statement are not needed for this project.

The measure concerns a plan for water-based recreation facilities for the Town of Ramseur and surrounding area. The proposed measure will provide 43,000 annual recreation user days.

The notice of intent not to prepare an environmental impact statement has been forwarded to the Environmental Protection Agency. The basic data developed during the environmental assessment are on file and may be reviewed by contacting Mr. Jesse L. Hicks, State Conservationist, Soil Conservation Service, Room 544, Federal Building, 310 New Bern Avenue, Raleigh, North Carolina 27611, telephone 919-755-4210. An environmental impact appraisal has been prepared and sent to various Federal, State, and local agencies and interested parties. A limited number of copies of the environmental impact appraisal are available to fill single copy requests at the above address.

Implementation of the proposal will not be initiated until April 9, 1979.

(Catalog of Federal Domestic Assistance Program No. 10.904, Watershed Protection and Development Program—Pub. L. 87-703, 16 U.S.C. 590 et. seq.)

DATED: March 5, 1979.

VICTOR H. BARRY, Jr.,
Deputy Administrator for Programs,

Soil Conservation Service.

(F.R. Doc. 79-7217 Filed 3-8-79; 8:45 am)

[3410-16-M]

TRI-COUNTY TURKEY CREEK WATERSHED, OKLAHOMA

Intent Not to Prepare an Environmental Impact Statement

Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR 1500); and the Soil Conservation Service Guidelines (7 CFR 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the remaining work in the Tri-County Turkey Creek Watershed project, Haskell, Jackson, and Greer Counties, Oklahoma.

The environmental assessment of this federally assisted action indicates that the remaining work in the project will not cause significant local, regional, or national impacts on the environment. As a result of these findings, Mr. Roland R. Willis, State Conservationist, has determined that the preparation and review of an environmental impact statement is not needed for the remaining work in this project.

The project concerns a plan for watershed protection and flood prevention. The remaining planned works of improvement include critical area treatment and eight floodwater retarding structures.

The notice of intent not to prepare an environmental impact statement has been forwarded to the Environmental Protection Agency. The basic data developed during the environmental assessment is on file and may be reviewed by interested parties at the Soil Conservation Service, Agricultural Center Building, Farm Road and Brumley Street, Stillwater, Oklahoma 74074. An environmental impact appraisal has been prepared and sent to various Federal, State, and local agencies and interested parties. A limited number of copies of the environmental impact appraisal is available to fill single copy requests.

No administrative action on implementation will be taken until May 8, 1979.

(Catalog of Federal Domestic Assistance Program No. 10.904, Watershed Protection and Flood Prevention Act—Public Law 83-506, 16 U.S.C. 1001-1008.)


VICTOR H. BARRY, Jr.,
Deputy Administrator
for Programs.

(F.R. Doc. 79-7225 Filed 3-8-79; 8:45 am)

[3410-16-M]

UPPER LITTLE MINNESOTA RIVER WATERSHED PROJECT, SOUTH DAKOTA

Intent Not to Prepare an Environmental Impact Statement for Deauthorization of Funding of the Upper Little Minnesota River Watershed

Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR Part 1500); and the Soil Conservation Service Guidelines (7 CFRPart 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the deauthorization of funding of the Upper Little Minnesota River Watershed Project, Marshall and Roberts Counties, South Dakota.

The environmental assessment of this action indicates that deauthorization of funding of the project will not cause significant adverse local, regional, or national impacts on the environment. As a result of these findings, Mr. Robert D. Swenson, State Conservationist, has determined that the preparation and review of an environmental impact statement is not needed for this action.

The project being deauthorized concerns a plan for watershed protection and flood prevention. The planned works of improvement include two single purpose floodwater retarding structures, and 13 miles of channel improvement.

The basic data developed during the environmental assessment are on file and may be reviewed by interested parties at the Soil Conservation Service office, Federal Building, 200
NOTICES

[6335-01-M]

COMMISSION ON CIVIL RIGHTS
INDIANA ADVISORY COMMITTEE
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 planning meeting of the Indiana Advisory Committee (SAC) of the Commission will convene at 7:00 p.m. and will end at 10:00 p.m. on April 2, 1979, in the ramada Inn, 1530 North Meridian Street, Indianapolis, Indiana 46202.

Persons wishing to attend this open meeting 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 the final draft of the Fort Wayne School Desegregation follow-up report. A report on the impact of the Insurance Redlining Report and conference released by the MWRO. The status of rechartering of the Indiana SAC.

This meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.


JOHN I. BINKLEY,
Advisory Committee Management Officer.

[FR Doc. 79-7173 Filed 3-7-79; 8:45 am]

[6335-01-M]

NEW JERSEY ADVISORY COMMITTEE
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 planning meeting of the New Jersey Advisory Committee (SAC) of the Commission will convene at 9:00 a.m. and will end at 3:00 p.m. on April 23, 1979, in the Hilton Gateway, Gateway Center, Newark, New Jersey 07102.

Persons wishing to attend this open meeting should contact the Committee Chairperson, or the Northeastern Regional Office of the Commission, 26 Federal Plaza, Room 1639, New York, New York 10007.

The purpose of this meeting is to discuss program planning.

This meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.


JOHN I. BINKLEY,
Advisory Committee Management Officer.

[FR Doc. 79-7175 Filed 3-7-79; 8:45 am]

[6335-01-M]

VERMONT ADVISORY COMMITTEE
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 planning meeting of the Vermont Advisory Committee (SAC) of the Commission will convene at 7:30 p.m. and will end at 9:30 p.m. on April 5, 1979, in the Tavern Motor Inn, Montpelier, Vermont.

Persons wishing to attend this open meeting should contact the Committee Chairperson, or the Northeastern Regional Office of the Commission, 26 Federal Plaza, Room 1639, New York, New York 10007.


JOHN I. BINKLEY,
Advisory Committee Management Officer.

[FR Doc. 79-7176 Filed 3-7-79; 8:45 am]

DEPARTMENT OF COMMERCE

Industry and Trade Administration

EXPORTERS' TEXTILE ADVISORY COMMITTEE
Public Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, as

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
amended, 5 U.S.C. App. (1976) notice is hereby given that a meeting of the Exporters’ Textile Advisory Committee will be held at 10:00 A.M., on April 18, 1979, in Room 3708, U.S. Department of Commerce, Main Commerce Building, 14th and Constitution Avenue, N.W., Washington, D.C. 20230.

The Committee, which is comprised of 30 members involved in textile and apparel importing, advises Department officials concerning ways of increasing U.S. exports of textile and apparel products.

The agenda for the meeting is as follows:

1. Review of Export Data
2. Report on Conditions in the Export Market
3. Recent Foreign Restrictions Affecting Textiles
4. Other Business

A limited number of seats will be available to the public on a first come basis. The public may file written statements with the Committee before or after the meeting. Oral statements may be prepared at the end of the meeting to the extent time is available.

Copies of the minutes of the meeting will be made available on written request addressed to the ITA Freedom of Information Officer, Freedom of Information Control Desk, Room 3100, U.S. Department of Commerce, Washington, D.C. 20230.

Further information concerning the Committee may be obtained from Arthur Garel, Director, Office of Textiles, Main Commerce Building, U.S. Department of Commerce, Washington, D.C. 20230, telephone 202-377-5078.

Dated: March 6, 1979.

ROBERT E. SHEPHERD,
Deputy Assistant Secretary for Domestic Business Development.

[3510–22–M]  National Oceanic and Atmospheric Administration

GULF OF MEXICO AND SOUTH ATLANTIC FISHERY MANAGEMENT COUNCIL’S CORAL REEF RESOURCES SUBPANELS

Public Meeting

AGENCY: National Marine Fisheries Service, NOAA.

SUMMARY: The Gulf of Mexico and South Atlantic Fishery Management Councils were established by Section 302 of the Fishery Conservation and Management Act of 1976 (Pub. L. 94-265), and the Councils have established Advisory Subpanels on corals which will meet to review a draft fishery management plan on corals.

DATES: The meeting will convene on Thursday, March 29, 1979, at 8:30 a.m., and adjourn at 4:30 p.m. The meeting is open to the public.

ADDRESS: The meeting will take place in Council headquarters at the Lincoln Center, Suite 881, 5401 West Kennedy Boulevard, Tampa, Florida.

FOR FURTHER INFORMATION CONTACT:

Wayne E. Swingle, Executive Director, Gulf of Mexico Fishery Management Council, Suite 881, 5401 West Kennedy Boulevard, Tampa, Florida 33609. Telephone: (813) 228-2815.

Dated: March 6, 1979.

WINFRED H. MEIBOHM,
Executive Director, National Marine Fisheries Service.

[FR Doc. 79–7228 Filed 3–8–79; 8:45 am]

[3510–22–M]  NEW ENGLAND FISHERY MANAGEMENT COUNCIL’S SCIENTIFIC AND STATISTICAL COMMITTEE

Public Meeting

AGENCY: National Marine Fisheries Service, NOAA.

SUMMARY: The New England Fishery Management Council was established by Section 302 of the Fishery Conservation and Management Act of 1976 (Pub. L. 94–265), and the Council has established the Scientific and Statistical Committee which will meet to discuss analysis of biological and economic impacts of silver hake and sea scallop management strategies.

DATES: The meeting will convene on Friday, March 23, 1979, at approximately 9:30 a.m. and will adjourn at approximately 5 p.m. The meeting is open to the public.

ADDRESS: The meeting will take place at the JFK Building, Room 1900A, Government Center, Cambridge Street, Boston, Massachusetts.

FOR FURTHER INFORMATION CONTACT:

New England Fishery Management Council, Peabody Office Building, One Newbury Street, Peabody, Massachusetts 01960. Telephone: (617) 535–5450.

SUPPLEMENTARY INFORMATION: For information on seating arrangements, changes to the agenda, and/or written comments, contact the Council.

Dated: March 6, 1979.

WINFRED H. MEIBOHM,
Executive Director, National Marine Fisheries Service.

[FR Doc. 79–7229 Filed 3–8–79; 8:45 am]

[3510–22–M]  DR. KENNETH S. NORRIS, UNIVERSITY OF CALIFORNIA

Notice of Modification of Permit

Notice is hereby given that, pursuant to the provisions of §§ 216.33(d) and (e) of the Regulations Governing the Taking and Importing of Marine Mammals (39 FR 1851, January 15, 1974), Scientific Research Permit No. 219, issued to Dr. Kenneth S. Norris, University of California at Santa Cruz, on January 31, 1978, is modified in the following manner:

1. Section A is modified by adding a new Section A-3, as follows:

“3. Aerial surveys of spinner porpoise may be conducted at 500 feet which may cause harassment of some individuals within the population.”
NOTICES


WINFRED H. MENTHOM, Associate Director, National Marine Fisheries Service.

[FR Doc. 79-7230 Filed 3-8-79; 8:45 am]

3510-13-M Office of the Secretary
NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM

Final General and Specific Criteria for Accrediting Laboratories That Test Thermal Insulation Materials; Correction and Notice of Fees and Charges To The accompanying Federal Register Notice of Test Thermal Insulation Materials; Correction AGENCY: Assistant Secretary of Commerce for Science and Technology.

ACTION: Correction of the notice announcing the final general and specific criteria for accrediting laboratories which test thermal insulation materials and the accompanying notice announcing the charges to accredit laboratories which test thermal insulation materials under the procedures of the National Voluntary Laboratory Accreditation Program (NVLAP). SUMMARY: One section of the general criteria, section G2.5.4, was inadvertently left out of the notice published in the Federal Register on January 18, 1979 (44 FR 3886-3905). In addition, the typical cost of proficiency sample testing, cited as $80 per test and charged in the accompanying Federal Register notice (44 FR 3906), should be $80 per year for each test method. This effectively reduces the fee for proficiency testing to one-half that cited in the notice since two such tests are typically required every year. Finally, there were several typographical errors which are corrected.

DATES: These corrections shall go into effect on March 9, 1979.

FOR FURTHER INFORMATION CONTACT:
Dr. Howard I. Forman, Deputy Assistant Secretary for Product Standards, Room 3876, U.S. Department of Commerce, Washington, DC 20230; (202) 377-3221.

SUPPLEMENTAL INFORMATION:
On January 18, 1979, the Department of Commerce (Department) announced in the Federal Register (44 FR 3886-3905) the issuance of final general and specific criteria for testing thermal insulation materials under the procedures of NVLAP. In an accompanying notice published in the Federal Register on the same day (44 FR 3906) the Department announced the fees and charges to accredit laboratories which test thermal insulation materials under NVLAP. Corrections are made in these notices as follows:

1. Page 3886, second column, second line under the heading "DATES", remove the parenthetical expression and substitute the words "February 17, 1979" without parentheses.

2. Page 3891, second column. Add after section **G2.5.3:** "**G2.5.4 Current regulations, test standards and specifications:** This item is identical to the section G2.5.4 which was contained in the proposed criteria (43 FR 45299).

3. Page 3891, second column, in section G2.6.1, third line. Insert the word "and" after "general".

4. Page 3892, first column, sixth line under Specific Criteria. Change the heading "Criteria S1" to "Criterion S1".

5. Page 3892, first column, ninth line in the NOTE which follows section S1.2. Change the word "Examiners" to "Evaluators".

6. Page 3906, third column, third line. Change the expression "nominally $2,095" to "typically $80 per year".

7. Page 3906, third column, twelfth line, Replace "$160" with "$80".

8. Page 3906, third column, seventeenth line under "Example Calculation". Replace "$320" with "$100".

9. Page 3906, third column, nineteenth line under "Example Calculation". Replace "$2,095" with "$1,935".


JORDAN J. BARUCH, Assistant Secretary for Science and Technology.

[FR Doc. 79-7042 Filed 3-8-79; 8:45 am]

3510-16-M Patent and Trademark Office
CLOSING ON TUESDAY, FEBRUARY 20, 1979, DUE TO HEAVY SNOW

Notice is hereby given of the following announcement, issued by the Patent and Trademark Office on February 21, 1979, designating February 20, 1979, as a holiday for the purpose of taking action or paying fees due that day in patent and trademark matters in the Patent and Trademark Office:


In view of the fact that Federal and District of Columbia government offices in the Washington, D.C. metropolitan area, including the Patent and Trademark Office, were officially closed on February 20, 1979, the Patent and Trademark Office will consider February 20, 1979, a "holiday within the District of Columbia" under 35 U.S.C. § 21. Any action or fee due that day will be considered as timely for the purposes of, e.g., 35
NOTICES

U.S.C. §§ 119, 133 and 151, if the action is taken, or fee paid, on February 21, 1979. Papers deposited in U.S. Department of Commerce District Offices on February 20, 1979, will similarly be considered timely for the purposes of 35 U.S.C. §§ 119, 133 and 151.

REVY D. TESTMEYER, Assistant Commissioner (Acting Commissioner) of Patents and Trademarks

MARCH 6, 1979.

[FR Doc. 79-7218 Filed 3-8-79; 8:45 am]

[6820-33-M]

COMMITTEE FOR PURCHASE FROM THE BLIND AND OTHER SEVERELY HANDICAPPED

PROCUREMENT LIST 1979

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Additions to Procurement List.

SUMMARY: This action adds to Procurement List 1979 a service to be provided by and a commodity to be produced by workshops for the blind or other severely handicapped.

EFFECTIVE DATE: March 9, 1979.

ADDRESS: Committee for Purchase from the Blind and Other Severely Handicapped, 2009 14th Street North, Suite 610, Arlington, Virginia 22201.

FOR FURTHER INFORMATION CONTACT:

C. W. Fletcher, (703) 557-1145


After consideration of the relevant matter presented, the Committee has determined that the service and the commodity listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46-48c, 85 Stat. 77.

Accordingly, the following service and commodity are hereby added to Procurement List 1978:

SIC 0782: Grounds Maintenance, Bldgs.

Class 8445: Scarf, Neckwear, 8445-00-549-5363.

C. W. Fletcher, Executive Director.

[FR Doc. 79-7184 Filed 3-8-79; 8:45 am]

[6820-33-M]

PROPOSAL LIST 1979

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Proposed Additions to Procurement List.

SUMMARY: The Committee has received proposals to add to Procurement List 1979 commodities to be produced by and service to be provided by workshops for the blind and other severely handicapped.

COMMENTS MUST BE RECEIVED ON OR BEFORE: April 11, 1979.

ADDRESS: Committee for Purchase from the Blind and Other Severely Handicapped, 2009 14th Street North, Suite 610, Arlington, Virginia 22201.

FOR FURTHER INFORMATION CONTACT:

C. W. Fletcher, (703) 557-1145

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2), 85 Stat. 77.

If the Committee approves the proposed additions, all entities of the Federal Government will be required to procure the commodities and service listed below from workshops for the blind or other severely handicapped.

It is proposed to add the following commodities and service to Procurement List 1979, November 15, 1978 (43 FR 53151):

Class None: Lead Seal with Cord, Postal Service Item No. 0615.

Class 7210: Mattress, Innerspring with Vinyl/Nylon Laminated Tricking.

Class 7290: Paper, Tole Typewriter Roll, 7290-00-223-7959 (GSA Regions 1, 2, 3, 7, 8, 9, and 10).

Class 7910:

Pad, Floor Polishing Machine—

7910-00-685-6898
7910-00-685-6897
7910-00-685-3993
7910-00-685-3992
7910-00-685-6899
7910-00-685-6890
7910-00-685-3910
7910-00-685-4239
7910-00-685-4240
7910-00-685-4242
7910-00-685-4241
7910-00-685-4245
7910-00-685-6566
7910-00-685-6562
7910-00-685-3912
7910-00-685-6569
7910-00-685-3915
7910-00-685-3916
7910-00-685-3914

Class 7920: Pad, Scouring, 7920-00-151-6120

SIC 7349: Custodial Service, Federal Building, Gallup, New Mexico.

C. W. Fletcher, Executive Director.

[FR Doc. 79-7185 Filed 3-8-79; 8:45 am]

[6355-01-M]

CONSUMER PRODUCT SAFETY COMMISSION

PRODUCT SAFETY ADVISORY COUNCIL

Meeting

AGENCY: Consumer Product Safety Commission.


SUMMARY: This notice announces a meeting of the Product Safety Advisory Council on Monday, March 26, 1979, from 9 a.m. to 5 p.m. and Tuesday, March 27, 1979, from 9 a.m. to 5:45 p.m. The meeting will be held at 1111 18th Street, N.W., Washington, D.C. 20207, Third Floor Conference Room.

FOR FURTHER INFORMATION CONTACT: Sadye E. Dunn, Office of the Secretary, Suite 300, 1111 18th Street, N.W., Washington, D.C. 20207, 202/634-7700.

SUPPLEMENTAL INFORMATION: The Product Safety Advisory Council was established by section 28 of the Consumer Product Safety Act, which provides that the Commission may consult with the Council before prescribing a consumer product safety rule or taking other action under the Act. The proposed agenda for Monday, March 26, includes issues related to CPSC's education and content of safety related public notifications involving corrective action. For Tuesday, March 27, the proposed agenda includes issues related to the revocation of regulations with specific focus on CPSC's safety standard for swimming pool slides and issues related to CPSC's proposed regulations for recordkeeping of consumer product safety complaints. The meeting is open to the public; however, space is limited. Persons who wish to make oral or written presentation to the Product Safety Advisory Council should notify the Office of the Secretary (see address above) by March 20, 1979. The notification should list the name of the individual or the responsible person, company, group or industry on whose behalf the presentation would be made.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
will be made, the subject matter, and the approximate time requested. Time permitting, these presentations and other statements from the audience to members of the Council may be allowed by the presiding officer.

DATED: March 6, 1979.

SADYE E. DUNN,
Secretary, Consumer Product
Safety Commission.
[FR Doc. 79-7136 Filed 3-8-79; 8:45 am]

[3910-01-M]
DEPARTMENT OF DEFENSE
Department of the Air Force
FLIGHT OPERATIONS IN THE SELLS AIRSPACE
OVERLYING THE PAPAGO INDIAN RESERVATION;
SOUTHERN ARIZONA
Public Hearing
MARCH 6, 1979.

An informal public hearing will be held for the purpose of soliciting comments from the public on the Draft Environmental Impact Statement (EIS) on Flight Operations in the Sells Airspace overlying the Papago Indian Reservation, Southern Arizona. The hearing is scheduled to be conducted on March 27, 1979 at 9 a.m. at the Santa Rosa Community Center on the Papago Indian Reservation. The presiding officer will be Colonel Win. E. Cordingly.

The Draft EIS was filed with the Environmental Protection Agency on February 9, 1979. The statement considers, as a continuing activity, the impacts of current and future aircrew training in the airspace over the Papago Indian Reservation, commonly referred to as the Sells Airspace. Training in this airspace is conducted by Air Force and Air National Guard units stationed at Luke AFB and Williams AFB near Phoenix, Arizona and at Davis-Monthan AFB and Tucson International Airport near Tucson, Arizona.

The following procedures will apply during the hearing. Individual speakers will be limited to five minutes with ten minutes for a group spokesman. There will be no relinquishing of time by one speaker to another. The time limit may be waived at the discretion of the presiding officer. Written statements in addition to, or in lieu of, oral presentations will be accepted. These should be submitted to the hearing officer or as directed at the hearing. Written statements must be received no later than April 2, 1979 in order to be included in the hearing record.

Directions to Santa Rosa are as follows: from Tucson take State Route 86 west to Covered Wells, then north on Indian Route 15 to Santa Rosa; from Phoenix take Interstate 10 south to State Route 93 near Casa Grande, south on Route 93 to Indian Route 15 and continue south to Santa Rosa.

FOR FURTHER INFORMATION CONTACT:
Mr. Thomas L. Lord, Headquarters
Tactical Air Command (HQ TAC/DEEV) Langley AFB, VA 23665, phone (804) 764-7844.

CAROL M. ROSE,
Air Force Federal Register
Liaison Officer.
[FR Doc. 79-7161 Filed 3-8-79; 8:45 am]

[6450-01-M]
DEPARTMENT OF ENERGY
NATIONAL PETROLEUM COUNCIL, TASK GROUPS OF THE COMMITTEE ON MATERIALS AND MANPOWER REQUIREMENTS
Notice of Meetings
Notice is hereby given that a subcommittee and two task groups of the Committee on Materials and Manpower Requirements will meet in March 1979. The National Petroleum Council was established to provide advice, information, and recommendations to the Secretary of Energy on matters relating to oil and natural gas or the oil and natural gas industries. The Committee on Materials and Manpower Requirements will analyze the potential constraints in these areas which may inhibit future production 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 the various task groups. The subcommittee scheduling a meeting is the Government Subcommittee. The two task groups scheduling meetings are the Task Group on Business Environment and the Task Group on Production Equipment.

The second meeting of the Government Subcommittee will be on Wednesday, March 21, 1979, starting at 9:00 a.m. in the Main Conference Room on the 26th floor of the Exxon Building, 500 Dallas Street, Houston, Texas. The tentative agenda for the meeting follows:

1. Introductory remarks by Chairman and Government Cochairman.
2. Discussion of the study methodology to be employed by the Government Subcommittee and a review of assignments.
4. Discussion of any other matters pertinent to the overall assignment of the Government Subcommittee.

The second meeting of the Business Environment Task Group will be on Thursday, March 15, 1979, starting at 9:00 a.m. in the Main Conference Room on the 26th floor of the General Crude Oil Company’s offices, One Allen Center Building, 500 Dallas Street, Houston, Texas. The tentative agenda for the meeting follows:

1. Introductory remarks by Chairman and Government Cochairman.
2. Discussion of the information needed by the Business Environment Task Group for completion of assignments.
3. Discussion of sources of information required by the Business Environment Task Group.

The third meeting of the Production Equipment Task Group will be rescheduled from Wednesday, February 28, 1979, to Wednesday, March 28, 1979, starting at 9:00 a.m. in Room 9192 on the 19th floor of the Exxon Building, 800 Bell Avenue, Houston, Texas.

The tentative agenda for the meeting follows:

1. Introductory remarks by Chairman and Government Cochairman.
2. Review of progress of the Production Equipment Task Group.
3. Discussion of the timetable of the Production Equipment Task Group.
4. Discussion of any other matters pertinent to the overall assignment of the Production Equipment Task Group.

The meetings are open to the public. The chairmen of the 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 wishes to file a written statement with the subcommittee or task groups will be permitted to do so, either before or after the meetings. Members of the public who wish to make oral statements should inform James R. Hemphill, Office of Resource Applications, 202/633-8383, prior to the meeting and reasonable provision will be made for their appearance on the agenda.

Summary minutes of the meetings will be available for public review at the Freedom of Information Public Reading Room, Room GA 152, DOE, 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.
NOTICES

Dated: March 1, 1979.

HAROLD D. BENGELESFORD, Director for Nuclear Affairs International Programs.

(3) Proposal Subsequent Arrangement Pursuant to Section 131 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2160) notice is hereby given of proposed “subsequent arrangements” under the Additional Agreement Between the Government of the United States of America and the European Atomic Energy Community (EURATOM) Concerning the Peaceful Uses of Atomic Energy and the Agreement for Cooperation Between the Governments of the United States of America and the Governments of Brazil, Canada, Japan, and Portugal. The subsequent arrangements to be carried out under the above mentioned agreements involve the following shipments:

<table>
<thead>
<tr>
<th>Contract No.</th>
<th>United States to</th>
<th>Description of material</th>
</tr>
</thead>
<tbody>
<tr>
<td>S-BR-27</td>
<td>Brazil</td>
<td>10 plates containing approximately 250 mg Uranium-238 with approximately 400 ppm U-235 as standard samples for X-ray diffraction to check phase transformation and change in crystalline dimensions at the Instituto de Energia Atomska, Sao Paulo, Brazil.</td>
</tr>
<tr>
<td>S-CA-253</td>
<td>Canada</td>
<td>20 mg of thorium enriched 80-99% in Th-232, for isotope dilution/mass spectrometric analysis of thorium in materials relating to fuel waste management and safeguards programs for Atomic Energy of Canada, Ltd., Whiteshell Nuclear Research Establishment, Pinawa, Canada.</td>
</tr>
<tr>
<td>S-CA-254</td>
<td>Canada</td>
<td>10 mg Plutonium oxide, enriched to 92.5% Pu-242 for trace analysis by isotope ratio for Atomic Energy of Canada, Ltd., at Whiteshell Nuclear Research Establishment, Pinawa, Canada.</td>
</tr>
<tr>
<td>S-CA-269</td>
<td>Canada</td>
<td>10 mg U-235 and 10 mg U-238 for determination of the age of ground water, as a desired parameter in the study of possible sites for disposal of nuclear waste, for Atomic Energy of Canada, Ltd., at Whiteshell Nuclear Research Establishment, Pinawa, Canada.</td>
</tr>
<tr>
<td>S-CA-357</td>
<td>Canada</td>
<td>500 curies of tritium gas, to provide a tritium beam at the McMaster University, FN Tandem Accelerator, at Ontario, Canada.</td>
</tr>
<tr>
<td>WC-CA-17</td>
<td>Canada</td>
<td>Five shipments, each containing 502 micrograms of Plutonium-237 to be used to study migration of radionuclides through geologic material, to Atomic Energy of Canada, Ltd., at the Whiteshell Nuclear Research Establishment, Pinawa, Canada.</td>
</tr>
<tr>
<td>MS-EU-330-97</td>
<td>Belgium</td>
<td>7.5 mg Uranium-238, with less than 1 ppm U-235, contained in 25 uranium-zirconium-dioxide pellets, for density measurements in the BR-2 reactor.</td>
</tr>
<tr>
<td>S-EU-531</td>
<td>Belgium</td>
<td>260 mg Neptunium-237 contained in 25 zirconium-dioxide pellets for measuring flux in the BR-2 reactor.</td>
</tr>
<tr>
<td>MS-EU-330-58</td>
<td>Belgium</td>
<td>42 mg Plutonium-239 contained in 25 zirconium-dioxide pellets, 42 mg Uranium-235 contained in 25 zirconium-dioxide pellets, and 275 mg Uranium-238 contained in 25 thorium-dioxide pellets, for measuring flux in the BR-2 reactor.</td>
</tr>
<tr>
<td>MS-EU-330-99</td>
<td>West Germany</td>
<td>113 mg Uranium-235 for use as target substance in the heavy ion accelerator UNILAC, Darmstadt, West Germany.</td>
</tr>
<tr>
<td>S-EU-538</td>
<td>West Germany</td>
<td>50 mg thorium enriched to greater than 83% in Th-232, and 100 mg Uranium enriched to greater than 99% U-235, for use as target material in nuclear-spectroscopy studies at the 7-MV-Tass de Graf accelerator at the Johann Wolfgang Goethe, Universitat.</td>
</tr>
<tr>
<td>S-JA-229</td>
<td>Japan</td>
<td>1 mg Uranium-235 enriched to greater than 99% and 1 mg Uranium-234 enriched to greater than 99% for use as a spike for mass spectrometry work at the University of Tokyo.</td>
</tr>
<tr>
<td>S-PO-4</td>
<td>Portugal</td>
<td>1 microcurie Plutonium-238 for radiochemical determination of Pu-239 in the environment by electrodeposition technique at the Laboratorio de Fisica e Engenharia Nucleares at Lisbon, Portugal.</td>
</tr>
</tbody>
</table>

For the Department of Energy.
In accordance with Section 131 of the Atomic Energy Act of 1954, as amended, it has been determined that the furnishing of the nuclear material will not be inimical to the common defense and security.

This subsequent arrangement will take effect no sooner than fifteen days after the date of publication of this notice.

For the Department of Energy.

Dated: March 5, 1979.

HAROLD D. BENGESDORF, Director for Nuclear Affairs, International Programs.

[6450-01-M]

Assistant Secretary for Resource Applications

SHORT-TERM LAUREL PROJECT RATES

Order Confirming and Approving Extension of Short-Term Power Rates on an Interim Basis

AGENCY: Department of Energy, Southeastern Power Administration (SEPA).

ACTION: Approval on Interim Basis of Short-Term Laurel Project Rates.

SUMMARY: The accompanying Rate Order No. SEPA-1 confirms and approves the extension of existing short-term rates for Laurel power on an interim basis to allow SEPA a limited amount of time within which to present and secure approval of long-term replacement rates.

DATES: Extension of rate approval on Interim basis effective April 1, 1979.

FOR FURTHER INFORMATION CONTACT:

Harry F. Wright, Administrator, Southeastern Power Administration, Department of Energy, Samuel Elbert Building, Elberton, Georgia 30635, (404) 203-3261.

SUPPLEMENTARY INFORMATION: The Economic Regulatory Administration has previously approved the short-term rates through March 31, 1978, in Orders dated April 21, September 20, and December 29, 1978. The extension of approval of short-term rates is subject to approval on a final basis by the Federal Energy Regulatory Commission pursuant to the Secretary's Delegation Order No. 0204-33.

NOTICES

Issued in Washington, DC, March 1, 1979.

GEORGE S. MCISAAC, Assistant Secretary, Resource Applications.

Order Confirming and Approving Extension of Short-Term Power Rates on an Interim Basis

MARCH 1979

In the matter of: Southeastern Power Administration—Laurel Project Power Rates Pursuant to Section 302(a) and 301(b) of the Department of Energy Organization Act, Public Law 95-91, the functions of the Secretary of the Interior and the Federal Power Commission under Section 5 of the Flood Control Act of 1944, 16 U.S.C. 822a, relating to the Southeastern Power Administration, have been transferred to and vested in the Secretary of Energy. By Delegation Order No. 0204-33, effective January 1, 1979, 43 FR 60536 (December 28, 1978), the Secretary of Energy delegated to the Assistant Secretary for Resource Applications the authority to develop power and transmission rates, acting by and through the Administrator, and to confirm, approve, and place in effect such rates on an interim basis and delegated to the Federal Energy Regulatory Commission (FERC) the authority to confirm and approve a final basis or to disapprove rates developed by the Assistant Secretary under the delegation. This rate order is issued pursuant to the delegation to the Assistant Secretary.

BACKGROUND

The Laurel Project began commercial operation as a hydroelectric generating facility on October 25, 1977. It was SEPA's original intention to sell one-half of the project's output to East Kentucky Power Cooperative, Inc. (East Kentucky), and to sell the other half to eight municipal customers in Kentucky. This power was transmitted for sale to these municipal customers to be transmitted through the facilities of East Kentucky and the Kentucky Utilities Company (Kentucky Utilities). However, SEPA and Kentucky Utilities failed prior to initial operation of the project to complete a contract for the transmission of this power to the eight municipal customers. Therefore, SEPA entered into a temporary contract (Contract No. 89-90-1501-054) for the sale of the entire output from the Laurel Project to East Kentucky, while negotiations with Kentucky Utilities continued, at the following short-term rates:

$65,000 per calendar month for capacity plus 10.0 mills per kilowatthour for energy declared and made available.

The term of the temporary contract has been extended several times until March 31, 1978. SEPA has now entered into a contract to sell the entire output of the project to East Kentucky until June 30, 1983, upon condition that East Kentucky relinquish its right to purchase from SEPA 25 MW of peaking power which it now receives from the Cumberland River Basin Projects. The 25 MW of peaking capacity and associated peaking energy would become available at the TVA-Kentucky utilities interconnections for sale by SEPA to the eight Kentucky municipalities.

The Economic Regulatory Administration (ERA), pursuant to the Secretary's Delegation Order No. 0204-4, effective October 1, 1977, confirmed and approved the short-term rate until March 31, 1979, through a series of Orders, the last dated December 29, 1978, 44 FR 1445. The process of developing long-term rates has been initiated. SEPA needs a limited amount of time beyond March 31, 1979, within which to develop the long-term rates for approval by the Economic Regulatory Administration (FERC) on a final basis, whichever occurs first.

DISCUSSION

ERA on several occasions invited and received both oral and written comments concerning the short-term rates. Comments, as reported by ERA, centered primarily upon issues that arose because SEPA and Kentucky Utilities have not entered into a contract to wheel Federal power to prospective municipal customers of SEPA. These comments indicated there were no objections to the short-term rates themselves as long as such rates do not prejudice the development of long-term rates nor remain in effect for a lengthy period of time. In approving the short-term rates, ERA established that no such prejudice was intended.

The short-term rates have been in effect since November 1, 1977, less than 10 months, and will be replaced within 3 months by long-term rates presently under consideration. Pending development of long-term rates, it is appropriate to confirm and approve on an interim basis an extension of the short-term rates for power sold to East Kentucky from the Laurel Project as requested by SEPA.

Order

In view of the foregoing and pursuant to the authority delegated to me by the Secretary of Energy, I hereby confirm and approve on an interim basis, effective April 1, 1979, an extension of the short-term rates for the sale of power generated at the Laurel Project to East Kentucky. These rates shall remain in effect on an interim basis until long-term rates are confirmed, approved, and placed in effect on an interim basis or until the FERC confirms and approves these or substitute short-term rates on a final basis, whichever occurs first.

Issued at Washington, DC, this 1st day of March 1979.

GEORGE S. MCISAAC, Assistant Secretary, Resource Applications.

[FR Doc. 79-7168 Filed 3-8-79; 8:45 am]

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
NOTICES

FEDERAL REGISTER, VOL. 44, NO. 48 — FRIDAY, MARCH 9, 1979

[6450-01-M]

Economic Regulatory Administration

GLENN MARTIN HELLER d.b.a. BEACON HILL GULF

Issuance of Proposed Remedial Order

Notice is hereby given that on March 6, 1979, the Proposed Remedial Order (PRO) summarized below was issued by the Northeast Enforcement District of the Economic Regulatory Administration (ERA) of the Department of Energy to Glenn Martin Heller d.b.a. Beacon Hill Gulf (Heller), 388 Cambridge Street, Boston, Massachusetts.

The PRO includes findings that Heller, a retailer of gasoline, overcharged its customers $77,406.22, in sales during the period December 1, 1976 through December 6, 1978 and that overcharges were continuing on the last day encompassed by the audit. Overcharged customers purchased from Heller at the Beacon Hill Gulf station located in Boston, Massachusetts. The reason for the overcharges is Heller's failure to properly calculate its selling prices in accordance with the applicable price regulations found in 10 CFR, 212, Subpart F.

The ERA has proposed in the PRO that Heller be required to reduce its selling prices to maximum lawful levels and refund the overcharges, with interest, by direct payments and price reductions for a period of thirty (30) months. If the total refund is not completed within thirty (30) months, any remaining amounts shall be paid to the U.S. Treasury.

In addition, the ERA has proposed that Heller be required to submit to the ERA certain data and calculations necessary for the ERA to determine the significant change in total allocations that have been made for this allocation period. Heller would be required to refund any additional overcharges, plus interest.

A copy of the PRO, with any confidential information deleted, may be obtained from the ERA at the following address:

Deputy District Director, Northeast Enforcement District, Economic Regulatory Administration, Department of Energy, 150 Causeway Street, Boston, Massachusetts 02114.

Anyone aggrieved may, on or before March 26, 1979, file a Notice of Objection with the Office of Hearings and Appeals in accordance with 10 CFR §205.193. Pursuant to 10 CFR §205.193, a Notice of Objection must be filed in duplicate, shall briefly describe how the person would be aggrieved by issuance of the PRO as a final Remedial Order, and shall state the person's intention to file a Statement of Objections pursuant to 10 CFR §205.196. No confidential information shall be included in a Notice of Objection.


In addition, any remaining amounts shall be paid to the specified period. Pursuant to 10 CFR 211.65(h), each refiner-buyer and refiner-seller is required to report to ERA in writing or by telefax the details of each transaction under the buy/sell list within forty-eight hours of the completion of arrangements therefor. Each report must identify the refiner-seller, the refiner-buyer, the refiners to whom the crude oil is to be delivered, the volumes of crude oil sold or purchased, and the period over which the delivery is expected to take place.

All reports and applications made under this notice should be addressed to: Chief, Crude Oil Allocation Branch, 20th Street Postal Station, P.O. Box 19028, Washington, D.C. 20036.

The PERA Public Information Office also has available a list of pending applications for buy/sell program allocations.

This notice is issued pursuant to Subpart G of DOE's regulations governing its administration procedures and sanctions, 10 CFR Part 205. Any person aggrieved may file an appeal with DOE's Office of Hearings and Appeals in accordance with Subpart H of 10 CFR Part 205. Any such appeal shall be filed on or before April 3, 1979.


Baron R. House, Assistant Administrator, Fuels Regulation, Economic Regulatory Administration.

BARTON ISSENDEN
Assistant Administrator for Enforcement, Economic Regulatory Administration.

[FR Doc. 79-T190 Filed 3-6-79; 8:45 am]

NOTICES

[6450-01-M]

REFINERS' CRUDE OIL ALLOCATION PROGRAM

Supplemental Notice of Allocation Period of October 1, 1978, Through March 31, 1979

The notice specified in 10 CFR 211.65(g) of the refiners' crude oil allocation (buy/sell) program for the allocation period of October 1, 1978, through March 31, 1979, was issued August 28, 1978. A corrected list was issued on September 18, 1978.

Since that list was published, the Economic Regulatory Administration (ERA) of the Department of Energy (DOE) has issued a number of additional allocations, most of these being emergency supplemental allocations issued pursuant to 10 CFR 211.65(o)(2). The ERA believes that the significant change in total allocations and sales obligations for the current allocation period caused by these additional allocations is good reason for publishing a supplemental allocation list at this time.

A supplemental buy/sell list for the allocation period October 1, 1978, through March 31, 1979, is hereby set forth below. Included as part of the list, as required by 10 CFR 211.65(g), are: the name of refiner-buyers and their eligible refiners; the quantity of crude oil each refiner-buyer is eligible to purchase; the total allocation obligation for all refiner-sellers; the fixed percentage share for each refiner-seller; and the quantity of crude oil that each refiner-seller is obligated to offer for sale to refiner-buyers. Also included is a separate list of the additional allocations that have been made since the corrected buy/sell list for this allocation period was issued on September 18, 1978.

The allocations for refiner-buyers on the supplemental buy/sell list were determined in accordance with 10 CFR 211.65(a), (b), and (c). Sales obligations for refiner-sellers were determined in accordance with 10 CFR 211.65(e) and (f). Any additional sales obligations that result from additional allocations being made during the current allocation period will be published with the buy/sell list for the April 1—September 30, 1979, allocation period.

The buy/sell list covers PAD Districts I through V, and amounts shown are in barrels of 42 gallons each, for the specified period. Pursuant to 10 CFR 211.65(h), each refiner-buyer and refiner-seller is required to report to ERA in writing or by telefax the details of each transaction under the buy/sell list within forty-eight hours of the completion of arrangements therefor. Each report must identify the refiner-seller, the refiner-buyer, the refiners to whom the crude oil is to be delivered, the volumes of crude oil sold or purchased, and the period over which the delivery is expected to take place.

All reports and applications made under this notice should be addressed to: Chief, Crude Oil Allocation Branch, 20th Street Postal Station, P.O. Box 19028, Washington, D.C. 20036.

Anyone who would like to obtain more information on the additional allocations that have been made for this allocation period may request copies of the decisions and orders that ERA has issued from: Economic Regulatory Administration, Public Information Office, 2000 M Street, N.W., Rm. B110, Washington, D.C. 20461, (202) 634-2170.

The ERA Public Information Office also has available a list of pending applications for buy/sell program allocations.

This notice is issued pursuant to Subpart G of DOE's regulations governing its administration procedures and sanctions, 10 CFR Part 205. Any person aggrieved may file an appeal with DOE's Office of Hearings and Appeals in accordance with Subpart H of 10 CFR Part 205. Any such appeal shall be filed on or before April 3, 1979.


Baron R. House, Assistant Administrator, Fuels Regulation, Economic Regulatory Administration.

[FR Doc. 79-T190 Filed 3-6-79; 8:45 am]
sellers is required to offer for sale to refiner-buyers. Refiner-sellers’ sales obligations were revised because a number of emergency supplemental allocations were issued to refiner-buyers.

<table>
<thead>
<tr>
<th>Refiner-sellers</th>
<th>Share</th>
<th>Sales obligations (barrels)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoco Oil Co.</td>
<td>0.009</td>
<td>887,533</td>
</tr>
<tr>
<td>Atlantic Richfield Co.</td>
<td>0.072</td>
<td>1,134,111</td>
</tr>
<tr>
<td>Chevron U.S.A., Inc.</td>
<td>0.006</td>
<td>2,201,817</td>
</tr>
<tr>
<td>Cities Service Co.</td>
<td>0.023</td>
<td>2,057,666</td>
</tr>
<tr>
<td>Continental Oil Co.</td>
<td>0.034</td>
<td></td>
</tr>
<tr>
<td>Exxon Co., U.S.A.</td>
<td>0.112</td>
<td></td>
</tr>
<tr>
<td>Getty Refining &amp; Marketing Co.</td>
<td>0.200</td>
<td>127,632</td>
</tr>
<tr>
<td>Gulf Refining &amp; Marketing Co.</td>
<td>0.085</td>
<td>1,065,486</td>
</tr>
<tr>
<td>Marathon Oil Co.</td>
<td>0.022</td>
<td>137,580</td>
</tr>
<tr>
<td>Mobile Oil Corp.</td>
<td>0.069</td>
<td>964,074</td>
</tr>
<tr>
<td>Phillips Petroleum Co.</td>
<td>0.039</td>
<td>246,914</td>
</tr>
<tr>
<td>Shell Oil Co.</td>
<td>0.107</td>
<td>747,820</td>
</tr>
<tr>
<td>Sun Co.</td>
<td>0.052</td>
<td>425,610</td>
</tr>
<tr>
<td>Texas Inc.</td>
<td>0.107</td>
<td>1,056,819</td>
</tr>
<tr>
<td>Union Oil Co. of California</td>
<td>0.043</td>
<td>1,411,620</td>
</tr>
</tbody>
</table>

Total sales: 12,498,017

1Granted Exception Relief—FEE 1738.
2Granted Exception Relief—FEE 2349.

ALLOCATIONS LISTED IN BUY/SELL LIST PUBLISHED SEPT. 5, 1978—ELIGIBLE REFINERIES—OCTOBER 1978 TO MARCH 1979

REGULAR ALLOCATIONS

<table>
<thead>
<tr>
<th>Refiner</th>
<th>Refinery location</th>
<th>Allocation (barrels)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asamera Oil, Inc.</td>
<td>Denver, Colo.</td>
<td>175,208</td>
</tr>
<tr>
<td>Bi-Petro, Inc.</td>
<td>Pana, Ill.</td>
<td>0</td>
</tr>
<tr>
<td>Carthage Four Corners</td>
<td>Woods Cross, Utah</td>
<td>0</td>
</tr>
<tr>
<td>CRA-Farmland Industries, Inc.</td>
<td>Scottsbluff, Neb.</td>
<td>0</td>
</tr>
<tr>
<td>CRA-Farmland Industries, Inc.</td>
<td>Phillipsburg, Kans.</td>
<td>0</td>
</tr>
<tr>
<td>Dow/Refinery</td>
<td>Bay City, Mich.</td>
<td>440,902</td>
</tr>
<tr>
<td>Evangeline Refining Co.</td>
<td>Jennings, La.</td>
<td>0</td>
</tr>
<tr>
<td>Farmers Union Central Exchange</td>
<td>Laurel, Mont.</td>
<td>1,396,657</td>
</tr>
<tr>
<td>Giant Industries</td>
<td>Bloomfield, N. Mex.</td>
<td>0</td>
</tr>
<tr>
<td>Hunt Oil Co.</td>
<td>Tuscaloosa, Ala.</td>
<td>1,523,518</td>
</tr>
<tr>
<td>Kentucky Oil &amp; Refining Co.</td>
<td>Hazard, Ky.</td>
<td>0</td>
</tr>
<tr>
<td>Little America Refining Co.</td>
<td>Sinclair, Wyo.</td>
<td>0</td>
</tr>
<tr>
<td>Little America Refining Co.</td>
<td>Casper, Wyo.</td>
<td>24,762</td>
</tr>
<tr>
<td>Macallan RP Oil Co.</td>
<td>Nophlet, Ark.</td>
<td>152,100</td>
</tr>
<tr>
<td>Marion Corp.</td>
<td>Mobile, Ala.</td>
<td>0</td>
</tr>
<tr>
<td>Mid-Tex Refining Corp.</td>
<td>Hearne, Tex.</td>
<td>0</td>
</tr>
<tr>
<td>Mount Airy</td>
<td>Mount Airy, La.</td>
<td>0</td>
</tr>
<tr>
<td>Newhall Refining Co.</td>
<td>Newhall, Calif.</td>
<td>0</td>
</tr>
<tr>
<td>OCS Corp.</td>
<td>Ocmulgee, Okla.</td>
<td>0</td>
</tr>
<tr>
<td>Pennzoil Co. (Athas)</td>
<td>Shreveport, La.</td>
<td>743,337</td>
</tr>
<tr>
<td>Plateau, Inc.</td>
<td>Bloomfield, N. Mex.</td>
<td>0</td>
</tr>
<tr>
<td>Plateau, Inc.</td>
<td>Roosevelt, Utah</td>
<td>116,027</td>
</tr>
<tr>
<td>Pride Refining Co.</td>
<td>Abilene, Tex.</td>
<td>906,452</td>
</tr>
<tr>
<td>Somerset Refining Co.</td>
<td>Somerset, Ky.</td>
<td>0</td>
</tr>
<tr>
<td>Southern Union</td>
<td>Lovington, N. Mex.</td>
<td>460,882</td>
</tr>
<tr>
<td>Southern Union</td>
<td>Monument, N. Mex.</td>
<td>663,530</td>
</tr>
<tr>
<td>Southwestern Refining Co.</td>
<td>La Barge, Wyo.</td>
<td>1,768</td>
</tr>
<tr>
<td>Texas American Petrochemicals, Inc.</td>
<td>West Branch, Mich.</td>
<td>54,422</td>
</tr>
<tr>
<td>Thunderbird Resources (Westco)</td>
<td>Cut Bank, Mont.</td>
<td>43,462</td>
</tr>
<tr>
<td>Thunderbird Resources (Westland)</td>
<td>Williston, N. Dak.</td>
<td>0</td>
</tr>
<tr>
<td>Western Refining Co.</td>
<td>Woods Cross, Utah</td>
<td>0</td>
</tr>
<tr>
<td>Wyoming Refining Co.</td>
<td>Newcastle, Wyo.</td>
<td>39,368</td>
</tr>
</tbody>
</table>

Total: 6,292,117

ALLOCATIONS FOR NEWLY CONSTRUCTED AND EXPANDED REFINING CAPACITY AND REACTIVATED REFINERIES

<table>
<thead>
<tr>
<th>Refiner</th>
<th>Refinery location</th>
<th>Estimated capacity (barrels/day)</th>
<th>Allocation (barrels)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Southernwest</td>
<td>La Barge, Wyo.</td>
<td>1,000</td>
<td>45,500</td>
</tr>
<tr>
<td>Western Refining</td>
<td>Woods Cross, Utah</td>
<td>1,500</td>
<td>63,250</td>
</tr>
<tr>
<td>Plateau, Inc.</td>
<td>Bloomfield, N. Mex.</td>
<td>1,500</td>
<td>113,500</td>
</tr>
</tbody>
</table>

Total: 427,700
sion issued a statement of policy that is one part of the Federal Energy Regulatory Commission (FERC). The staff recognizes that changes in proposed curtailment plans resulting from regulations issued under NGPA will probably require substantive changes in the staff’s analysis. Therefore, comments received on this preliminary environmental analysis will be considered to be informal comments, and no party will be bound by its preliminary comments or precluded from filing comments when the draft environmental impact statement is issued. These informal comments are requested merely to assist the staff in developing a comprehensive and relevant format for curtailment impact statements. Neither the preliminary analysis nor the request for comments are intended to be a formal part of the environmental phase of this proceeding. Neither establish a precedent to be followed in future curtailment cases. The only purpose of this one-time analysis is to identify and resolve possible problems associated with the new format. This preliminary environmental analysis has been sent to all parties to this proceeding, the Environmental Protection Agency, and to other Federal, state, and local agencies identified in the summary sheet in the analysis. The preliminary environmental analysis is on file at the Commission and is available for public inspection at the Commission’s Office of Public Information, Room 1000, 825 North Capitol Street, N.E., Washington, D.C. 20426, and at the Commission’s regional office located at 730 Peachtree Building, Atlanta, Georgia 30308. Copies are also available in limited quantities from the Commission’s Office of Public Information.

Any person who wishes to do so may file comments on the preliminary environmental analysis within 45 days of March 9, 1979.

KENNEDY F. PLUMB
Secretary.
NOTICES

At the hearing, the DOE will receive comments regarding the use of the exceptions process as a means of mitigating any hardships or inequities that the refining and petrochemical industry of Puerto Rico is presently incurring. In addition, the DOE will receive recommendations concerning other types of regulatory adjustments that might appropriately be made. Any person who 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 will preside at the hearing. A transcript of the hearing will be made and may be purchased from the reporter. The entire record of the hearing will be retained by DOE and will be made available for inspection at the Office of Hearings and Appeals. The effective dates for the increased rate adjustments and placing in increased power rates in effect on an interim basis are: April 1, 1979, for Rate Schedule P-3, F-2, E-2, and Section 2, Tex-La Electric Cooperative contract (through TP&L); and January 1, 1979, for application of Rate Schedule P-3 under Section 1.05(a) and Rate Schedule EE-2 under Section 1.06 of the Aluminum Contract.

FOR FURTHER INFORMATION CONTACT:
Walter M. Bowers, Chief, Division of Power Marketing, Southwestern Power Administration, Department of Energy, F.C. Drawer 1619, Tulsa, Oklahoma 74101 (918) 581-7529

SUPPLEMENTARY INFORMATION:
Rate Schedule P-3 for peaking power supersedes Rate Schedule F-2 (Revised). Rate Schedules F-2 (Integrated System) and F-3 (Oklahoma Utility Companies) for firm power supersedes Rate Schedule P-1. Rate Schedule F-1. Rate Schedule F-1. Rate Schedule IC-2 for interruptible capacity supersedes Rate Schedule IC. Rate Schedule EE-2 for excess energy supersedes Rate Schedule EE. Contract No. 14-02-011-864, Section 2, Tex-La Electric Cooperative (through TP&L) supersedes rate in Section 2 of that contract. Energy Regulatory Administration conditional confirmation and approval of the above present rate expire March 31, 1979. Rate Schedule P-3 applied to power and energy sales under Section 1.02 of the Aluminum Contract supersedes contract rates under Section 1.05(b) of that contract. Federal Power Commission confirmation of the present rate contract expires December 31, 1978. Rate Schedule EE-2 applied to secondary energy sales under Section 1.04 of the Aluminum Contract supersedes contract rates under Section 1.06 of that contract. Federal Power Commission confirmation of the present contract rate expires December 31, 1983.

Issued in Washington, DC, March 1, 1979.

GEORGE S. McISSAC, Assistant Secretary, Resource Applications.
March 1, 1979.

In the matter of: Southwestern Power Administration—System Rates; Aluminum Contract Rates.

Pursuant to Sections 202(a) and 305(b) of the Department of Energy Organization Act, Public Law 95-91,
the functions of the Secretary of the Interior and the Federal Power Commission under Section 5 of the Flood Control Act of 1944, 16 U.S.C. 825s, for the Southwestern Power Administration (SWPA) were transferred to and vested in the Secretary of Energy. By Delegation Order No. 0204-33, effective January 1, 1979, 53 F.R. 60636 (December 26, 1976), the Secretary of Energy delegated to the Assistant Secretary for Resource Applications the authority to develop power and transmission rates, acting by and through the Administrator, and to confirm, approve, and place in effect such rates on an interim basis, and delegated to the Federal Energy Regulatory Commission (FERC) the authority to confirm and approve on a final basis or to disapprove rates developed by FERC, and to confirm, approve, and place in effect such rates the Administrator, and to confirm, approve, and place in effect such rates the Assistant Secretary under the delegation. This rate order is issued pursuant to the delegation to the Assistant Secretary.

BACKGROUND

Existing Rates

The rates that are the subject of this order supersede the following existing SWPA rates:

<table>
<thead>
<tr>
<th>Existing Rate</th>
<th>Effective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate Schedule F-1, Firm Power</td>
<td>Aug. 9, 1957</td>
</tr>
<tr>
<td>Rate Schedule F-2 (Gresho Peak)</td>
<td>June 1, 1979</td>
</tr>
<tr>
<td>Rate Schedule EE, Excess Energy</td>
<td>Aug. 9, 1957</td>
</tr>
<tr>
<td>Rate Schedule IC, Interruptible Ca.</td>
<td>June 11, 1958</td>
</tr>
<tr>
<td>Contract Rate in Section 2, Con.</td>
<td>June 4, 1958</td>
</tr>
<tr>
<td>tract No. 14-02-001-864, Tex-La</td>
<td></td>
</tr>
<tr>
<td>Electric Cooperative, Inc. (through TP&amp;L)</td>
<td></td>
</tr>
<tr>
<td>Contract Rates in Sections 1.05(A)</td>
<td>Jan. 1, 1974,</td>
</tr>
<tr>
<td>and 1.06, Contract No. Ispa-514</td>
<td></td>
</tr>
<tr>
<td>Arkansas Power &amp; Light Company (AP&amp;L)</td>
<td></td>
</tr>
<tr>
<td>Reynolds Metals Company</td>
<td></td>
</tr>
</tbody>
</table>

The four rate schedules apply generally to customers purchasing power and energy from SWPA's integrated system, as distinguished from purchases from individual projects. The capacity and energy charges in the firm power and peaking power rate schedules have not been changed since 1957. The most recent confirmation and approval of the rate schedules was by the Economic Regulatory Administration (ERA) of the Department of Energy on November 30, 1978, 43 F.R. 57180 (December 6, 1978). This extended the confirmation and approval of the rate schedules through March 31, 1979, subject to the opportunity for further public comment. Subsequently, by Under Contract No. 14-02-001-864, executed in 1958, SWPA sold firm power and energy to the Tex-La Elec-

tric Cooperative, Inc. (Tex-La) under the F-1 Schedule. Subsequently, in 1968, this contract was amended to provide for a rate which was slightly lower than the F-1 rate. This is a barrierline sale under which, pursuant to the terms of a separate contract with Texas Power and Light Company (TP&L), TP&L provides 15,000 kilowatts of capacity and all associated energy to Tex-La for SWPA's account at a rate similar to the F-1 rate. SWPA charges Tex-La for this service at a rate which equals the amount TP&L charges SWPA for providing this service for the government. Confirmation and approval of this rate was extended by ERA at the same time as for the four system rate schedules.

Under Contract No. Ispa-514 (Alumnum Contract), executed in 1952, SWPA sells peaking power to the Arkansas Power and Light Company (AP&L), which in turn sells high load factor power to the Reynolds Metals Company (Reynolds) for use in its aluminum reduction plant. Service under the contract began in 1954 and will continue through December 31, 1983. The contract provides for rate adjustments every five years, subject to specified limits. The applicable rate for the 21st through 25th years, 1974-1978, is 3.75 mills per kilowatt-hour.

The Aluminum Contract also provides for SWPA to sell secondary energy to AP&L when it is available from certain reservoir projects integrated through the Denison-Norfork transmission line of SWPA. The contract rates for secondary energy were confirmed and approved by FPC in 1952, for the term of the contract, with no contractual provisions for review or redetermination. The contract rate for the 21st through 30th years is 2 mills per kilowatt-hour.

PUBLIC NOTICE AND COMMENT

The Southwestern Power Administration prepared a Current Power Repayment Study dated December 1977 for the integrated system, which showed that the current system rate schedules and contract rates failed to produce revenues sufficient to pay all power costs and the investment allocated to power in a reasonable period of years as required by Section 5 of the Flood Control Act of 1944. The Revised Power Repayment Study dated December 1977 showed that in order to accomplish repayment, average annual revenues would have to be increased by $20.1 million. This would be an increase of about 25 percent over current revenue levels for the integrated system. SWPA then developed Tentative Rate Schedules from a Rate Design Study dated March 1978, which schedules, when applied to estimated power and energy sales, would produce the additional revenues.

The public participation process produced numerous and varied questions and comments. All of these have been considered; many have been accepted and incorporated in developing the revised rates which are confirmed, approved, and placed in effect by this order. The Revised Power Repayment Study dated November 1978, prepared after consideration of these comments, shows that in order to accomplish repayment, an increase in average annual revenues of $16.5 million, or 32 percent above the current annual revenues from the integrated system, is needed. Responses to the major comments, criticisms and alternatives offered during the comment period are explained in the following discussion.

DISCUSSION

ARKCO CONTRACTS

During the course of the public review of the Current and Revised Power Repayment Studies, the SWPA staff also continued its examination of the assumptions made in the studies. In keeping with the intent of the Arkansas Electric Cooperative Corpora-

tion (Arkco) to transfer operation of its Bailey and Fitzhugh thermal generating plants to AP&L around 1980, the staff had assumed the termination of the contracts, numbered 14-02-001-864 and 14-02-001-1114, in 1980. Contract obligations and recent amendments made such assumptions inappropriate and dictated a revision to the studies.
The contract having the major effect on the Power Repayment Studies is the Bailey pooling arrangement wherein SWPA schedules operation of the Bailey generating plant and is able to sell hydro energy when surplus water is available at a fuel-saving rate, to replace thermal energy which otherwise would have been generated by Arkco. By operating the two systems, SWPA realized a saving in the past and to estimate the replacements which have been made in the past, present, and future, and therefore, is not responsible for SWPA transmission costs, and should not be charged for the cost of purchased energy. They also contend that SWAP has changed accounting methodology from that used when the contract was approved, creating the alleged shortfall.

The company's arguments on transmission costs and accounting methodology lack merit because SWPA's operations are on a system basis and that part of the power and energy supplied is delivered through multiple interconnections with AP&L. Power and energy from the SWPA system cannot be specified as coming from a particular project at any particular time. Initial approval by FPC was justified as a sale from the integrated system, as opposed to a busbar sale. The cost of the integrated transmission system, as well as the cost of purchased energy for system support was included as a part of the costs assigned to this service. Standard accounting methodology must apply to all sales from the system.

The propriety of a thirty-year contract for the sale of power to a nonpreference customer without the right of withdrawal is not without substantial doubt. However, by its terms the Aluminum Contract expires in 1984. AP&L and Reynolds have been notified that the contract will not be renewed. Thus the power involved will be available for sale to preference customers within five years.

As to the Aluminum Contract rate limit of 122% percent of the initial rate for the last five year period of the 30-year contract, this limitation has been determined to be inconsistent with the mandates of Section 5 of the Flood Control Act of 1944 and thus be unenforceable. This limit operates at this time to prevent the charging of rates "having regard to the recovery" of operating costs from AP&L. Moreover, by precluding adequate cost recovery from AP&L, the limit results in an increase of system rates to consumers served by preference customers, thereby precluding disposal of power.
to such consumers "at the lowest possible rates" consistent with sound business principles.

Based on the above considerations, it is thus reasonable to require AP&E to pay for power received during the last five years at the same rate determined at this time to apply to all customers.

An Aluminum Contract rate study has been developed which outlines the history of operations and shows the estimated deficiencies under the contract rate limitations over the years. No adjustment has been made in the Power Repayment Studies to reflect this shortfall because it would require Congressional action to forgive such a past deficiency under requirements of Section 5 of the Flood Control Act of 1944. It has been suggested that the repayment of the deficiency under the Aluminum Contract be postponed until 1990, when the investments are all repaid. However, SWPA found that if this were done, surplus revenues at that time would be incapable of paying the postponed deficiency with imputed interest in any period of time.

PRIOR DEFICIENCIES

Numerous comments were received objecting to the inclusion of previous system deficiencies in the costs to be recovered from future users. Section 5 of the Flood Control Act of 1944 requires that all costs associated with the power marketing activities of the government be recovered from the rates. If costs are not paid in a certain year, they must be deferred for payment when revenues become sufficient to do so. The DOE manual on repayment (formerly Department of the Interior 730 DM 4, adopted for DOE by IMD 1701, when it was determined to go public during the information forums) recognizes this and provides that deficiencies in any year are to be capitalized and repaid with imputed interest in later years even before funds are applied to the reduction of the debt associated with the original investment. In addition, Congressional action amending Section 5 of the Flood Control Act of 1944 would be required to forgive such past deficiencies.

OPERATING EXPENSES

A number of comments questioned the Corps' estimate of its future operation and maintenance costs as too high, based largely on a comparison of prior increases. We have no reason to believe that the estimates are unreasonable. The Corps considers past price trends, but also reviews other factors, such as use of equipment, past maintenance expenses and practices, and personnel needs and costs. It also includes a project-by-project look at what may be required. The Corps' actual O&M expenses for FY 1975, 1976, and 1977 have increased by 18.5 percent, 15.4 percent, and 24.2 percent. Their estimates for FY 1977 proved to be too low, and their estimates for FY 1978 are closely in line with actual figures received by SWPA recently.

Another comment was that Corps' replacement costs may have been included under O&M expenses. This possibility is considered in the action that was taken to reduce the estimates of future replacements.

SWPA's estimates of purchased energy costs also were questioned as too high. These costs, involving fuel cost estimates as well as other costs, are estimated pursuant to the Departmental Manual (DOI 730 DM 4; DOE IMD 1701) for the five-year cost evaluation period. In the past, SWPA estimated future costs for purchased energy by determining the quantities of energy available from known sources, ranking such sources in increasing order of cost and then estimating the total cost according to the usage required.

The method now used is an area approach of basing the cost for purchased thermal energy for five years through 1982 on expected costs in the Southwest Power Pool area and by averaging in fuel costs weighted by type of thermal energy available in the Southwest area.

SWPA's estimate of the projected area weighted average fuel cost was only one part of its attempt to be realistic and reasonable in estimating the cost of purchased energy in FY 1982. The final estimate for that year of 26.1 mills per kilowatt-hour takes into account considerably higher estimated fuel costs, as well as the area average costs.

Purchased energy costs to SWPA for FY 1975, 1976, and 1977 increased by 2.4 percent, 32 percent, and 128.3 percent. SWPA does not have firm contracts for the large quantity of energy purchased during critical years. It paid from 3.5 mills per kilowatt-hour to 40.5 mills per kilowatt-hour during FY 1977, and a review of possible sources of purchased energy to SWPA for the future indicates that the price will probably average from 20.3 mills per kilowatt-hour in FY 1979 to 26.1 mills per kilowatt-hour in FY 1982.

Every attempt is, and will be, made to minimize system purchased energy costs. However, for the purpose of determining costs expected in future years, the final cost estimate appears to be both reasonable and realistic for under both good and bad water conditions.
NOTICES

and 5 mills for all kilowatt-hours over 440 per month. A 40 cents per kilowatt-hour charge is provided where the customer takes delivery from and at the voltage of the 138 or 161 kilovolt facilities owned or leased by the government, or at low or intermediate voltages from substations and transmission facilities, and if the government is thereby relieved of additional transmission costs. A discount of 10 cents is allowed if delivery of power and energy is made from the 69, 138 or 161 kilovolt facilities owned or leased by the government and if transformation and substation facilities are required at the point of delivery and are furnished by the power customer at no cost to the government.

Rate Schedules P-2 and P-3 supersede Rate Schedule P-1 for firm power service. The P-2 rate adopts the adder principal for transmission and transformation service charges, as opposed to the present capacity discount theory, and energy blocking levels have been changed to charge for the first 100 hours, for the next 340 hours, and for all in excess of 440 hours use per kilowatt. The P-2 rate also provides for reimbursement to SWPA of purchased 'energy costs where the specific costs can be determined for a customer. At this time, this provision would apply to the cities of Fulton and Lamar, Missouri.

The P-3 Rate Schedule applies only to sales to Oklahoma and Arkansas municipalities served through the new Oklahoma Companies arrangements, and provides for single capacity and energy charges for federal power and energy, and for reimbursement for thermal generation provided by the Public Service Company of Oklahoma (PSO) and the Oklahoma Gas and Electric Company (OG&E). The new Oklahoma Companies arrangements provide for borderline power and energy sales to a number of municipalities in the service areas of PSO and OG&E, SWPA has separate contracts with each company. The contracts provide for SWPA to pay transmission service charges imposed by the companies for service to SWPA preference customers. The charges are broken down into capacity and energy components and are different for each company. There are also separately-stated charges for transformation to load center delivery when SWPA also pays the transmission costs. SWPA is reimbursed for the cost of energy purchases under the contracts by the customers. A part of the transmission costs are borne by the customers through the application of the rate for load center service.

The present Rate Schedule P-2 (Revised) applies to the sales of peaking power from SWPA's 161 kilovolt high voltage grid with a guarantee of a minimum of 1200 kilowatt-hours per kilowatt. The capacity charge is $1.20 per kilowatt, and the energy charge is 2 mills per kilowatt-hour. There is a Transmission Service Charge to recover SWPA's costs in providing delivery service beyond its own high voltage grid. At this time, the only customers billed for a Transmission Service Charge are the Associated Electric Cooperative ($2,647,100 annually) and the city of Hermann, Missouri ($655,700 annually).

Rate Schedule P-3 superseded Rate Schedule P-2 (Revised). The transmission service charge is retained pending the successful completion of negotiations with the Associated Electric Cooperatives for a new contract. The Transmission Service Charge will terminate when the new contract takes effect, as provided in Public Law 95-456.

One group of comments regarding rate structure urged the blocking of the energy rate to more closely relate to the product SWPA has to sell, that is, peaking power and energy, and to make the rate schedules between peaking and firm consistent. The suggestion was made to charge the first block from 150 kilowatt-hours per kilowatt per month to 100 kilowatt-hours per kilowatt per month, and the second block from the next 250 kilowatt-hours per kilowatt per month to the next 340 kilowatt-hours per kilowatt per month. This recommendation has been adopted.

The principle of increasingly higher charges for energy for each succeeding energy block is continued in the firm power rate schedules and is now included in the peaking power rate schedule. This inverted rate principle is appropriate because the higher the load factor, the more purchased energy costs are included. Since SWPA has limited firm hydro energy for sale, the inverted rate is intended to discourage high load factor usage in the firm rate schedules and to recover purchased energy costs in all rate schedules.

The energy blocks have been adjusted to conform more closely with the characteristics of SWPA's hydro supply, as has previously been the case with the guaranteed minimum 1200 kilowatt-hours per kilowatt per year of energy under the current P-2 (Revised) Rate Schedule. With this adjustment, the first block in the firm power rate becomes 100 hours use per kilowatt per month instead of 50. The breaking point of 440 hours use per kilowatt per month is maintained as a practical dividing point of approximately 60 percent load factor use per month to cover the general range of supply to customers purchasing their full firm power requirements, as distinguished from customers who require energy at high load factor use.

The guaranteed minimum 1200 kilowatt-hours per kilowatt per year of energy under the peaking rate schedule can be applied to the one remaining contract by SWPA, for 1500 hours use per kilowatt per year of energy with Tex-La, as well as the 2400 hour contract with AP&L. There are some purchased energy costs incurred to meet these lower energy commitments in the peaking rate, but not nearly the quantity needed as load factors increase.

Rate Schedule EE-2 replaces Rate Schedule EE for Excess Energy and Rate Schedule IC-2 replaces Rate Schedule IC for Interruptible Capacity.

The contractual rate under Contract No. 14-02-001-864, Tex-La Electric Cooperative (through TP&E), has been increased to equal the costs of service from the Texas Power and Light Company (TP&E) to Tex-La for the account of SWPA. TP&E buys power and energy from SWPA at the system peaking rate. When this rate is increased, SWPA must increase its contract rate to Tex-La. SWPA in turn, to recover costs, must increase its contract rate to Tex-La.

Section 106(A) of the Aluminum Contract provides that the Secretary, upon further redetermination, may retroactively adjust the peaking power and energy rates under the Aluminum Contract to the beginning of the then current five-year period or from January 1, 1979. For this reason, Rate Schedule P-3, applicable to other SWPA customers similarly situated, is appropriate for billings under the Aluminum Contract beginning January 1, 1979. While there is no contractual provision for change in the secondary energy rate of 2 mills per kilowatt-hour, it is also appropriate that AP&L pay the same rate as other customers for this service under the Rate Schedule EE-2, which is 3 mills per kilowatt-hour.

ENVIRONMENTAL IMPACT

SWPA has reviewed the possible environmental impacts of the rate adjustments under consideration and has concluded that because the impacts are speculative and insignificant, no environmental impact statement is required under the National Environmental Policy Act of 1969 (NEPA).
**NOTICES**

13073

**PRICE STABILITY**

SWPA is a "government enterprise" within the meaning of the price standards of the President's Council on Wage and Price Stability. The rate increases approved herein comply with the operating margin limitations of these standards because the revenues will be only those necessary to cover SWPA's costs and expenses. The reduction in the capacity charge by 10 cents per kilowatt per month until the Truman Project is on line will avoid any controversy as to the possibility of an impermissible operating surplus within the meaning of the standards.

**REVISED STUDIES**

Subsequent to the close of the public participation period, new Power Repayment Studies dated November 1978 were developed, which incorporated the changes discussed above and other minor adjustments. The Revised Power Repayment Study dated November 1978 shows that in order to accomplish repayment average annual revenues would have to be increased by $16.5 million. This would be an increase of about 33 percent above current revenue levels for the integrated system. SWPA, then developed new system rate schedules from its Rate Design Study dated November 1978, which schedules, when applied to estimated power and energy sales, will produce the additional revenues.

The first step of the two-step rate adjustment will produce an additional $1.49 million annually before the Harry S. Truman Project becomes operative.

**AVAILABILITY OF INFORMATION**

Information regarding this rate adjustment including studies, comments, transcripts, and other supporting material are available for public review in the offices of the Southwestern Power Administration, 333 W. 4th, Tulsa, Oklahoma 74101 and in the Office of the Director of Power Marketing Coordination, 12th & Pennsylvania Avenue N.W., Washington, D.C. 20461.

**SUBMISSION TO THE FEDERAL ENERGY REGULATORY COMMISSION**

The rates herein confirmed, approved, and placed in effect on an interim basis, together with supporting documents, will be submitted promptly to the Federal Energy Regulatory Commission for confirmation and approval on a final basis.

**ORDER**

In view of the foregoing and pursuant to the authority delegated to me by the Secretary of Energy, I hereby:

1. Confirm and approve on an interim basis, effective April 1, 1979, the attached five Rate Schedules and one Contract Rate for the Southwestern Power Administration, which supersede and replace the rate schedules and contract rate named:

<table>
<thead>
<tr>
<th>Rate</th>
<th>Rate superseded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate Schedule P-3, Peaking P-2 (Revised).</td>
<td></td>
</tr>
<tr>
<td>Rate Schedule P-2, Firm F-1, Firm Power.</td>
<td>Rate Schedule P-3, Peaking P-2 (Revised).</td>
</tr>
<tr>
<td>Rate Schedule P-2, Firm F-1, Firm Power.</td>
<td>Rate Schedule P-3, Peaking P-2 (Revised).</td>
</tr>
<tr>
<td>Rate Schedule EE-2, Excess EE, Excess Energy</td>
<td>Rate Schedule EE-2, Excess EE, Excess Energy</td>
</tr>
<tr>
<td>Rate Schedule IC-1, Inter-IC, Interruptible Capacity</td>
<td>Rate Schedule IC-1, Inter-IC, Interruptible Capacity</td>
</tr>
<tr>
<td>Cooperative (through Tex-La Electric)</td>
<td>Cooperative (through Tex-La Electric)</td>
</tr>
</tbody>
</table>

These rates shall remain in effect on an interim basis for a period of 12 months unless such period is extended or until the FERC confirms and approves these or substitute rates on a final basis.

2. Confirm and approve on an interim basis, effective January 1, 1979, the application of Rate Schedule P-3 under Section 1.05(A) of Contract No. Issa-514, Arkansas Power and Light Company/Riddles Metals Company (Alumnum Contract). This power and energy sales provided under Section 1.02 of that contract, and the application of Rate Schedule EE-2 under Section 1.06 to secondary energy sales provided under Section 1.04 of that contract. These rates shall remain in effect on an interim basis for five years or until the FERC confirms and approves these or substitute rates on a final basis.

Issued at Washington, D.C. this 1st day of March 1979.

GEORGE S. MCISAC,
Assistant Secretary, Resource Applications.

**Auxiliary Power and Peaking Energy. The rates approved herein comply with the operating margin limitations of these standards because the revenues will be only those necessary to cover SWPA's costs and expenses. The reduction in the capacity charge by 10 cents per kilowatt per month until the Truman Project is on line will avoid any controversy as to the possibility of an impermissible operating surplus within the meaning of the standards.

**MONTHLY RATES**

**CAPACITY CHARGE**

(a) During the period until the first day of the month following the date the first power generating unit at the Harry S. Truman Dam is placed in commercial operation in the integrated system of SWPA, the capacity charge shall be:

- $1.30 per kilowatt of Peaking Billing Demand for delivery at 138 or 161 kilovolts.
- Commencing on the first day of the month following the date the first power generating unit at the Harry S. Truman Dam is placed in commercial operation in the integrated system of SWPA, the capacity charge shall be:

<table>
<thead>
<tr>
<th>Rate</th>
<th>Rate superseded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate Schedule P-3, Peaking P-2 (Revised).</td>
<td></td>
</tr>
<tr>
<td>Rate Schedule P-2, Firm F-1, Firm Power.</td>
<td>Rate Schedule P-3, Peaking P-2 (Revised).</td>
</tr>
<tr>
<td>Rate Schedule P-2, Firm F-1, Firm Power.</td>
<td>Rate Schedule P-3, Peaking P-2 (Revised).</td>
</tr>
<tr>
<td>Rate Schedule EE-2, Excess EE, Excess Energy</td>
<td>Rate Schedule EE-2, Excess EE, Excess Energy</td>
</tr>
<tr>
<td>Rate Schedule IC-1, Inter-IC, Interruptible Capacity</td>
<td>Rate Schedule IC-1, Inter-IC, Interruptible Capacity</td>
</tr>
<tr>
<td>Cooperative (through Tex-La Electric)</td>
<td>Cooperative (through Tex-La Electric)</td>
</tr>
</tbody>
</table>

(b) Supplementary Peaking Energy: $0.0035 per kilowatt-hour of Supplementary Peaking Energy.

**Capacity charge adjustments for conditions of service.**

(a) A charge of $0.20 per kilowatt-hour for the first 1,200-kilowatt-hours per year accumulated as scheduled each month.

(b) A charge of $0.007 per kilowatt-hour for energy in excess of the first 1,200-kilowatt-hours per year per year accumulated as scheduled each month.

**ENERGY CHARGE**

(a) Peaking Energy:

<table>
<thead>
<tr>
<th>Rate</th>
<th>Rate superseded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate Schedule P-3, Peaking P-2 (Revised).</td>
<td></td>
</tr>
<tr>
<td>Rate Schedule P-2, Firm F-1, Firm Power.</td>
<td>Rate Schedule P-3, Peaking P-2 (Revised).</td>
</tr>
<tr>
<td>Rate Schedule P-2, Firm F-1, Firm Power.</td>
<td>Rate Schedule P-3, Peaking P-2 (Revised).</td>
</tr>
<tr>
<td>Rate Schedule EE-2, Excess EE, Excess Energy</td>
<td>Rate Schedule EE-2, Excess EE, Excess Energy</td>
</tr>
<tr>
<td>Rate Schedule IC-1, Inter-IC, Interruptible Capacity</td>
<td>Rate Schedule IC-1, Inter-IC, Interruptible Capacity</td>
</tr>
<tr>
<td>Cooperative (through Tex-La Electric)</td>
<td>Cooperative (through Tex-La Electric)</td>
</tr>
</tbody>
</table>

(b) Supplementary Peaking Energy: $0.0035 per kilowatt-hour of Supplementary Peaking Energy.

(c) A customer which receives Hydro and/or Seasonal Peaking Power at two or more delivery voltages will be charged the adjustment associated with the lower voltage, provided, however, that such charge shall not apply to the number of kilowatts of Peaking Billing Demand which exceed the Peaking Actual Demand recorded at the lower voltage for a particular month or for the preceding eleven months.

For unauthorized overruns. For each billing period during which there is a violation involving an unauthorized overrun, the capacity charge for energy overrun shall be charged at rates as of SWPA's capacity. If such overrun is determined to be inadvertent, such charge shall be billed and paid for at twelve times the rate for Peaking Energy set forth in (b)(2)(l)(A), above.

**Transmission service charge.** Where transmission service is provided through facilities.
NOTICES

Applicable: To wholesale power customers purchasing Firm Power and Firm Energy at points of delivery from the transmission lines at SWPA's facilities owned and operated by SWPA or which are defined by contract with the customer as a part of the system of SWPA (SWPA Integrated System). This notice will be issued to each customer who is subject to these rates. Applicable rates will be sent at such time as SWPA determines that they become effective. Note that the rates described in this notice are interim rates and that permanent rates are expected to be published in the future. For further information, contact SWPA's Marketing Department.

Firm Power Rate Schedule F-2*—WHOLESALE RATES FOR FIRM POWER (CUSTOMERS FROM SWPA INTEGRATED SYSTEM)

Effect: As of April 1, 1979, and thereafter in accordance with Rule Order No. SWPA-1 of the Assistant Secretary for Resource Applications issued March 1, 1979.

Available in the marketing area of Southwestern Power Administration (SWPA), described generally as the States of Arkansas, Kansas, Louisiana, Missouri, Oklahoma, and Texas.

Applicable: To wholesale power customers purchasing Firm Power and Firm Energy at points of delivery from the transmission lines at SWPA's facilities owned and operated by SWPA or which are defined by contract with the customer as a part of the system of SWPA (SWPA Integrated System).

Character of Service: Three-phase, alternating current, delivered at approximately 60 hertz, at the nominal voltage and points of delivery, and in such quantities as specified by contract (Firm Contract Demand). All power requirements, other than peaking power from SWPA, which exceed the Firm Contract Demand shall be obtained from a source of power supply other than SWPA.

ENERGY ASSOCIATED WITH FIRM POWER

1. SWPA will furnish Firm Energy to a customer which has no alternative source of power supply, and which does not purchase peaking power and energy from SWPA, in amounts not less than two consecutive hours and/or Seasonal Peaking Power scheduled for delivery is reduced by SWPA for a period or periods of not less than two consecutive hours by reason of an outage caused by either an uncontrollable force, or the installation, maintenance, or replacement of equipment, the customer's capacity charge for such month will be reduced for each such reduction in service by an amount computed under the formula—

\[ R = \frac{R \times C \times K \times H}{E} \]

with the factors defined as follows:

- \( R \) = the amount of reduction in the monthly capacity charge for a particular reduction of not less than two consecutive hours during any month, except that the total amount of any such reduction in the capacity charge for any month shall not be greater than the product of the capacity charge times the Peaking Contract Demand.
- \( C \) = the capacity charge plus applicable adjustments for conditions of service for Hydro and/or Seasonal Peaking Power for such month.
- \( K \) = the number of kilowatts of such particular reduction in Hydro and/or Seasonal Peaking Power.
- \( H \) = the number of hours of such particular reduction.

Rate Schedule F-2*—WHOLESALE RATES FOR FIRM POWER (CUSTOMERS FROM SWPA INTEGRATED SYSTEM)

Effective: As of April 1, 1979, and thereafter in accordance with Rule Order No. SWPA-1 of the Assistant Secretary for Resource Applications issued March 1, 1979.

Available in the marketing area of Southwestern Power Administration (SWPA), described generally as the States of Arkansas, Kansas, Louisiana, Missouri, Oklahoma, and Texas.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979

Applicable: To wholesale power customers purchasing Firm Power and Firm Energy at points of delivery from the transmission lines at SWPA's facilities owned and operated by SWPA or which are defined by contract with the customer as a part of the system of SWPA (SWPA Integrated System). This notice will be issued to each customer who is subject to these rates. Applicable rates will be sent at such time as SWPA determines that they become effective. Note that the rates described in this notice are interim rates and that permanent rates are expected to be published in the future. For further information, contact SWPA's Marketing Department.

Firm Power Rate Schedule F-2*—WHOLESALE RATES FOR FIRM POWER (CUSTOMERS FROM SWPA INTEGRATED SYSTEM)

Effect: As of April 1, 1979, and thereafter in accordance with Rule Order No. SWPA-1 of the Assistant Secretary for Resource Applications issued March 1, 1979.

Available in the marketing area of Southwestern Power Administration (SWPA), described generally as the States of Arkansas, Kansas, Louisiana, Missouri, Oklahoma, and Texas.

Applicable: To wholesale power customers purchasing Firm Power and Firm Energy at points of delivery from the transmission lines at SWPA's facilities owned and operated by SWPA or which are defined by contract with the customer as a part of the system of SWPA (SWPA Integrated System).

Character of Service: Three-phase, alternating current, delivered at approximately 60 hertz, at the nominal voltage and points of delivery, and in such quantities as specified by contract (Firm Contract Demand). All power requirements, other than peaking power from SWPA, which exceed the Firm Contract Demand shall be obtained from a source of power supply other than SWPA.

ENERGY ASSOCIATED WITH FIRM POWER

1. SWPA will furnish Firm Energy to a customer which has no alternative source of power supply, and which does not purchase peaking power and energy from SWPA, in amounts not less than two consecutive hours and/or Seasonal Peaking Power scheduled for delivery is reduced by SWPA for a period or periods of not less than two consecutive hours by reason of an outage caused by either an uncontrollable force, or the installation, maintenance, or replacement of equipment, the customer's capacity charge for such month will be reduced for each such reduction in service by an amount computed under the formula—

\[ R = \frac{R \times C \times K \times H}{E} \]

with the factors defined as follows:

- \( R \) = the amount of reduction in the monthly capacity charge for a particular reduction of not less than two consecutive hours during any month, except that the total amount of any such reduction in the capacity charge for any month shall not be greater than the product of the capacity charge times the Peaking Contract Demand.
- \( C \) = the capacity charge plus applicable adjustments for conditions of service for Hydro and/or Seasonal Peaking Power for such month.
- \( K \) = the number of kilowatts of such particular reduction in Hydro and/or Seasonal Peaking Power.
- \( H \) = the number of hours of such particular reduction.

Rate Schedule F-2*—WHOLESALE RATES FOR FIRM POWER (CUSTOMERS FROM SWPA INTEGRATED SYSTEM)

Effective: As of April 1, 1979, and thereafter in accordance with Rule Order No. SWPA-1 of the Assistant Secretary for Resource Applications issued March 1, 1979.

Available in the marketing area of Southwestern Power Administration (SWPA), described generally as the States of Arkansas, Kansas, Louisiana, Missouri, Oklahoma, and Texas.

Applicable: To wholesale power customers purchasing Firm Power and Firm Energy at points of delivery from the transmission lines at SWPA's facilities owned and operated by SWPA or which are defined by contract with the customer as a part of the system of SWPA (SWPA Integrated System). This notice will be issued to each customer who is subject to these rates. Applicable rates will be sent at such time as SWPA determines that they become effective. Note that the rates described in this notice are interim rates and that permanent rates are expected to be published in the future. For further information, contact SWPA's Marketing Department.

Firm Power Rate Schedule F-2*—WHOLESALE RATES FOR FIRM POWER (CUSTOMERS FROM SWPA INTEGRATED SYSTEM)

Effect: As of April 1, 1979, and thereafter in accordance with Rule Order No. SWPA-1 of the Assistant Secretary for Resource Applications issued March 1, 1979.

Available in the marketing area of Southwestern Power Administration (SWPA), described generally as the States of Arkansas, Kansas, Louisiana, Missouri, Oklahoma, and Texas.

Applicable: To wholesale power customers purchasing Firm Power and Firm Energy at points of delivery from the transmission lines at SWPA's facilities owned and operated by SWPA or which are defined by contract with the customer as a part of the system of SWPA (SWPA Integrated System). This notice will be issued to each customer who is subject to these rates. Applicable rates will be sent at such time as SWPA determines that they become effective. Note that the rates described in this notice are interim rates and that permanent rates are expected to be published in the future. For further information, contact SWPA's Marketing Department.

Firm Power Rate Schedule F-2*—WHOLESALE RATES FOR FIRM POWER (CUSTOMERS FROM SWPA INTEGRATED SYSTEM)

Effect: As of April 1, 1979, and thereafter in accordance with Rule Order No. SWPA-1 of the Assistant Secretary for Resource Applications issued March 1, 1979.

Available in the marketing area of Southwestern Power Administration (SWPA), described generally as the States of Arkansas, Kansas, Louisiana, Missouri, Oklahoma, and Texas.
NOTICES

Firm actual demand. The term “Firm Actual Demand” for any month means the maximum coincidental 30-minute integrated demand recorded during such month.

Firm contract demand. The term “Firm Contract Demand” means the minimum rate in kilowatts which SWPA is by contract obligated to deliver Firm Energy during any 30-minute period of any billing period.

Firm billing demand. Unless otherwise provided by contract, the term “Firm Billing Demand” for any month means either the “Firm Contract Demand”, or the “Firm Actual Demand”, whichever is greater.

Adjustment for reduction in service. If during a month SWPA is unable to fulfill its contract commitment to deliver Firm Power and Firm Energy for a period or periods of not less than two consecutive hours by reason of an outage caused by either an uncontrollable force, or the installation, maintenance, or replacement of equipment, the customer's capacity charge for such month will be reduced for each such reduction in service by an amount computed under the formula: 

R = C x K x H

with the factors defined as follows:
R = the amount of reduction in the monthly capacity charge for a particular reduction in service of not less than two consecutive hours during any month, except that the total amount of any such reduction in the capacity charge for any month shall not be greater than the product of the capacity times the Firm Contract Demand.
K = the number of kilowatts of such particular reduction in Firm Power.
H = the number of hours of such particular reduction.
TH = the total number of hours in such month.

RATE SCHEDULE P-1—WHOLESALE RATES FOR FIRM POWER

(Customers Through Oklahoma Utility Companies)

Effective: As of April 1, 1979, and thereafter in accordance with Rate Order No. SWPA-1 of the Assistant Secretary for Resource Applications issued March 1, 1979.

Available: In the marketing area of Southwestern Power Administration (SWPA), and the service areas of the Public Service Company of Oklahoma and Oklahoma Gas and Electric Company (Oklahoma Utility Companies), described generally as the States of Arkansas, Kansas, Louisiana, Missouri, Oklahoma, and Texas.

Applicable: To wholesale power customers purchasing Firm Power and Firm Energy from SWPA (SWPA-Customer Contract) at points of delivery on transmission facilities owned by the Oklahoma Utility Companies which demand power and Firm Energy from transmission facilities owned by the Oklahoma Utility Companies.

Character and Conditions of Service: Three-phase, alternating current, delivered at approximately 60 hertz, at the nominal voltage and points of delivery, and in such quantities and times and in such amounts as SWPA determines to be available.

ENERGY ASSOCIATED WITH FIRM POWER

1. SWPA will furnish Firm Energy to a customer purchasing such energy from SWPA from the system of the Oklahoma Utility Companies, in such quantities as may be required to fulfill its system load requirements.

Monthly Rates

CAPACITY CHARGE

(a) During the period until the first day of the month following the date the first power generation unit at the Harry S. Truman Dam is placed in commercial operation in the integrated system of SWPA, the capacity charge shall be $1.95 per kilowatt of Billing Demand.

(b) Commencing on the first day of the month following the date the first power generating unit at the Harry S. Truman Dam is placed in commercial operation in the integrated system of SWPA, the capacity charge shall be $1.95 per kilowatt of Billing Demand.

ENERGY CHARGE

(i) $0.0035 per kilowatt-hour for federally generated Firm Energy.

(ii) An amount in dollars equal to the actual cost to SWPA, of thermal-generated energy purchased by SWPA specifically for service to the customer.

Adjustment for power factor: The customer will be required to maintain an average power factor at each point of delivery of not less than 95 percent (95%) lagging. Such average power factor will be that defined and computed under the SWPA-Customer Contract.

For each 1 percent (1%), or major fraction thereof, by which average power factor is less than 95 percent (95%), the customer's monthly bill for Firm Power and Firm Energy will be increased by 1 percent (1%).

Actual demand. The “Actual Demand” will be for any month the number of kilowatts equal to the sum of the highest 30-minute integrated demands recorded during such month at the point or points of delivery.

Contract demand. The “Contract Demand” will be for any month the highest 30-minute integrated demand in kilowatts at which SWPA is obligated during such month to cause energy to be delivered to the customer.

Billing demand. The “Billing Demand” for any month during the period when the system load requirements of the customer are fulfilled by power and energy purchased from SWPA will be either the “Contract Demand” or the “Actual Demand”, whichever is greater.

2. The “Billing Demand” for any month during the period on and after the date when the system load requirements of the customer are fulfilled by power and energy purchased from SWPA will be a source of power supply other than SWPA, will be the “Contract Demand”.

Adjustment for reduction in service. If during any month SWPA is unable to fulfill its contract requirement to deliver Firm Power and Firm Energy for a period or periods of not less than two consecutive hours by reason of an outage caused by either an uncontrollable force, or the installation, maintenance, or replacement of equipment, the customer's capacity charge for such month will be reduced for each such reduction in service by an amount computed under the formula:

R = C x K x H

TH

with the factors defined as follows:
R = the amount of reduction in the monthly capacity charge for a particular reduction in service of not less than two consecutive hours during any month, except that the total amount of any such reduction in the capacity charge for any month shall be greater than the product of the capacity times the Firm Contract Demand.
K = the number of kilowatts of such particular reduction in Firm Power.
H = the number of hours of such particular reduction.
TH = the total number of hours in such month.

RATE SCHEDULE IC—WHOLESALE RATES FOR EXCESS ENERGY

Effective: As of April 1, 1979, and thereafter in accordance with Rate Order No. SWPA-1 of the Assistant Secretary for Resource Applications issued March 1, 1979.

Available: In the marketing area of Southwestern Power Administration (SWPA), described generally as the States of Arkansas, Kansas, Louisiana, Missouri, Oklahoma, and Texas.

Applicable: To wholesale power customers who by contract may purchase Excess Energy.

Character and Conditions of Service: Three-phase, alternating current, delivered at approximately 60 hertz, at the nominal voltage and points of delivery specified by contract.

ENERGY ASSOCIATED WITH RATE SCHEDULE IC

Excess Energy will be furnished at such times and in such amounts as SWPA determines to be available.

RATE

Energy charge: $0.003 per kilowatt-hour.

RATE SCHEDULE IC-2—WHOLESALE RATES FOR INTERRUPTIBLE CAPACITY

Effective: As of April 1, 1979, and thereafter in accordance with Rate Order No. SWPA-1 of the Assistant Secretary for Resource Applications issued March 1, 1979.

Available: In the marketing area of Southwestern Power Administration (SWPA), described generally as the States of Arkansas, Kansas, Louisiana, Missouri, Oklahoma, and Texas.

Applicable: To wholesale power customers purchasing Interruptible Capacity which is received by the customer at points of delivery from transmission lines or facilities owned and operated by SWPA.

Character and Conditions of Service: Three-phase, alternating current, delivered
at approximately 60 hertz, at the nominal voltage and points of delivery, and in such quantities as specified by contract.

**ENERGY ASSOCIATED WITH INTERRUPTIBLE CAPACITY**

Energy associated with Interruptible Capacity will be furnished by SWPA at such times and in such amounts as SWPA determines to be available.

**DAILY RATE**

Capacity charge: $0.05 per kilowatt of Interruptible Billing Demand.

Energy charge: $0.0035 per kilowatt-hour.

**Intermittent billing demand.** The term "Intermittent Billing Demand" for any day means an amount equal to either:

1. The maximum rate in kilowatts which SWPA is obligated to deliver energy associated with interruptible capacity or the greatest 30-minute integrated demand recorded during such day, whichever is greater.
2. The maximum rate in kilowatts for the delivery of energy associated with interruptible capacity scheduled during such day, if the customer scheduled and received only interruptible capacity from the Government during such day, or
3. The maximum rate in kilowatts which SWPA is obligated to deliver energy associated with interruptible capacity, whichever is greater.

**Energy sale or exchange.** At the option of SWPA, energy associated with Interruptible Capacity purchased by a customer shall be either:

(i) Paid for at the energy charge, or
(ii) Returned to SWPA, kilowatt-hour for kilowatt-hour in accordance with agreement of the parties at the time of purchase, or in the absence of such an agreement, metered within 12 months after the date of such purchase, as scheduled by SWPA but at a rate of delivery within the excess available capability of the customer’s generating facilities.

If a customer, for any reason, fails or refuses to return all or any portion of the energy as scheduled by SWPA under part (ii), above, the number of kilowatt-hours not so returned shall be billed and paid for at eleven times the energy charge.

**WHOLESALE RATES FOR POWER AND ENERGY SOLD TO TEXAS ELECTRIC COOPERATIVE, INC. (CONTRACT NO. 14-02-001-801)***

**Effective:** As of April 1, 1979, and thereafter in accordance with Rate Order No. SWPA-1 of the Assistant Secretary for Resource Applications issued March 1, 1979.

**Applicable:** To the Power and energy purchased by Tex-La Electric Cooperative, Inc. from the Southeastern Power Administration under the Power Sales Agreement dated October 20, 1958, Contract No. 14-02-001-801, between Southwestern Power Administration and Tex-La Electric Cooperative, Inc. (Tex-La).

**Capacity and Energy Charges:** Sections 2, 3, and 5, respectively, of Contract No. 14-02-001-801, are amended to read as follows:

"Section 2. Compensations by Tex-La to Government. (a) Tex-La shall compensate the Government each month for firm power capacity and associated energy purchased under Section 1, hereof, at the following rates:

**CAPACITY CHARGE**

(a) During the period until the twelfth day of the month following the date the first power generating unit at the Harry S. Truman Dam is placed in commercial operation in the integrated system of SWPA, the capacity charge shall be $1.73 per kilowatt per month of 'Billing Demand', as defined in Section 3, hereof.

(b) Commencing on the twelfth day of the month following the date the first power generating unit at the Harry S. Truman Dam is placed in commercial operation in the integrated system of SWPA, the capacity charge shall be $1.86 per kilowatt per month of 'Billing Demand', as defined in Section 3, hereof.

**ENERGY CHARGE**

(ii) $0.00459 per kilowatt-hour for the next 440 kilowatt-hours per month of 'Billing Demand'.

(iii) $0.00659 per kilowatt-hour for each kilowatt-hour delivered to Tex-La during any month in excess of 440 kilowatt-hours per month of 'Billing Demand'.

"Section 3. Billing Demand. The 'Billing Demand' for any month for firm power capacity purchased by Tex-La from the Government under Section 1 hereof, shall be the number of kilowatts computed under the formula—

\[ BD = \frac{A \times C}{B} \]

with the factors defined as follows:

- BD = Tex-La Billing Demand for any particular month.
- A = The sum of the maximum 30-minute integrated demands recorded during such month at the points of delivery to the Tex-La members served from the system of the Company, but not less than 75% of the greatest 30-minute integrated demand established during the 12-month period ending with such month.
- B = The greatest Factor 'A' established during the 12-month period ending with such month.
- C = 15,000 kilowatts.

"Section 35. Firm Energy Accounting. The quantity of energy associated with firm power capacity (hereinafter referred to as "firm energy") purchased by Tex-La from the Government each month shall be computed under the formula—

\[ FE = FD \times TE \]

with the factors defined as follows:

- FE = The total number of kilowatt-hours of firm energy purchased by Tex-La from the Government during any particular month.
- FD = 15,000 kilowatts.
- TE = The sum total number of kilowatt-hours of energy delivered to Tex-La during such month as metered at the points of delivery designated by the Government pursuant to Section 5, hereof.

D = Either the highest sum of the 30-minute maximum integrated demands recorded at the points of delivery to Tex-La members designated by the Government served from the system of the Company during such month, or the highest sum of the 30-minute maximum integrated demands recorded at the points of delivery to Tex-La members designated by the Government served from the system of the Company during the preceding eleven months, whichever is greater."

[PR Doc. 79-7127 Filed 3-8-79; 8:45 am]

**[6210-01-M]**

**FEDERAL RESERVE SYSTEM**

**ATTICA BANK CORP.**

Formation of Bank Holding Company

Attica Bank Corporation, Attica, Kansas, has applied for the Board's approval under §3(a)(1) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(1)) to become a bank holding company by acquiring 96.67 per cent of the voting shares (less directors' qualifying shares) of The First National Bank of Attica, Attica, Kansas. The factors that are considered in acting on the application are set forth in §3(c) of the Act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than March 30, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice, in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.


**THEODORE E. ALLISON,**

Secretary of the Board.

[PR Doc. 79-7127 Filed 3-8-79; 8:45 am]

**[6210-01-M]**

**BANK HOLDING COMPANIES**

Proposed De Novo Nonbank Activities

The bank holding companies listed in this notice have applied, pursuant to section 4(c)(3) of the Bank Holding Company Act (12 U.S.C. § 1843(c)(3)) and section 225.4(b)(1) of the Board's Regulation Y (12 CFR § 225.4(b)(1)), for permission to engage de novo (or continue to engage in an activity earlier commenced de novo), directly or indirectly, solely in the activities indicated, which have not been engaged in by the Board of Governors to be closely related to banking.

With respect to each application, interested persons may express their views to the appropriate Federal Re-
serve Bank on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interest, or unsound banking practices." Any comment on an application that requests a hearing must include a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of that proposal.

Each application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank indicated for that application. Comments and requests for hearing should identify clearly the specific application to which they relate, and should be submitted in writing and received by the appropriate Federal Reserve Bank not later than March 30, 1979.

A. Federal Reserve Bank of San Francisco, 400 Sansome Street, San Francisco, California 94110.

FIRST BANCORPORATION, Salt Lake City, Utah (industrial loan and insurance activities; Utah: to engage, through its subsidiary, Foothill Thrift and Loan, in the fact trial loan business; and to act as agent for the sale of life and accident and health insurance directly related to its extensions of credit. These activities would be conducted from an office in Salt Lake City, Utah, and the geographic area to be served is principally the Salt Lake City area, but may extend throughout Utah.

B. Other Federal Reserve Banks: None.


THEODORE E. ALLISON, Secretary of the Board.

[FR Doc. 79-7122 Filed 3-8-79; 8:45 am]

FIRST BANKSHARES OF WYOMING

Formation of Bank Holding Company

First Bankshares of Wyoming, Cheyenne, Wyoming, has applied for the Board's approval under § 3(a)(1) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(1)) to become a bank holding company by acquiring 80 percent or more of the voting shares of The First National Bank and Trust Company of Wyoming, Cheyenne, Wyoming, Wyoming State Bank, Cheyenne, Wyoming, and First Wyoming Bank in Wheatland, Wheatland, Wyoming. The factors that are considered in acting on the application are set forth in §3(c) of the Act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than March 30, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.


THEODORE E. ALLISON, Secretary of the Board.

[FR Doc. 79-7130 Filed 3-8-79; 8:45 am]

LOS HACENDADOS, INC.

Formation of Bank Holding Company

Los Hacendados, Inc., Clayton, New Mexico, has applied for the Board's approval under §3(a)(1) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(1)) to become a bank holding company by acquiring 80 percent or more of the voting shares (less directors' qualifying shares) of First National Bank in Clayton, Clayton, New Mexico 88020, a bank that has been in operation in that location since 1906.

The factors that are considered in acting on the application are set forth in §3(c) of the Act (12 U.S.C. § 1842(c)).

Los Hacendados, Inc., Clayton, New Mexico, has also applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. § 1843(c)(8)) and §225.4(b)(2) of the Board's Regulation Y (12 CFR §225.4(b)(2)), for permission to engage de novo as agent or broker in the sale of insurance as agent or broker in the sale of insurance. Any request for a hearing on this proposal must include a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing.


THEODORE E. ALLISON, Secretary of the Board.

[FR Doc. 79-7129 Filed 3-8-79; 8:45 am]

FEDERAL REGISTER, VOL 44, NO. 48—FRIDAY, MARCH 9, 1979
or at the Federal Reserve Bank of Kansas City.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than March 31, 1979.


THEODORE E. ALLISON,
Secretary of the Board.

[FR Doc. 79-7132 Filed 3-8-79; 8:45 am]

[6210-01-M]

MAINLAND BANCSHARES, INC.
Formation of Bank Holding Company

Mainland Bancshares, Inc., La Marque, Texas, has applied for the Board's approval under § 3(a)(1) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(1)) to become a bank holding company by acquiring 80 per cent or more of the voting shares of First Bank of La Marque, La Marque, Texas. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Dallas. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than April 25, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.


THEODORE E. ALLISON,
Secretary of the Board.

[FR Doc. 79-7132 Filed 3-8-79; 8:45 am]

[6210-01-M]

TENNESSEE VALLEY BANCORP, INC.

Proposed Expansion of Activities of Tennessee Valley Life Insurance Company, Phoenix, Arizona


Applicant states that its subsidiary would engage in the expanded activities of underwriting, as reinsurer, accident and health insurance and joint life insurance which are directly related to extensions of credit by its bank holding company system. These activities would be performed from offices of Applicant's subsidiary in Phoenix, Arizona, and the geographic area to be served is the State of Tennessee. Such activities have been specified by the Board in section 225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of section 225.4(b).

Interested persons may express their views on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interest, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Atlanta or the Federal Reserve Bank of San Francisco.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than April 2, 1979.


THEODORE E. ALLISON,
Secretary of the Board.

[FR Doc. 79-7134 Filed 3-8-79; 8:45 am]

[6210-01-M]

ZIONS UTAH BANCORPORATION

Acquisition of Bank

Zions Utah Bancorporation, Salt Lake City, Utah, has applied for the Board's approval under § 3(a)(3) of the Bank Holding Company Act (12 U.S.C. § 1842(a)(3)) to acquire 98.8 per cent of the voting shares of Zions First National Bank of Cedar City, Cedar City, Utah. The factors that are considered in acting on the application are set forth in § 3(c) of the Act (12 U.S.C. § 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of San Francisco. Any person wishing to comment on the application should submit views in writing to the Reserve Bank to be received not later than March 30, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.


THEODORE E. ALLISON,
Secretary of the Board.

[FR Doc. 79-7135 Filed 3-8-79; 8:45 am]
NOTICES

SUPPLEMENTARY INFORMATION:

The holders of the new drug applications listed below have not submitted annual reports of experience with the drugs as required and have advised the FDA that marketing of the drugs involved has been discontinued. The applicants have requested withdrawal of approval of the new drug applications and have waived their opportunities for hearings.

<table>
<thead>
<tr>
<th>NDA No.</th>
<th>Drug Name</th>
<th>Applicant's name and address</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-205</td>
<td>Metroline</td>
<td>Pennington Corp., P.O. Box 1710, Rochester, NY 14601</td>
</tr>
<tr>
<td>4-298</td>
<td>Metroline with Phenobarbital</td>
<td>Merrell-National Labs., Division of Richardson-Merrell, Cincinnati, OH 45215</td>
</tr>
<tr>
<td>5-307</td>
<td>Mercuric Hydrate</td>
<td>Parke, Davis &amp; Co., Box 118-GPO, Detroit, MI 48222</td>
</tr>
<tr>
<td>5-616</td>
<td>Liquid Germicidal Detergent</td>
<td>Mead Johnson, Inc., West Point, PA 19486</td>
</tr>
<tr>
<td>6-305</td>
<td>Methadone Hydrochloride</td>
<td>The Upjohn Co., 711 Portage Rd., Kalamazoo, MI 49002</td>
</tr>
<tr>
<td>6-311</td>
<td>Methadone Hydrochloride</td>
<td>Novacol Chemical Co., Inc., 211-23 Atlantic Ave., Brooklyn, NY 11237</td>
</tr>
<tr>
<td>8-66</td>
<td>Ureacaine HCI Solution</td>
<td>Abbott Laboratories, North Chicago, IL 60064</td>
</tr>
<tr>
<td>8-477</td>
<td>Sodium Phosphate P-32</td>
<td>Pennington Corp.</td>
</tr>
<tr>
<td>8-480</td>
<td>Malotran</td>
<td>ICN Pharmaceuticals, Inc., 5040 Lester Rd., Cincinnati, OH 45213</td>
</tr>
<tr>
<td>8-725</td>
<td>Sodium Sulfoctamide Ophthalmal Ointment</td>
<td>The Central Pharmacal Corp., 112-123 East Third St., Seymour, IN 47274</td>
</tr>
<tr>
<td>9-211</td>
<td>Neomycin</td>
<td>Abbott Laboratories, 112-123 East Third St., Seymour, IN 47274</td>
</tr>
<tr>
<td>9-510</td>
<td>Aureomycin-103</td>
<td>Abbott Laboratories, 112-123 East Third St., Seymour, IN 47274</td>
</tr>
<tr>
<td>9-513</td>
<td>Cortisone Acetate</td>
<td>Rexall Drug Co., 3001 North Kingshighway, St. Louis, MO 63118</td>
</tr>
<tr>
<td>9-758</td>
<td>Reserpine</td>
<td>Morton Pharmaceuticals, 1625-39 North Highland, Memphis, TN 38103</td>
</tr>
<tr>
<td>9-769</td>
<td>Barbital Sodium</td>
<td>Phillips Rexall Laboratories, 330 Oak St., Columbus, OH 43216</td>
</tr>
<tr>
<td>9-858</td>
<td>Blocaclin HCI 0.5%</td>
<td>Sterling Drug Inc., 99 Park Ave., New York, NY 10016</td>
</tr>
<tr>
<td>9-912</td>
<td>Rauw-Tina</td>
<td>W. L. Gore &amp; Associates, Inc., 3824 E. Butterfly Road, St. Louis, MO 63139</td>
</tr>
<tr>
<td>9-919</td>
<td>Raczistran 51</td>
<td>Abbott Laboratories, 112-123 East Third St., Seymour, IN 47274</td>
</tr>
<tr>
<td>11-313</td>
<td>Nafluoride</td>
<td>Abbott Laboratories, 112-123 East Third St., Seymour, IN 47274</td>
</tr>
<tr>
<td>11-499</td>
<td>Estrotrix</td>
<td>Abbott Laboratories, 112-123 East Third St., Seymour, IN 47274</td>
</tr>
<tr>
<td>12-416</td>
<td>Stedylab Delfectamidene</td>
<td>Western Research Laboratories, Inc., 202 South Central Ave., Baltimore, MD 21202</td>
</tr>
<tr>
<td>12-429</td>
<td>Metranil Duncaen</td>
<td>Meyer Laboratories, 1900 West Commercial Blvd., Ft. Lauderdale, FL 33312</td>
</tr>
<tr>
<td>12-729</td>
<td>Chymotest</td>
<td>Chremaley Pharmaceuticals Inc., 12741 Capital Ave., Oko Park, MI 48227</td>
</tr>
<tr>
<td>12-737</td>
<td>Wilpo</td>
<td>Dersey Laboratories, Box 83228, Lincoln, NE 68501</td>
</tr>
<tr>
<td>14-648</td>
<td>Rcovdamine-47</td>
<td>Abbott Laboratories, 112-123 East Third St., Seymour, IN 47274</td>
</tr>
<tr>
<td>14-674</td>
<td>Thalacurie</td>
<td>Bioline Laboratories, Inc., 302 South Broadway, St. Louis, MO 63102</td>
</tr>
<tr>
<td>16-138</td>
<td>Carbocaine HCI 4.5%</td>
<td>Sterling Drug, Inc., 112-123 East Third St., Seymour, IN 47274</td>
</tr>
<tr>
<td>16-274</td>
<td>Hippuran-131</td>
<td>Abbott Laboratories, 112-123 East Third St., Seymour, IN 47274</td>
</tr>
<tr>
<td>16-428</td>
<td>Vaniol</td>
<td>Recwell Laboratories, Inc., 210 Main Street West, Blairstown, NJ 07825</td>
</tr>
<tr>
<td>16-598</td>
<td>Penicilllin tetramethyl</td>
<td>Eastern Research Laboratories, Inc., 202 South Central Ave., Baltimore, MD 21202</td>
</tr>
<tr>
<td>16-607</td>
<td>Covrup</td>
<td>Meyer Laboratories, 1900 West Commercial Blvd., Ft. Lauderdale, FL 33312</td>
</tr>
<tr>
<td>16-641</td>
<td>Chloromeridin Hg 293</td>
<td>Bioline Laboratories, Inc., 302 South Broadway, St. Louis, MO 63102</td>
</tr>
<tr>
<td>16-652</td>
<td>Pertevac-99m</td>
<td>Abbott Laboratories, 112-123 East Third St., Seymour, IN 47274</td>
</tr>
<tr>
<td>16-676</td>
<td>Penicilllin tetramethyl</td>
<td>Philips Rexall Laboratories, Inc., Fishers, IN 46038</td>
</tr>
<tr>
<td>16-726</td>
<td>Technetium Te 99m</td>
<td>Allergan Pharmaceuticals, Inc., 2525 Dupont Drive, Irvine, CA 92712</td>
</tr>
<tr>
<td>17-121</td>
<td>Sodium Pertechnetate Te 99m</td>
<td>Abbott Laboratories, 112-123 East Third St., Seymour, IN 47274</td>
</tr>
<tr>
<td>17-259</td>
<td>Chlorine Phosphate P23</td>
<td>Abbott Laboratories, 112-123 East Third St., Seymour, IN 47274</td>
</tr>
<tr>
<td>17-250</td>
<td>Strenex-65</td>
<td>Abbott Laboratories, 112-123 East Third St., Seymour, IN 47274</td>
</tr>
<tr>
<td>17-476</td>
<td>Mektov 93 Automatic Liquid Extractor</td>
<td>Abbott Laboratories, 112-123 East Third St., Seymour, IN 47274</td>
</tr>
<tr>
<td>17-439</td>
<td>Maccareen-131</td>
<td>Abbott Laboratories, 112-123 East Third St., Seymour, IN 47274</td>
</tr>
<tr>
<td>18-341</td>
<td>Tin-131H</td>
<td>Abbott Laboratories, 112-123 East Third St., Seymour, IN 47274</td>
</tr>
<tr>
<td>20-333</td>
<td>Cordysac Acetate</td>
<td>Abbott Laboratories, 112-123 East Third St., Seymour, IN 47274</td>
</tr>
</tbody>
</table>
Therefore, under the Federal Food, Drug, and Cosmetic Act (Sec. 505(e), 76 Stat. 792 as amended. (21 U.S.C. 355(e))), and under authority delegated to the Director of the Bureau of Drugs (21 CFR 5.62), approval of the new drug applications listed above, and supplements thereto, is hereby withdrawn on the grounds that the applicants have failed to make reports under section, 505(j) of the act (21 U.S.C. 355(j)) and §§ 310.330 or 310.302 (e) and (f) of the new drug regulations (21 CFR 310.330 and 310.302(e) and (f)).

This order will become effective on March 19, 1979.

Dated: February 27, 1979.

J. Richard Crout, Director, Bureau of Drugs.

[FR Doc. 79-6584 Filed 3-8-79; 8:45 am]

[1505-01-M]

FOOD AND DRUG ADMINISTRATION

(Docket No. 78N-0427)

SAFETY OF CERTAIN FOOD INGREDIENTS

Opportunity for Public Hearing

[NOTE: This document originally appeared in the FEDERAL REGISTER for Wednesday, March 7, 1979 through an editorial oversight. It is reprinted in this issue to meet the Tuesday/Friday publication schedule assigned to the Food and Drug Administration, Health, Education, and Welfare Department. In addition, the Federal Register Document Number and file time is corrected to read as shown below.]

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This document announces an opportunity for public hearing on the safety of certain ascorbic acids and certain copper salts to determine if they are generally recognized as safe (GRAS) or subject to a prior sanction. This action accords with procedures of a comprehensive safety review that the agency is conducting. Interested persons are invited to give their views on the safety of these substances.

DATE: Requests to make oral presentations at the public hearing must be postmarked on or before April 8, 1979.

ADDRESS: Written requests to the Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20014, and to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION:

In the FEDERAL REGISTER of July 25, 1973 (38 FR 20053), the Commissioner of Food and Drugs issued a notice advising the public that an opportunity would be provided for oral presentations of data, information, and views at public hearings to be conducted by the Select Committee on GRAS Substances of the Life Sciences Research Office, Federation of American Societies for Experimental Biology (hereinafter, the Select Committee), about the safety of ingredients used in food to determine whether they are GRAS or subject to a prior sanction.

The Commissioner now gives notice that the Select Committee is prepared to conduct public hearings on the following categories of food ingredients: certain ascorbates (L-ascorbic acid, calcium L-ascorbate, sodium L-ascorbate, ascorbyl palmitate, erythorbic acid, and sodium erythorbate for direct food use); and certain copper salts (cupric gluconate, cupric citrate, cupric iodide for direct food use, and copper sulfate for direct food use and food-packaging materials).

The public hearing will provide an opportunity, before the Select Committee reaches its final conclusions, for any interested person(s) to present scientific data, information, and views on the safety of these substances, in addition to comments previously submitted in writing as a result of notices published in the FEDERAL REGISTER of July 25, 1973 (38 FR 20053) and April 17, 1974 (39 FR 13798), and March 28, 1978 (43 FR 12941).

The Select Committee has reviewed all the available data and information on the categories of food ingredients listed above and, for each, has considered which one of the following five tentative conclusions would be appropriate:

1. There is no evidence in the available information that demonstrates or suggests reasonable grounds to suspect, a hazard to the public when the substance is used at levels that are now current or that might reasonably be expected in the future.

2. There is no evidence in the available information that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when the substance is used at levels that are now current and in the manner now practiced. However, it is not possible to determine, without additional data, whether a significant change in consumption would constitute a dietary hazard.

3. Although no evidence in the available information demonstrates a hazard to the public when the substance is used at levels that are now current and in the manner now practiced, uncertainties exist requiring that additional studies be conducted. (This finding does not apply to the substances covered by this notice.)

4. The evidence is insufficient to determine that the adverse effects reported are not deleterious to the public health when the substance is used at levels that are now current and in the manner now practiced. (This finding does not apply to the substances covered by this notice.)

5. The information available is not sufficient to make a tentative conclusion. (This finding does not apply to the substances covered by this notice.)

The following table lists each ingredient, the Select Committee's tentative conclusion (keyed to the five types of conclusions listed above), and the available information on which the Select Committee reached its conclusions:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Select committee tentative conclusion</th>
<th>Scientific literature review (order No.; price code; price)</th>
<th>Animal study report (order No.; Other Information (order No.; price code; price) price code; price)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascorbates: l-Ascorbic acid</td>
<td>1</td>
<td>PB-245-510/AS (ascorbic acid); A-16; $12.50.</td>
<td></td>
</tr>
<tr>
<td>Sodium L-ascorbate</td>
<td>1</td>
<td>PB-245-510/AS (ascorbic acid); A-16; $12.50.</td>
<td></td>
</tr>
<tr>
<td>Calcium L-ascorbate</td>
<td>1</td>
<td>PB-245-510/AS (ascorbic acid); A-16; $12.50.</td>
<td></td>
</tr>
<tr>
<td>Ascorbyl palmitate (Palmityl L-ascorbate)</td>
<td>1</td>
<td>PB-245-510/AS (ascorbic acid); A-16; $12.50.</td>
<td></td>
</tr>
<tr>
<td>Erythorbic acid (D-Isosorbic acid)</td>
<td>2</td>
<td>PB-245-510/AS (ascorbic acid); A-16; $12.50.</td>
<td></td>
</tr>
<tr>
<td>Sodium erythorbate (Sodium D-Isosorbic acid)</td>
<td>2</td>
<td>PB-245-510/AS (ascorbic acid); A-16; $12.50.</td>
<td></td>
</tr>
</tbody>
</table>

1. Teratological evaluation of FDA 71-68 (ascorbic acid) in mice and rats, by Food and Drug Research Labs., Inc., under FDA contract (PB-245-510/AS); A-16; $12.50.

2. Toxicity and teratogenicity studies in ascorbic acid submitted by the University of Arizona.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
Copper salts: Direct food in use:
- Copper sulfate
- Copper gluconate
- Cuprous iodide

Copper sulfate

Food packaging materials:
- Copper sulfate

3. Mutagenic evaluation (Tier 1) of compound FDA 71-63 (ascorbic acid) by Litton Bionetics, Inc., under FDA contract (PB-241-901/AS); $6.00.

1. Mutagenic evaluation (Tier 1) of compound FDA 71-62 (copper gluconate) by Litton Bionetics, Inc., under FDA contract (PB-275-940/AS); $4.50.

2. Mutagenic evaluation (Tier 1) of FDA 75-70, cuprous iodide technical by Litton Bionetics, Inc., under FDA contract (PB-219-263/AS); $5.25.

3. Investigations on the toxic and teratogenic effects of GRAS substances on the developing chick embryo: Sodium ascorbate; submitted by Ohio State.

4. Investigations on the toxic and teratogenic effects of GRAS substances on the developing chick embryo: Sodium erythorbate; submitted by Ohio State.

5. Investigations on the toxic and teratogenic effects of GRAS substances to the developing chicken embryos: Calcium ascorbate; FDA in-house investigation.

6. Investigations of the toxic and teratogenic effects of GRAS substances to the developing chicken embryos: Erythorbic acid; submitted by St. Louis University School of Medicine.

7. Study of mutagenic effects of sodium erythorbate (No. 71-63); submitted by Stanford Research Institute.


11. Comparison of metabolism of ascorbic acid and tocopherol acid; FCC No. 0037; Merck Institute of Therapeutic Research.

12. Absorption of L-ascorbic acid across membrane vesicles from guinea pig small intestine and renal cortex; inhibited by d-erythorbate; 1978; Biochemistry and Biophysical Actin (in press).


2. Letter dated October 29, 1976, with attachments to G. W. Irving, M.D.

3. Letter dated June 28, 1978 to P. R. Senti, M.D.


5. One year chronic oral toxicity of copper gluconate W10219A in beagle dogs; research report No. 955-0335; Warner-Lambert Research Institute.


8. Investigation of the toxic and teratogenic effects of GRAS substances to the developing chick embryos; copper gluconate; FDA in-house investigation.

9. Investigation of the toxic and teratogenic effects of GRAS substances to the developing chick embryos; copper gluconate; FDA in-house memorandum.

NOTICES

Reports in the table with "PB" prefixes may be obtained from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161.

In addition to the information contained in the documents listed in the table above, the Select Committee supplemented its reviews, where appropriate, with specific information from specialized sources as announced in a previous hearing opportunity published in the Federal Register of September 23, 1974 (39 FR 34218).

The Select Committee's tentative reports on (1) L-ascorbic acid, calcium and sodium L-ascorbylates, ascorbyl palmitate, erythorubic acid, and sodium erythorbate for direct food use, and (2) copper gluconate and cuprous iodide for direct food use, and copper sulfate for direct food use and food packaging materials are available for review at the offices of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and also at the Public Information Office, Food and Drug Administration, Rm. 3807, 200 C St. SW., Washington, DC 20204. In addition, all reports and documents used by the Select Committee to review the ingredients are available for review at the office of the Hearing Clerk.

To schedule the public hearing, the Select Committee must be informed of the number of persons who wish to attend and the amount of time requested to give their views. Accordingly, any interested person who wishes to appear at the public hearing to make an oral presentation shall so inform the Select Committee in writing addressed to the Select Committee on GRAS Substances, Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9550 Rockville Pike, Bethesda, MD 20814. A copy of each such request, identified with the Hearing Clerk docket number found in brackets in the heading of this document, shall be sent to the Select Committee at the address noted above, and must be postmarked not later than 10 days before the scheduled date of the hearing. A copy of any written views will be sent to the Hearing Clerk, Food and Drug Administration, and will be placed on public display in that office.

A public hearing will be presided over by a member of the Select Committee. Hearings will be transcribed by a reporting service, and a transcript of each hearing may be purchased directly from the reporting service and will be placed on public display in the office of the Hearing Clerk, Food and Drug Administration.

Dated: March 1, 1979.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Regulatory Affairs.

(FR Doc. 79-6785 Filed 3-8-79; 8:45 am)

[4110-39-M]

National Institute of Education

PANEL FOR THE REVIEW OF LABORATORY
AND CENTER OPERATIONS

Correction

In 44 FR appearing on page 11272 in the issue of Wednesday, February 28, 1979, the first paragraph should show that the next meeting of the Panel for the Review of Laboratory and Center Operations will be held on March 17-18 in the Conference Center of the One Washington Circle Hotel, One Washington Circle, N.W., Washington, D.C.

Dated: March 7, 1979

GRADY MCGONAGIL,
Staff Director, Panel for the
Review of Laboratory and
Center Operations.

(FR Doc. 79-7263 Filed 3-8-79; 8:45 am)
NOTICES


PRESTON VALIEN,
OE Delegate to the Council.

[FR Doc. 79-7193 Filed 3-8-79: 8:45 am]

DESEGREGATION OF PUBLIC EDUCATION

Closing Date for Transmittal of Applications for Fiscal Year 1979

Applications are invited for the following programs under the authority of Title IV of the Civil Rights Act of 1964, as amended ("the Act"); 42 U.S.C. 2000c et seq.:

1. State Educational Agency programs for race, sex, and national origin desegregation assistance, under section 403 of the Act;

2. Training Institute programs for race and sex desegregation assistance, under section 404 of the Act;


The purpose of the awards is to help solve problems related to the race, sex, and national origin desegregation of public elementary and secondary schools.

Applications for Race, Sex, and National Origin Desegregation Assistance Center (DAC) programs are not covered by this notice. Under section 180.36 of the program regulations (45 CFR 180), the Commissioner may approve the continuation of existing DAC programs for an additional period if they meet the criteria in that section. If the Commissioner determines that particular programs will not be continued, a separate notice will be published announcing the closing date for the geographic areas served by those programs.

Applications for the Special Grants to School Boards for Race and National Origin Desegregation will not be covered by a notice of closing date. Applicants for these grants may apply at any time, but should first review the eligibility requirements contained in §§180.04 and 180.11(a) and (b) of the program regulations.

Closing date for transmission of applications: Applications for awards must be mailed or hand delivered by April 23, 1979.


Proof of mailing must consist of a legible U.S. Postal Service dated postmark or a legible mail receipt with the date of mailing stamped by the U.S. Postal Service. Private metered postmarks or mail receipts will not be accepted without a legible date stamped by the U.S. Postal Service. (NOTE: The U.S. Postal Service does not uniformly provide a dated postmark. Applicants should check with their local post office before relying upon this method.) Applicants are encouraged to use registered or at least first class mail.

Each late applicant will be notified that its application will not be considered in the current competition.

Applications delivered by hand: An application that is hand delivered must be taken to the U.S. Office of Education, Application Control Center, Room 3036, Regional Office Building 3, 7th and D Streets, S.W., Washington, D.C.

The Application Control Center will accept hand-delivered applications between 8:00 a.m. and 4:00 p.m. (Washington, D.C. time) daily, except Saturdays, Sundays, and Federal holidays.

Applications that are hand delivered will not be accepted after 4:00 p.m. on the closing date.

Available funds: The total appropriation for Title IV for FY 1979 is $41,350,000. Of that amount, approximately $15,150,000 is available for the programs covered by this notice. It is estimated that $8,300,000 will be obligated for awards to State Educational Agencies; $5,500,000 for awards for Training Institute programs; and $1,350,000 for awards to School Boards for sex desegregation assistance.

The above funds are expected to support an estimated 144 projects.

The amount of the award for the above projects is anticipated to be between $20,000 and $500,000.

These figures are only estimates and do not bind the U.S. Office of Education.

Application forms: Application forms and program information packages are expected to be ready for mailing by March 8, 1979. They may be obtained by writing to the Division of Technical Assistance, Equal Educational Opportunity Programs, U.S. Office of Education (Room 2181-J, FOB-6), 400 Maryland Avenue, S.W., Washington, D.C. 20202.

Applications must be prepared and submitted in accordance with the regulations, instructions, and forms included in the program information packages. Applicants for school board grants should be aware that the Commissioner will consider without a legible date stamped applications for assistance, the financial and other resources that the ap-
The National Park Service is extending public comment period on proposed snowmobile policy.

**PROPOSED SNOWMOBILE POLICY**

**Extension of Public Comment Period**

**AGENCY:** National Park Service, Interior.

**ACTION:** Extension of public comment period on proposed snowmobile policy.

**FOR FURTHER INFORMATION CONTACT:**

Chief, Office of Management Policy, National Park Service, 18th and C Streets, NW, Washington, D.C. 20240.

The National Park Service is extending the public review of its proposed revisions to its management policy on snowmobiles. The proposed policy and an explanation of changes made to the policy were printed in the Federal Register, Vol. 43, No. 236 for Thursday, December 7, 1978, 43 FR 57352.

Written comments will be accepted until April 2, 1979. They may be offered individually or in addition to any oral comments given at the public meetings which were conducted during the month of January.


**NOTICES**

**[4310-02-M]**

**Bureau of Indian Affairs**

**NEAR RESERVATION DESIGNATIONS**

This notice is published in exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 230 DM 2.

In accordance with Title 25—Indians, Chapter 1—Bureau of Indian Affairs, Department of the Interior, Subchapter D—Social Welfare, Part 20—Financial Assistance and Social Services Program (25 CFR 20) the Assistant Secretary—Indian Affairs has designated certain locales as "Near reservation" locations for the extension of Bureau of Indian Affairs financial assistance and/or social services. The locales listed alphabetically below by Bureau Agency Jurisdiction are those designated for this purpose.

**Agency:** Pamunpe. Tribes: Kaw, Otse-Missouria, Ponca, Tonkawa, Pawnee.

"Near reservation" location: North Boundary—From the west end of Grant County, along the Oklahoma-Kansas state line, to the east boundary of Kay County; South Boundary—Commencing northeast corner of Kay County, south on Kay County line to Kawk City thence southwest to the Arkansas River, following Arkansas River to Cimarron Turnpike. South Boundary—Commencing from junction of Arkansas River and Cimarron Turnpike west on Cimarron Turnpike to State Highway 18, south on State Highway 18 to the Cimarron River, west along the Cimarron River to Coyle, Oklahoma, thence along State Highway 33 west to Kingfisher, Oklahoma. West Boundary—Commencing at Kingfisher, Oklahoma, north on State Highway 81 to the Garfield County line, west along the Garfield County line to the west boundary of Garfield County, thence north along the west boundaries of Garfield and Grant Counties to the Oklahoma-Kansas state line. (All of the above within the state of Oklahoma.)

Agency: Concho. Tribes: Cheyenne-Arapaho.

"Near reservation" location: Woodward, Major, Kingfisher, Canadian, Blaine, Dewey, Custer, Washita, Beckham, Roger Mills, Counties and that southeastern portion of Ellis County which falls within the former reservation boundaries. (All of the above within the state of Oklahoma.)

**[4310-04-M]**

**Bureau of Land Management**

**MOTORIZED VEHICLES ON PUBLIC LANDS: CLOSURE TO USE**

Notice is hereby given that use of motorized vehicles on certain public lands within the Rogue Wild and Scenic River boundary in Josephine County, Oregon, is prohibited in accordance with the provisions of 43 CFR 6010.4. This closure does not apply to emergency, law enforcement, and federal or other government vehicles while being used for official or emergency purposes, or vehicles authorized by permit or contract.

The area affected by this closure notice is located approximately 3/4 river miles downstream from the Grave Creek Boat Landing, an area called Whisky Creek. The legal description of the closed land is: Williamette Meridian, T. 33 S., R. 8 W., Sec. 34, NW1/4. A pin and box gate is located in the NW1/4 of Sec. 34 as a management tool, but has been vandalized many times.

The use of this public land by motorized vehicles has increased the possibility of vandalism to the Whisky Creek Cabin, which is on the National Historic Register. The gate not only limits access to the cabin, but also to the Rogue River Trail and the Canyon itself. The road leading into the Whisky Creek Cabin is very steep and rugged. Over use of this road by vehicles will cause excessive erosion and a hazard to the public.

The closure is effective immediately and will remain in effect no later than February 22, 1980, or when the scheduled Activity Plan for the Wild Section of Rogue River, under the administration of the Bureau of Land Management and the U.S. Forest Service, is completed. Prior to a decision on permanent closure of the identified...
NOTICES

13085

land, public comment will be accepted through scheduled public participation in the formation of the Activity Plan.

Violations of the regulations shall be punishable by a fine of not more than $1,000 or imprisonment for more than 12 months, or both.

County points of access to the area will be posted. Maps showing the area described above are available for examination at the Medford District Office, Bureau of Land Management, 310 West Sixth Street, Medford, Oregon.

Dated this 2nd day of March, 1979.

George C. Francis,
District Manager.

[PR Doc. 79-7220 Filed 3-8-79; 3:45 am]

[4310-84-M]

[AA-6663-A through AA-6663-J]

ALASKA

Alaska Native Claims Selection


As to the lands described below, the applications, as amended, are properly filed, and meet the requirements of the Alaska Native Claims Settlement Act and of the regulations issued pursuant thereto. These lands do not include any lawful entry perfected under or being maintained in compliance with laws leading to acquisition of title.

In view of the foregoing, the surface estate of the following described lands, selected pursuant to Sec. 12(a), aggregating approximately 86,978 acres, is considered proper for acquisition by Ekwok Natives Limited, and is hereby approved for conveyance pursuant to Sec. 14(a) of the Alaska Native Claims Settlement Act:


Seward Meridian, Alaska (Unsurveyed)

T. 9 S., R. 49 W.
Sec. 19, excluding the Nushagak River;
Sec. 20, excluding Native allotment AA-7691 Parcel B;
Secs. 21, 22 and 28, all;
Sec. 23, excluding Native allotment A-034034 Parcel B;
Secs. 30 and 31, all.

Sec. 32, excluding Native allotment AA-6397 Tract A.

Containing approximately 5,350 acres.

T. 10 S., R. 48 W.
Secs. 4, 5, and all;
Secs. 9 and 10, all;
Secs. 14, 15, and 16, all.

Containing approximately 5,092 acres.

T. 9 S. R. 49 W.
Secs. 1 to 12, inclusive, all;
Sec. 13, excluding Native allotments AA-7688, AA-7768 and the Nushagak River;
Secs. 14 to 21, inclusive, all;
Sec. 22, excluding Native allotment AA-6380 Parcel B;
Sec. 23, excluding U.S. Survey No. 4978, Native allotment AA-6380 Parcel B and the Nushagak River;
Sec. 24, excluding Native allotment AA-7766 and the Nushagak River;
Sec. 25, excluding the Nushagak River;
Sec. 26, excluding U.S. Survey No. 3694, U.S. Survey No. 4978 and the Nushagak River;
Sec. 27, excluding U.S. Survey No. 4978 and the Nushagak River;
Sec. 28, excluding Native allotment AA-7678;
Secs. 29, 30, 31, and 32, all;
Sec. 33, excluding Native allotments AA-7678, AA-7690 Parcel B and the Nushagak River;
Sec. 34, excluding U.S. Survey No. 4978, Native allotment AA-7678 and the Nushagak River;
Sec. 35, excluding U.S. Survey No. 4978 and the Nushagak River;
Sec. 36, all.

Containing approximately 20,763 acres.

T. 10 S. R. 49 W.
Sec. 1, all;
Secs. 2 and 3, excluding the Nushagak River;
Sec. 4, excluding Native allotments AA-7690 Parcel B, AA-7775 Parcel B and the Nushagak River;
Sec. 5, excluding Native allotment AA-7775 Parcel B and the Nushagak River;
Sec. 6, all;
Sec. 7, excluding Native allotment AA-7794 Parcel B;
Secs. 8 and 9, excluding the Nushagak River;
Secs. 10, 11, 12, and 15, all;
Sec. 16, excluding the Nushagak River;
Sec. 17, excluding Native allotment AA-7711 and the Nushagak River;
Sec. 18, excluding Native allotments AA-7714 Parcel B, AA-7774, AA-8115 and the Nushagak River;
Sec. 19, excluding Native allotment AA-8115 and the Nushagak River;
Sec. 20, excluding the Nushagak River;
Secs. 21 and 22, all;
Sec. 27 to 30, inclusive, all;
Sec. 31, excluding Native allotments AA-7660 Parcel A and AA-7716;
Sec. 32, excluding Native allotment AA-7660 Parcel A;
Sec. 33, all.

Containing approximately 14,888 acres.

T. 11 S. R. 49 W.
Secs. 4 and 5, all;
Sec. 6, excluding Native allotments AA-7697 Parcel A, AA-7710 and the Nushagak River;
Sec. 7, excluding the Nushagak River;
Secs. 8, 9, and 10, all;
Secs. 17 to 20, inclusive, all;

Secs. 28 to 33, inclusive, all.

Containing approximately 10,602 acres.

T. 9 S. R. 50 W.
Secs. 7, 13 and 14, all;
Sec. 19, excluding Native allotment AA-7694 Parcel A;
Sec. 22, excluding Native allotment AA-7714 Parcel A;
Secs. 23 to 27, inclusive, all;
Secs. 30 to 35, inclusive, all.

Containing approximately 10,619 acres.

T. 10 S. R. 50 W.
Sec. 1, excluding Native allotment AA-7775;
Sec. 2, all;
Sec. 12, excluding Native allotment AA-7712 Parcel A;
Sec. 13, excluding Native allotment AA-7774 and the Nushagak River;
Sec. 24, excluding Native allotments AA-7683, AA-7774 and the Nushagak River;
Sec. 25, excluding the Nushagak River;
Sec. 26, excluding Native allotment AA-7684 and the Nushagak River;
Secs. 27, 28, and 34, all;
Sec. 29, excluding Native allotments AA-7684, AA-7707 Parcel B, AA-7702 and the Nushagak River;
Sec. 35, excluding the Nushagak River.

Containing approximately 5,796 acres.

T. 11 S. R. 50 W.
Sec. 1, excluding Native allotments AA-7677 Parcel A, AA-7716 and the Nushagak River;
Sec. 2, excluding Native allotments AA-7677 Parcel A, AA-7715 and the Nushagak River;
Secs. 11 to 14, inclusive, excluding the Nushagak River;
Secs. 23 to 27, inclusive, excluding the Nushagak River;
Secs. 33 and 34, excluding the Nushagak River;
Secs. 35, excluding Native allotment AA-7712 Parcel B and the Nushagak River;
Secs. 36 and 37, excluding the Nushagak River.

Containing approximately 7,475 acres.

T. 9 S. R. 51 W.
Sec. 1, all;
Secs. 8 to 13, inclusive, all;
Secs. 24, all;
Sec. 24 and 25, excluding Native allotment AA-7800 Parcel A.

Containing approximately 6,223 acres.

Aggregating approximately 25,659 acres.

Total aggregated acreage approximately 86,978 acres.

The conveyance issued for the surface estate of the lands described above shall contain the following reservations to the United States:

1. The subsurface estate therein, and all rights, privileges, immunities, and appurtenances, of whatsoever nature, accruing unto said estate pursuant to the Alaska Native Claims Settlement Act of December 18, 1971 (85 Stat. 683, 704; 43 U.S.C. 1601, 1611(c) (Supp. V, 1975)); and

2. Pursuant to Sec. 17(b) of the Alaska Native Claims Settlement Act of December 18, 1971 (85 Stat. 683, 704; 43 U.S.C. 1601, 1611(b) (Supp. V, 1975)), the following easements, referenced by easement (identification number GEI) on the easement maps in case file AA-6663-EE are reserved to the United States and subject to further regulation thereby:

FEDERAL REGISTER, Vol. 44, No. 48—Friday, March 9, 1979
NOTICES

13086

a. (EIN 1 D9, D1, L, C1, C5) A streamside easement twenty-five (25) feet in width from site EIN 1 C4 southerly to public lands. The usage of roads and trails will be controlled by applicable State or Federal law or regulation.

b. (EIN 15 C4) A site easement in the ordinary high water mark in Sec. 11, T. 9 S., R. 50 W., Seward Meridian, on the right bank of the Nushagak River. The site is for camping, staging and vehicle use.

c. (EIN 15a C4) An easement for a proposed access trail twenty-five (25) feet in width from site EIN 15 C4 southerly to public lands. The usage of roads and trails will be controlled by applicable State or Federal law or regulation.

d. (EIN 5 B9) A fishery management and public use easement twenty-five (25) feet in width upland of and parallel to the ordinary high water mark on all banks and an easement on the entire bed of the Kokwok River from its confluence with the Nushagak River in Sec. 19, T. 10 S., R. 49 W., Seward Meridian, northwesterly to the western boundary of Sec. 6, T. 9 S., R. 51 W., Seward Meridian. Purpose is to provide for public use of waters having highly significant present recreational use.

e. (EIN 5 D9) A streamside easement twenty-five (25) feet in width from site SIN 11a C4 southerly to public lands. The usage of roads and trails will be controlled by applicable State or Federal law or regulation.

2. Valid existing rights therein, if any, including but not limited to those created by and applicable to lands described under Sec. 6(p) of the Alaska Statehood Act of July 4, 1958 (72 Stat. 339, 341; 46 U.S.C. Ch. 2, Sec. 6(p) (1970)), contract, permit, right-of-way or easement, and the right of the lessee, contractor, permittee, or grantee to the complete enjoyment of all rights, privileges, and benefits. Further pursuant to Sec. 17(b)(2) of ANCSA, any valid existing right recognized by ANCSA shall continue to have whatever right of access as is now provided for under existing law.

3. Airport Lease A-058768, containing 88.58 acres, described as Tract B, U.S. survey 4676, issued to the State of Alaska, Department of Public Works, Division of Aviation (now the Department of Transportation and Public Facilities) under the provisions of the Act of May 24, 1929 (45 Stat. 728-729, 49 U.S.C. 211-214 (1970)).

4. Requirements of Sec. 14(c) of the Alaska Native Claims Settlement Act of December 18, 1971 (86 Stat. 888, 703; 43 U.S.C. 1601, 1613(c) (Supp. V, 1976)), that the grantee hereunder convey to or to any, of the lands hereinabove granted, as are prescribed in said section; and

5. The terms and conditions of the agreement dated January 18, 1977, between the Secretary of the Interior, Bristol Bay Native Corporation, Ekwok Natives Limited and Ekwok Natives Limited is hereby executed as a separate agreement in a form acceptable to the Bureau of Land Management, Alaska State Office, 701 C Street Anchorage, Alaska 99513.

Ekwok Natives Limited, is entitled to conveyance of 92,169 acres of land selected pursuant to Sec. 12(a) of the Alaska Native Claims Settlement Act. To date approximately 86,978 acres of this entitlement have been approved for conveyance; the remaining entitlement of approximately 5,182 acres will be conveyed at a later date.

Pursuant to Sec. 14(f) of the Alaska Native Claims Settlement Act, conveyance of the subsurface estate of the lands described above shall be granted to Bristol Bay Native Corporation when conveyance is granted to Ekwok Natives Limited, for the surface estate and shall be subject to the same conditions as the surface conveyance.

Only the following inland water body within the described lands is considered to be navigable:

Nushagak River.

In accordance with Departmental regulation 43 CFR 2680.7(d), notice of this decision is being published once in the Federal Register and once a week, for four (4) consecutive weeks, in the Anchorage Times. Any party claiming a property interest in lands affected by this decision may appeal the decision to the Alaska Native Claims Appeal Board, P.O. Box 2433, 

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
NOTICES

ANCHORAGE, Alaska 99510 with a copy served upon both the Bureau of Land Management, Alaska State Office, 701 C Street, Box 10, Anchorage, Alaska 99513 and the Regional Solicitor, Office of the Solicitor, 510 L Street, Suite 408, Anchorage, Alaska 99501, also:

1. Any party receiving service of this decision shall have 30 days from the receipt of this decision to file an appeal.

2. Any unknown parties, any parties unable to be located after reasonable efforts have been expended to locate, and any parties who failed or refused to sign the return receipt shall have until April 9, 1979 to file an appeal.

3. Any party known or unknown who may claim a property interest which is adversely affected by this decision shall be deemed to have waived those rights which were adversely affected unless an appeal is timely filed with the Alaska Native Claims Appeals Board.

4. If Ekwok Natives Limited, or Bristol Bay Native Corporation objects to any easement which is identified herein for eminent domain, a petition for reconsideration is not filed by the time the decision becomes final, the Board of Eminent Domain is to make any such easement.

To avoid summary dismissal of the appeal, there must be strict compliance with the regulations governing such appeal. Further information on the manner of and requirements for filing an appeal may be obtained from the Bureau of Land Management, 701 C Street, Box 13, Anchorage, Alaska 99513. If an appeal is taken the adverse parties to be served are:

Ekwok Natives Limited, Ekwok, Alaska 99580.

Bristol Bay Native Corporation, P.O. Box 198, Dillingham, Alaska 99576.

JUDITH A. KAMINS, Chief, Division of ANCSA Operations.

(FR Doc. 79-7159 Filed 3-8-79; 8:45 am)

[4310-55-M]

Fish and Wildlife Service

CONSULTATION ON THE PITTSON COMPANY’S PROPOSED MARINE TERMINAL AND OIL REFINERY, EASTPORT, MAINE

Hearings

SUMMARY: Public Hearings will be held, as part of a consultation conducted pursuant to section 7 of the Endangered Species Act of 1973, as amended, seeking information and comment on the impacts the Pittston Company’s proposed marine terminal and oil refinery, to be located in Eastport, Maine, may have on the endangered bald eagle, and on ways any adverse impacts can be avoided.

DATES: Hearings March 28, 1979, 7 p.m., Eastport Municipal Auditorium, Head Memorial High School, High St., Eastport, Maine; March 29, 1979, 7 p.m., Augusta Civic Center, Cushnoc Auditorium, Community Dr., Augusta, Maine; March 30, 1979, 7 p.m., U.S. Post Office and Court House Building, Room 208, Devonshire and Milk Sts., Boston, Massachusetts. Close of Record: April 13, 1979.

FOR FURTHER INFORMATION CONTACT:

Howard Larsen, Regional Director (Ext. 200), Paul Nickerson, Endangered Species Coordinator (Ext. 200), Paul Nickerson, Endangered Species Coordinator (Ext. 200), Bill Whalen, Public Affairs (Ext. 206), U.S. Fish and Wildlife Service, One Gateway Center, Suite 700, Newton Corner, Massachusetts 02158, phone: (617) 965-5100.

SUPPLEMENTARY INFORMATION: The Pittston Company submitted an application to the U.S. Environmental Protection Agency (EPA) for a wastewater discharge permit under the Clean Water Act for its proposed marine terminal and oil refinery to be constructed on Campcook Bay in Eastport, Maine. On September 13, 1978, the Pittston Company conducted public hearings in Eastport, Maine. On February 14, 1979, the Service issued a Biological Opinion concluding...
the Pittston Company's proposed marine terminal and oil refinery are unlikely to jeopardize the continued existence of the peregrine falcon, but that project is likely to jeopardize the continued existence of the bald eagle.

On February 7 and February 23, 1979, the Pittston Company submitted additional information on the impacts of the project on the bald eagle and possible modifications in project design or operation. EPA and the Service agreed on March 5, 1979, to reinitiate section 7 consultation in light of these recent submittals.

Public Hearings will be held as part of the consultation process seeking information on the impacts of the proposed marine terminal and oil refinery on the bald eagle and on ways that those impacts might be avoided.

Any interested person who desires to present oral comments at the hearings may schedule an oral presentation in advance of the hearings by contacting Paul Nickerson in Boston, Mass. at 617-965-5100 (Ext. 216). In addition, an opportunity to schedule an oral presentation will be provided at the hearings themselves.

Interested parties are encouraged to submit written comments and statements, which will also be considered and may be submitted directly to Regional Director, U.S. Fish and Wildlife Service, One Gateway Center, Newton Corner, Massachusetts 02158. All written comments and statements must be received by April 13, 1979. Copies of the Service's Biological Opinion of December 21, 1979, or of the Pittston Company's recent submittals, can be obtained from the Service's Regional Director at the address stated above.

Dated: March 6, 1979.

LYNN A. GREENWALT, Director, U.S. Fish and Wildlife Service.
[FR Doc. 79-7221 Filed 3-8-79; 8:45 am]

[4510-30-M] DEPARTMENT OF LABOR
Employment and Training Administration
EMPLOYMENT TRANSFER AND BUSINESS COMPETITION DETERMINATIONS UNDER THE RURAL DEVELOPMENT ACT
Applications

The organizations listed in the attachment have applied to the Secretary of Agriculture for financial assistance in the form of grants, loans, or loan guarantees in order to establish or improve facilities at the locations listed for the purposes given in the attached list. The financial assistance would be authorized by the Consolidated Farm and Rural Development Act, as amended, 7 USC 1924(b), 1932, or 1942(b).

The Act requires the Secretary of Labor to determine whether such Federal assistance is calculated to or is likely to result in the transfer from one area to another of any employment or business activity provided by operations of the applicant. It is permissible to assist the establishment of a new branch, affiliate or subsidiary, only if this will not result in increased unemployment in the place of present operations and there is no reason to believe the new facility is being established with the intention of closing down an operating facility.

The Act also prohibits such assistance if the Secretary of Labor determines that it is calculated to or is likely to result in an increase in the production of goods, materials, or commodities; or the availability of services or facilities in the area, when there is not sufficient demand for such goods, materials, commodities, services, or facilities to employ the efficient capacity of existing competitive commercial or industrial enterprises, unless such financial or other assistance will not have an adverse effect upon existing competitive enterprises in the area.

The Secretary of Labor's review and certification procedures are set forth at 29 CFR Part 75. In determining whether the applications should be approved or denied, the Secretary will take into consideration the following factors:

1. The overall employment and unemployment situation in the local area in which the proposed facility will be located.
2. Employment trends in the same industry in the local area.
3. The potential effect of the new facility upon the local labor market, with particular emphasis upon its potential impact upon competitive enterprises in the same area.
4. The competitive effect upon other facilities in the same industry located in other areas (where such competition is a factor).
5. In the case of applications involving the establishment of branch plants or facilities, the potential effect of such new facilities on other existing plants or facilities operated by the applicant.

All persons wishing to bring to the attention of the Secretary of Labor any information pertinent to the determinations which must be made regarding these applications are invited to submit such information in writing within two weeks of publication of this notice. Comments received after the two-week period may not be considered. Send comments to: Administrator, Employment and Training Administration, 601 D Street NW, Washington, D.C. 20213.

Signed at Washington, D.C. this ninth day of March 1979.

ERNEST G. GREEN, Assistant Secretary for Employment and Training.

Applications Received During the Week Ending March 2, 1979

<table>
<thead>
<tr>
<th>Name of applicant and location of enterprise</th>
<th>Principal product or activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Dore Corporation, Marysville, California</td>
<td>Manufacture of metal overhead garage doors</td>
</tr>
</tbody>
</table>

[FR Doc. 79-7179 Filed 3-8-79; 8:45 am]
[4510-30-M]

DEPARTMENT OF LABOR

Employment and Training Administration

EMPLOYMENT TRANSFER AND BUSINESS COMPETITION DETERMINATION UNDER THE RURAL DEVELOPMENT ACT

Reconsideration and Designation of a Hearing Officer in the Matter of Brodhead Nail Co.

A. PURPOSE

Notice is hereby given that pursuant to the authority contained in section 310B(d)(3) of the Consolidated Farm and Rural Development Act, as amended (7 U.S.C. 1932(d)(3)), and implementing regulations at 29 CFR 75.11(b)(6) the Employment and Training Administration of the Department of Labor (ETA) is providing for reconsideration of its October 13, 1978 certification of noncompliance in the matter of the application for financial assistance submitted by the Brodhead Nail Company. Interested parties are invited to participate in the review in the manner and time indicated in the Rules of Procedure set forth below.

B. BACKGROUND

Under Section 310B of the Consolidated Farm and Rural Development Act, as amended (the Act), the Secretary of Agriculture is authorized to make and insure loans "for the purpose of improving, developing, or financing business, industry, and employment and improving the economic and environmental climate in rural communities." Section 310B(d), however, prohibits the extension of any financial or other assistance which is calculated or likely to result in either: (1) the displacement of workers at any of the applicant's current business locations; or (2) an increase in production beyond demand to employ the efficient capacity of existing competitive enterprises, unless the assistance will not have an adverse effect upon existing competitive enterprises in the area.

Subsection 310B(d)(3) affords the Secretary of Labor 30 days within which to review applications submitted under this section and certify noncompliance with the statutory restrictions. In the event that the Secretary of Labor exercises his authority under this section to issue a negative certification, subsection 310B(d)(3) prohibits the extension of any assistance.

Pursuant to these statutory provisions, Brodhead Nail Company has applied to the Department of Agriculture for a $2,000,000 loan guarantee. The purpose of the requested assistance is to finance construction of a nail mill facility at Swannanoa, North Carolina capable of producing a full commercial line of steel wire nails.

ETA received copies of the Brodhead application from the Department of Agriculture on September 13, 1978, starting the 30-day statutory period for review. Pursuant to the procedures set forth in the Department of Labor regulations at 29 CFR Part 75, Information concerning this application was published in the Federal Register on September 19, 1978, at 43 FR 42494. In response to this invitation, the Department received adverse comments from a competitor, Bethlehem Steel Corporation, on October 10, 1978. Copies of the material submitted by them was forwarded to the applicant pursuant to 29 CFR 75.11(b)(3) to afford an opportunity for rebuttal. The 30-day period for Department of Labor review, however, was due to expire on October 13, 1978, but was extended for the period for comment afforded to the applicant to submit rebuttal evidence.

Based on information contained in the application and supporting materials, and other evidence-gathered in the course of reviewing this application, the Department of Labor determined that the requested assistance was not calculated or likely to result in the displacement of workers at any of the applicant's current business locations. The materials submitted by Bethlehem Steel Corporation, however, supported a determination that the proposed manufacture of steel nails was likely to increase production when there was not sufficient demand to employ the efficient capacity of existing enterprises. In view of this evidence the Department of Labor issued a negative certification on October 13, 1978. Although this determination had the effect of barring the assistance requested from Agriculture, the Department of Labor indicated that it would reconsider its action in accordance with 29 CFR 75.11(b)(6) if either the applicant or the Secretary of Agriculture were to furnish additional evidence bearing on the market capacity issue.

On November 9, 1978, Brodhead Nail Company submitted rebuttal evidence wherein it contended inter alia that the line of nails it would manufacture at its proposed plant would not infringe on the domestic nail market, but would rather cut into the market for nails produced by foreign mills. According to the applicant, the proposed nail mill facility would produce and market packaged nails which are now available largely from foreign producers. The applicant cited reports of a growing demand for this type of packaged nail which it maintained is currently being satisfied in the area of the applicant's proposed facility almost exclusively by foreign producers. This information would tend to support a determination that the requested assistance would not have an adverse impact on existing competitive enterprises in the United States.

In view of the difficult issues raised by the particularly complex and conflicting factual information presented in the adverse comments submitted by Bethlehem Steel and in the applicant's request for reconsideration, ETA is providing for the designation of a hearing officer to reconsider its October 13, 1978 certification of noncompliance with the Act. The request for reconsideration has been forwarded, together with a copy of the record upon which the decision was made, to the Chief Administrative Law Judge of the Department of Labor. The proceedings in this matter shall be in accordance with the Rules of Procedure set forth below.

C. RULES OF PROCEDURE

(1) A hearing officer will be designated by the Chief Administrative Law Judge, United States Department of Labor, to perform the functions required by these rules.

(2) The parties of record shall be the Brodhead Nail Company and the Bethlehem Steel Corporation.

(3) Any State employment security agency, individual employer or worker, or any organization or association of employers or workers, or the public, having an interest in these proceedings, may apply for permission to participate in these proceedings as an interested party. The United States Department of Labor, represented by the Solicitor of Labor, may participate as an "amicus curiae". Any State employment security agency, person, organization, or association described above, may apply for permission to participate in these proceedings as an interested party in filing the Notice in the Federal Register.

(4) The hearing officer shall afford all parties 30 days from the date of this notice to submit or decline to submit any appropriate legal brief.

(5) The hearing officer may conduct further factfinding as appropriate to elicit any additional information deemed relevant or necessary to reach a determination.

(6) The hearing officer shall review the certification of noncompliance on
NOTICES

E. RECOMMENDED DECISION

The hearing officer shall prepare a recommended decision which shall state its legal and/or factual bases. The hearing officer shall transmit the recommended decision along with a certified record of the proceedings to the Assistant Secretary for Employment and Training who shall render a final decision in the matter.

Signed at Washington, D.C. on May 9, 1979.

RAY MARSHALL,
Secretary of Labor

[FR Doc. 79-7206 Filed 3-8-79; 8:45 am]

[Docket No. 79-7206]

Office of Federal Contract Compliance Programs

EQUAL EMPLOYMENT OPPORTUNITY

OFCCP Regional Office Contact Points for Pre-Award Clearance Requests

The Heads of Agencies Memorandum which follows furnishes an updated list of OFCCP Regional Office telephone numbers which are the contact points for pre-award clearance requests.


RAY MARSHALL,
Secretary of Labor

[FR Doc. 79-7206 Filed 3-8-79; 8:45 am]

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979

The foregoing information will also be published in the Federal Register.

[FR Doc. 79-7207 Filed 3-8-79; 8:45 am]
NOTICES


ROBERT B. LACATHER,
Assistant Secretary for
Mine Safety and Health.

[F.R. Doc. 79-7210 Filed 3-8-79; 8:45 a.m.]

[4510-43-M]

[Petition for Modification of Application of
Mandatory Safety Standard]

Climax Molybdenum Company, 13949 West Colfax Avenue, Golden, Colorado 80401, has filed a petition to modify the application of 30 CFR 57.12-1 (circuit overload protection) to its Climax Mine, located in Climax, Colorado. This 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 follows:

1. The petitioner requests permission to operate its slusher motors with the circuit breakers and ground protection currently used.

2. The slusher motors have overload protection in the form of circuit breakers of the correct type and capacity. These circuit breakers provide both instantaneous and thermal tripping.

3. The slusher motors are grounded in such a way that should the overload system malfunction, the slusher motor frame would not become energized and there would be no shock hazard to the employee.

4. The petitioner has used its present system of circuit breakers, or a comparable fusing system, and grounding protection since its mine opened over forty years ago. During that time no employee has ever been electrocuted or suffered an injury from electrical shock from the slusher motors. Nor has any employee ever been killed or injured as a result of any fire attributable to alleged imperfections in the slusher motor electrical system.

5. The petitioner states that the engineering and operation of its slusher motors achieve no less protection for its miners than that provided by the standard.

REQUEST FOR COMMENT

Persons interested in this petition may furnish written comments on or before April 9, 1979. 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.


ROBERT B. LACATHER,
Assistant Secretary for
Mine Safety and Health.

[F.R. Doc. 79-7210 Filed 3-8-79; 8:45 a.m.]

[CLIMAX MOLYBDENUM CO.]

Petition for Modification of Application of Mandatory Safety Standard

Climax Molybdenum Company, 13949 West Colfax Avenue, Golden, Colorado 80401, has filed a petition to modify the application of 30 CFR 57.12-1 (circuit overload protection) to its Climax Mine, located in Climax, Colorado. This 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 follows:

1. The petitioner requests permission to operate its slusher motors with the circuit breakers and ground protection currently used.

2. The slusher motors have overload protection in the form of circuit breakers of the correct type and capacity. These circuit breakers provide both instantaneous and thermal tripping.

3. The slusher motors are grounded in such a way that should the overload system malfunction, the slusher motor frame would not become energized and there would be no shock hazard to the employee.

4. The petitioner has used its present system of circuit breakers, or a comparable fusing system, and grounding protection since its mine opened over forty years ago. During that time no employee has ever been electrocuted or suffered an injury from electrical shock from the slusher motors. Nor has any employee ever been killed or injured as a result of any fire attributable to alleged imperfections in the slusher motor electrical system.

5. The petitioner states that the engineering and operation of its slusher motors achieve no less protection for its miners than that provided by the standard.

REQUEST FOR COMMENT

Persons interested in this petition may furnish written comments on or before April 9, 1979. 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.


ROBERT B. LACATHER,
Assistant Secretary for
Mine Safety and Health.

[F.R. Doc. 79-7210 Filed 3-8-79; 8:45 a.m.]

[4510-43-M]

[Petition for Modification of Application of
Mandatory Safety Standard]

Kanawha Coal Company, P.O. Box 38, Ashford, West Virginia 25003, has filed a petition to modify the application of 30 CFR 75.305 (weekly examination for hazardous conditions) to its Madison Mine #1 located in Boone County, West Virginia. This 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 follows:

1. Instead of traveling the length of return air entries to examine for hazardous conditions as required by the standard, the petitioner requests permission to make the return air examinations on a weekly basis from surface locations.

2. Surface locations exist at the petitioner's mine for readily making surface measurements.

3. Traveling the entire length of the return air entry presents a greater danger to miners than the proposed alternative method of making measurements from surface locations.

4. The petitioner's mine does not have a comparable fusing system, and the slusher motor in such a way that should the overload system malfunction, the slusher motor frame would not become energized and there would be no shock hazard to the employee.

5. The petitioner states that the engineering and operation of its slusher motors achieve no less protection for its miners than that provided by the standard.

REQUEST FOR COMMENT

Persons interested in this petition may furnish written comments on or before April 9, 1979. 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.


ROBERT B. LACATHER,
Assistant Secretary for
Mine Safety and Health.

[F.R. Doc. 79-7210 Filed 3-8-79; 8:45 a.m.]
NOTICES

<table>
<thead>
<tr>
<th>Date</th>
<th>Document Name</th>
<th>Page(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1979-03-09</td>
<td>UTAH STATE STANDARDS Notice of Approval</td>
<td>1-5</td>
</tr>
</tbody>
</table>

UTAH STATE STANDARDS

Notice of Approval

1. Background: Part 1953 of title 29, Code of Federal Regulations, prescribes procedures under Section 18 of the Occupational Safety and Health Act of 1970 (hereinafter called the Act) by which the Regional Administrator for Occupational Safety and Health (hereinafter called the Regional Administrator) under a delegation of authority from the Assistant Secretary of Labor for Occupational Safety and Health (hereinafter called the Assistant Secretary), (29 CFR 1953.4) will review and approve standards promulgated pursuant to a State Plan which has been approved in accordance with Section 18(c) of the Act and 29 CFR Part 1902. On January 10, 1973, notice was published in the Federal Register (38 FR 11795) of the approval of the Utah Plan and the adoption of Subpart E to Part 1902 containing the decision.

The Utah Plan provides for the adoption of Federal Standards as State Standards by:

1. Advisory Committee recommendation.
2. Publication in newspapers of general/major circulation with a 30-day waiting period for public comment and hearing(s).
3. Commission order adopting the standards and designating an effective date.
4. Providing certified copies of Rules and Regulations or Standards to the Office of the State Archivist.

Section 1953.113 of Subpart E sets forth the State's schedule for adoption of Federal Standards. By letter dated January 25, 1979, from Ronald H. Joseph, Administrator, Utah Occupational Safety and Health Division, to Curtis A. Foster, Regional Adminis-trator, and incorporated as part of the Plan, the State submitted rules and regulations concerning 29 CFR 1910.1000 Air Contaminants, Table Z-1 (Amended), 43 FR 19624, Friday, May 5, 1978 and 29 CFR 1910.1000 Air Contaminants, Table Z-1 (Amended), 43 FR 57602, Friday, December 8, 1978. These standards, which are contained in the Utah Occupational Safety and Health Rules and Regulations for General Industry, were promulgated per the requirements of Utah Code annotated 1955, Title 69-46-1, and in addition, published in newspapers of general/major circulation throughout the State. No public comment was received and no hearings held.

The Standards for Occupational Exposure to Air Contaminants, Table Z-1 (Amended) was adopted by the Industrial Commission of Utah, Archives File Number 3096 and 3097 on January 4, 1979, pursuant to Title 35-9-6 Utah Code annotated 1953.

2. Decision: The State submission having been reviewed in comparing with the Federal Standards, it has been determined that the State Standards are identical to the Federal Standards and accordingly should be approved.

3. Location of Supplement for Inspection and Copy: A copy of the standards supplement, along with the approved plan, may be inspected and copied during normal business hours at the following locations: Office of the Regional Administrator, Room 1554, Federal Office Building, 1611 Stout Street, Denver, Colorado 80224; Utah State Industrial Commission, UOSHA Offices at 448 South 400 East, Salt Lake City, Utah 84111; and the Technical Data Center, Room N2439R, 3rd Constitution Avenue, N.W., Washington, D.C. 20210.

4. Public Participation: Under 29 CFR 1953.2(c), the Assistant Secretary may prescribe alternative procedures to expedite the review process or for other good cause which may be consistent with applicable laws. The Assistant Secretary finds that good cause exists for not publishing the supplement to the Utah State Plan as a proposed change and making the Regional Administrator's approval effective upon publication for the following reason:

The Standards were adopted in accordance with the procedural requirements of State-law which permitted public comments, and further public participation would be repetitive.

This decision is effective March 9, 1979.

(Sec. 18, Pub. L. 91-596, 84 Stat. 1608 (29 U.S.C. 697).)
NOTICES

[4510-22-M]

[Secretary of Labor's Order 1-79]

AIRLINE DEREGULATION ACT OF 1978

Delegation of Authority and Assignment of Responsibility

1. Purpose. To delegate authority and assign responsibility in the Department of Labor for the implementation and administration of the Secretary of Labor's responsibilities under the Airline Deregulation Act of 1978.

2. Authority and Directives Affected.

a. Authority. This Order is issued pursuant to the Airline Deregulation Act of 1978, Pub. L. No. 95-504.

b. Directives Affected. The authorities delegated herein are in addition to those delegated in Secretary's Orders 6-78, 9-77, and 4-75, which Orders remain in effect.

3. Background. The Airline Deregulation Act of 1978 curtails the regulatory authority of the Civil Aeronautics Board in order to increase competition within the U.S. domestic airlines industry. Under provisions of the Act, protection would be afforded to all employees who had four years of service upon enactment. Certain protection provisions, such as first right of hire, are effective immediately. Other monetary protection would be provided for employees deprived of employment or adversely affected with respect to compensation by a "quarantying dislocation" as determined by the Civil Aeronautics Board and occurring during the first ten years after enactment.

4. Delegation of Authority and Assignment of Responsibility.

a. The Assistant Secretary for Employment and Training is delegated authority and assigned responsibility under the Airline Deregulation Act of 1978 for:

(1) The development, promulgation, and administration of policies, regulations and procedures concerning benefit payments required under Section 43(d)(2).

(2) Maintenance of liaison with the Civil Aeronautics Board; and beginning January 1, 1983, the Department of Transportation, under the Sunset provisions of the Act.

(3) The determination of individual eligibility and the administration of monthly benefit payments from a separate account maintained in the Treasury of the United States to be known as the Airline Employees Protective Account, to affected employees, as provided by Section 43 (a), (b), (c), (d) and (e).

b. The Assistant Secretary for Labor shall arrange for the representation of affected employees in cases involving the possibility of group representation through labor unions. The Solicitor of Labor shall provide legal advice and assistance to all Department of Labor officials relating to the implementation of this Order.

c. Entering into agreements with agencies of the Federal Government, as required, to carry out responsibilities under this Act.

6. Effective Date. This Order is effective February 15, 1979.

[4510-28-M]

INVESTIGATIONSregarding CERTIFICATION OF ELIGIBILITY TO APPLY FOR WORKER ADJUSTMENT ASSISTANCE

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Bureau of International Affairs, has instituted investigations pursuant to Section 221(a) of the Act and 29 CFR 90.12.

The purpose of each of the investigations is to determine whether absolute or relative increases of imports or articles like or directly competitive with articles produced by the worker's firm and an appropriate subdivision thereof have contributed importantly to an absolute decline in sales or production, or both, of such firm or subdivision and to the actual or threatened total or partial separation of a significant number or proportion of the workers of such firm or subdivision.

Petitioners meeting these eligibility requirements will be certified as eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act in accordance with the provisions of Subpart B of 29 CFR Part 30. The investigations will further proceed as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

Pursuant to 29 CFR 90.13, the petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing: Provided, Such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than March 19, 1979.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than March 19, 1979.

The petitions filed in this case are available for inspection at the Office
INVESTIGATIONS REGARDING CERTIFICATIONS OF ELIGIBILITY TO APPLY FOR WORKER ADJUSTMENT ASSISTANCE

The petitioners have received the petitions filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 ("the Act") and are in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, has instituted investigations pursuant to Section 221(a) of the Act and 29 CFR 90.12.

The purpose of each of the investigations is to determine whether absolute or relative increases of imports of articles produced by the workers' firm or an appropriate subdivision thereof have contributed importantly to an absolute decline in sales or production, or both, of such firm or subdivision and to the actual or threatened total or partial separation of a significant number or proportion of the workers of such firm or subdivision.

Petitioners meeting these eligibility requirements will be certified as eligible to apply for adjustment assistance, at the address shown below, not later than March 19, 1979. Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than March 19, 1979.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Signed at Washington, D.C., this 28th day of February 1979.

MARVIN M. FOKIS, Director, Office of Trade Adjustment Assistance.

APPENDIX

<table>
<thead>
<tr>
<th>Petitioner:</th>
<th>Location</th>
<th>Date received</th>
<th>Date of petition</th>
<th>Petition No.</th>
<th>Articles produced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amherst Coal Company</td>
<td>Fanco, Va.</td>
<td>2/22/79</td>
<td>2/15/79</td>
<td>TA-W-4, 840</td>
<td>Metallurgical coal</td>
</tr>
<tr>
<td>Plant (workers)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bow Sportswear (ILGWU)</td>
<td>Lodi, N.J.</td>
<td>2/12/79</td>
<td>2/12/79</td>
<td>TA-W-4, 845</td>
<td>Ladies sportswear</td>
</tr>
<tr>
<td>Capehart Corporation Sales Division</td>
<td>New York, N.Y.</td>
<td>1/30/79</td>
<td></td>
<td>TA-W-4, 844</td>
<td>Stereo modules</td>
</tr>
<tr>
<td>Carol Foundations, Incorporated</td>
<td>Hato Tejas, Bayamon, P.R.</td>
<td>2/22/79</td>
<td>2/12/79</td>
<td>TA-W-4, 845</td>
<td>Brasiers</td>
</tr>
<tr>
<td>Columbian Rope Co. (ACTWU)</td>
<td>Jefferson, La.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>G.C. Fashions (workers)</td>
<td>Glencoe, N.Y.</td>
<td>2/16/79</td>
<td>2/12/79</td>
<td>TA-W-4, 847</td>
<td>Ladies coats</td>
</tr>
<tr>
<td>Plant #1 (ACTWU)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>J. Dee Sportsware, Incorporated</td>
<td>Paulsboro, N.J.</td>
<td>2/12/79</td>
<td>1/22/79</td>
<td>TA-W-4, 849</td>
<td>Uniforms</td>
</tr>
<tr>
<td>Kingston Orans (workers)</td>
<td>Fayetteville, Tenn.</td>
<td>2/16/79</td>
<td>2/12/79</td>
<td>TA-W-4, 851</td>
<td>Women's apparel</td>
</tr>
<tr>
<td>Natale Knitting Mills (workers)</td>
<td>Chilhowie, Va.</td>
<td>2/14/79</td>
<td>2/14/79</td>
<td>TA-W-4, 852</td>
<td>Men's and ladies sweaters and leotards</td>
</tr>
<tr>
<td>OMNOCO (workers)</td>
<td>Inwood, N.Y.</td>
<td>2/16/79</td>
<td>1/30/79</td>
<td>TA-W-4, 853</td>
<td>Children's, women's and men's sportswear</td>
</tr>
<tr>
<td>Texten, Inc., Spedel Division (company)</td>
<td>Overland Park, Kan.</td>
<td>2/22/79</td>
<td>2/14/79</td>
<td>TA-W-4, 855</td>
<td>Electronic liquid crystal display watch modules</td>
</tr>
<tr>
<td>Tru-Fit Knitwear, Incorporated</td>
<td>Brooklyn, N.Y.</td>
<td>2/11/79</td>
<td>2/10/79</td>
<td>TA-W-4, 856</td>
<td>Ladies sweaters</td>
</tr>
<tr>
<td>(ILGWU)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
INVESTIGATIONS REGARDING CERTIFICATIONS OF ELIGIBILITY TO APPLY FOR WORKER ADJUSTMENT ASSISTANCE

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, has instituted investigations pursuant to Section 221(a) of the Act and 29 CFR 90.12.

The purpose of each of the investigations is to determine whether absolute of relative increases of imports of articles like or directly competitive with articles produced by the workers' firm or an appropriate subdivision thereof have contributed importantly to an absolute decline in sales or production, or both, of such firm or subdivision and to the actual or threatened total or partial separation of a significant number or proportion of the workers of such firm or subdivision.

Petitioners meeting these eligibility requirements will be certified as eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act in accordance with the provisions of Sub-part B of 29 CFR Part 90. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

Pursuant to 29 CFR 90.13, the petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing. Provided, Such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than March 19, 1979.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than March 19, 1979.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Signed at Washington, D.C., this 28th day of February 1979.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

---

### Appendix

<table>
<thead>
<tr>
<th>Petition/Union/workers or former workers of</th>
<th>Location</th>
<th>Date received</th>
<th>Date of petition</th>
<th>Petition No.</th>
<th>Articles produced</th>
</tr>
</thead>
<tbody>
<tr>
<td>Broderick &amp; Bascom Rope Company</td>
<td>St. Louis, Mo</td>
<td>2/22/79</td>
<td>2/15/79</td>
<td>TA-W-4, 858</td>
<td>Warehouse of wire rope and general office.</td>
</tr>
<tr>
<td>(USWA)</td>
<td></td>
<td></td>
<td></td>
<td>TA-W-4, 859</td>
<td>Steel wire rope.</td>
</tr>
<tr>
<td>(USWA)</td>
<td></td>
<td></td>
<td></td>
<td>TA-W-4, 861</td>
<td>Purchase and sell textile machinery.</td>
</tr>
<tr>
<td>(OCWAW)</td>
<td></td>
<td></td>
<td></td>
<td>TA-W-4, 863</td>
<td>Ferrite magnetic cores.</td>
</tr>
<tr>
<td>(company)</td>
<td></td>
<td></td>
<td></td>
<td>TA-W-4, 865</td>
<td>Ladies sportswear, and men's and ladies sweaters.</td>
</tr>
<tr>
<td>Eaton Corporation, Mansfield Plant</td>
<td>Mansfield, Ohio</td>
<td>2/20/79</td>
<td>2/21/79</td>
<td>TA-W-4, 866</td>
<td>Administrative and support services.</td>
</tr>
<tr>
<td>(Allied Ind. Wkrs)</td>
<td></td>
<td></td>
<td></td>
<td>TA-W-4, 867</td>
<td>Ladies footwear.</td>
</tr>
<tr>
<td>(workers)</td>
<td></td>
<td></td>
<td></td>
<td>TA-W-4, 869</td>
<td>Sportswear.</td>
</tr>
<tr>
<td>(USWA)</td>
<td></td>
<td></td>
<td></td>
<td>TA-W-4, 877</td>
<td>Men's suits, top coats, slacks, and sportcoats.</td>
</tr>
<tr>
<td>(workers)</td>
<td></td>
<td></td>
<td></td>
<td>TA-W-4, 879</td>
<td>Ladies footwear.</td>
</tr>
</tbody>
</table>

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on December 12, 1978 in response to a worker petition received on December 6, 1978 which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing ladies' coats at Mar-Cal, Los Angeles, California.

The Notice of Investigation was published in the Federal Register on December 19, 1978 (43 FR 59180). No public hearing was requested and none was held.

In a letter dated February 6, 1979 the petitioner requested withdrawal of the petition. On the basis of the withdrawal, continuing the investigation would serve no purpose. Consequently the investigation has been terminated.

Signed at Washington, D.C. this 23rd day of February 1979.

MARTIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

NOTICES

[4510-28-M]
Office of the Secretary

[TA-W-4706]

REPUBLIC STEEL CORP.

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-4706: investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 223 of the Act.

The investigation was initiated on January 15, 1979 in response to a worker petition received on January 9, 1979 which was filed by the United Steelworkers of America on behalf of workers and former workers producing carbon steel, carbon steel and alloyed steel bars and bar products at the Buffalo, New York plant in the Buffalo District of Republic Steel Corporation. The investigation revealed that the plant primarily produces carbon and alloy steel bars.

The Notice of Investigation was published in the Federal Register on January 26, 1979 (44 FR 5533): No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Republic 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 criteria has not been met:

That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated.

Average employment in the Buffalo District increased from 1977 to 1978. Employment increased in each quarter of 1978 compared to the respective quarter of the previous year.

No partial separations occurred. There is no immediate threat of separations to workers at the Buffalo District plant.

CONCLUSION

After careful review, I determine that all workers of the Buffalo, New York plant in the Buffalo District of Republic Steel Corporation 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 5th day of March 1979.

HARRY J. GILMAN,
Supervisory Economist, Office of Foreign Economic Research.

[FR Doc. 79-7211 Filed 3-8-79; 8:45 am]

NATIONAL SCIENCE FOUNDATION

THE ADVISORY COMMITTEE FOR ENGINEERING

Amendment to the Notice of Meeting

The Subcommittee on Engineering Chemistry and Energetics of the Advisory Committee for Engineering will be meeting in Washington, D.C. on March 19 and 20.

The Notice of Meeting that appeared in the Federal Register on Wednesday, February 28, 1979, stated that the meeting would be held in Room 543. This has been changed and the meeting will now be held in Room 1242.

If there are any questions concerning the meeting, please call Dr. Marshall Lin, 202-632-5867.

March 5, 1979.

M. REBECCA WINKLER,
Committee Management Coordinator.

[FR Doc. 79-7150 Filed 3-8-79; 8:45 am]

EXECUTIVE COMMITTEE OF THE ADVISORY COMMITTEE FOR ENVIRONMENTAL BIOLOGY

Meeting

In accordance with the Federal Advisory Committee Act, as amended Public L. 92-463, the National Science Foundation announces the following meeting:

NAME: Executive Committee of the Advisory Committee for Environmental Biology.

DATE AND TIME: March 26 & 27, 1979, 8:30 a.m. to 5:00 p.m.


TYPE OF MEETING: Closed.
NOTICES

CONTACT PERSON: Dr. John L. Brooks, Deputy Division Director, Environmental Biology, Room 336, National Science Foundation, Washington, D.C. 20550. (202) 632-7318.

PURPOSE OF EXECUTIVE COMMITTEES: To provide advice and recommendations concerning support of research in ecology and population biology and physiological ecology.

AGENDA: To review and evaluate internal records leading to an overview and appraisal of administrative performance in the Ecology Program and the Population Biology and Physiological Ecology Program.

REASON FOR CLOSING: The data being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are within exemptions (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 Director, NSF, in accordance with the provisions of Section 10(d) of Pub. L. 92-463, the Federal Advisory Committee Act.

March 5, 1979.

M. REBECCA WINKLER, Committee Management Coordinator.

[FR Doc. 79-7149 Filed 3-8-79; 8:45 am]

[7555-01-M]

FEDERAL ADVISORY COMMITTEES

Review

The National Science Foundation is conducting a comprehensive review of its advisory groups and is soliciting input from all interested persons for this evaluation.

In the letter of February 25, 1977, to the heads of Executive Departments and Establishments, the President expressed his concern about the number and usefulness of Federal advisory committees, and directed that the comprehensive review be conducted on a zero-based concept and be predicated on the principle that all committees should be abolished except those (1) for which there is a compelling need; (2) which have truly balanced membership; and (3) which conduct their business as openly as possible consistent with the law and their mandate. He further stated that each agency should provide for open and public participation in its review process to the maximum extent possible.

All comments should be directed to the Committee Management Coordinator, Division of Financial and Administrative Management, Room 248, National Science Foundation, Washington, D.C. 20550, no later than March 30, 1979. These comments will be forwarded to the appropriate officials in the review process.

In accordance with the President's letter and further instructions from the General Services Administration, the review will be conducted by the Director, NSF, and will encompass the following advisory groups:

- Advisory Committee for Applied Science & Research Applications Policy
- Advisory Committee for Astronomical Sciences
- Advisory Committee for Atmospheric Sciences
- Advisory Committee for Behavioral and Neural Sciences
- Advisory Committee for Chemistry
- Advisory Committee for Earth Sciences
- Advisory Committee for Engineering
- Advisory Committee for Environmental Biology
- Advisory Committee for Information Science and Technology
- Advisory Committee for International Programs
- Advisory Committee for Materials Research
- Advisory Committee for Mathematical and Computer Sciences
- Advisory Committee for Ocean Sciences
- Advisory Committee for Physics
- Advisory Committee for Physiology, Cellular & Molecular Biology
- Advisory Committee for Policy Programs
- Advisory Committee for Policy Research and Analysis and Science Resources Studies
- Advisory Committee for Social Sciences
- Advisory Committee for Two-Year College Science Education Needs Assessment
- Advisory Committee on Science and Society
- Alan T. Waterman Award Committee
- DOE/NSF Nuclear Science Advisory Committee
- National Science Foundation Advisory Council

President's Committee on the National Medal of Science

March 5, 1979.

M. REBECCA WINKLER, Committee Management Coordinator.

[FR Doc. 79-7149 Filed 3-8-79; 8:45 am]

[7590-01-M]

NUCLEAR REGULATORY COMMISSION

REVIEW OF NRC'S ADVISORY COMMITTEES

This is to announce that the Nuclear Regulatory Commission is seeking public comment in connection with the annual comprehensive review of advisory committees now being undertaken in accordance with Office of Management and Budget guidance provided in Circular No. A-63, Transmittal Memorandum No. 5, dated March 7, 1977.

This annual government-wide zero-base review takes into account the following considerations: (1) is there a compelling need for each committee, because, for example, the information or advice cannot be obtained from other sources within the agency or other agencies; (2) does each committee have truly balanced membership in terms of points of view represented and functions to be performed; and (3) does each committee conduct its business as openly as possible consistent with the law and its mandate.

A brief description of the NRC's advisory committee which is now undergoing review follows:

Advisory Committee on Reactor Safeguards. This committee was established by Section 29 of the Atomic Energy Act of 1954, as amended, to review safety studies and facility license applications and to advise the Commission with regard to the hazards of proposed or existing reactor facilities and the adequacy of proposed reactor safety standards. It is composed of a maximum of 15 members who represent diverse scientific and engineering specialties relating to nuclear reactor design, construction and operation. This committee, its subcommittees and working groups hold approximately 110 meetings annually and issues about 60 reports.

The NRC is required to complete its review not later than April 16, 1979. Therefore, any public comments and recommendations concerning NRC's advisory committees should be provided to the NRC as soon as possible, and in any event no later than April 6, 1979. Interested persons should direct their comments in writing to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Advisory Committee Management Officer.

Dated at Washington, D.C., this 6th day of March, 1979.

John C. Hoyle, Advisory Committee Management Officer.

[FR Doc. 79-7149 Filed 3-8-79; 8:45 am]

[3190-01-M]

OFFICE OF THE SPECIAL REPRESENTATIVE FOR TRADE NEGOTIATIONS

[Doc. No. 301-13]

TANNER'S COUNCIL OF AMERICA 301 COMMITTEE

Indefinite Postponement of Hearings

Because of substantial progress in negotiations, hearings scheduled for March 13 and 14 are hereby indefinitely postponed. A further announce-
ment will be made in the near future. Pursuant to Federal Register notice of January 17, 1979, hearings were scheduled for February 27 and 28, 1979, with respect to proposed action on certain articles from Japan under Section 301 of the Trade Act. (See Federal Register of January 17, 1979, page 3590.) This action was proposed in response to Japanese import restrictions on leather exported from the United States and elsewhere. These hearings were rescheduled for March 13 and 14, 1979 by Federal Register notice of Friday, February 23, 1979.

WILLIAM E. BARREDA, Assistant Special Trade Representative.

[FR Doc. 79-7163 Filed 3-8-79; 3:45 am]

[8320-01-M]

VETERANS ADMINISTRATION
ADVISORY COMMITTEE ON STRUCTURAL SAFETY OF VETERANS ADMINISTRATION FACILITIES

Meeting

The Veterans Administration gives notice pursuant to Public Law 92-463 that a meeting of the Advisory Committee on Structural Safety of Veterans' Administration Facilities will be held in Room 442 at the Lafayette Building, 811 Vermont Avenue, NW., Washington, D.C. on April 6, 1979, at 10 a.m. The Committee members will review Veterans Administration construction standards and criteria relating to fire, earthquake and other disaster resistant construction.

The meeting will be open to the public, up to the seating capacity of the room. Because of the limited seating capacity, it will be necessary for those wishing to attend to contact Mr. James Letier, Director, Civil Engineering Service, Office of Construction, Veterans Administration Central Office (phone 202-389-2864), prior to April 5, 1979.


By direction of the Administrator:

MAURY S. CRALLE, Jr., Assistant Deputy Administrator for Financial Management and Construction.

[FR Doc. 79-7170 Filed 3-7-79; 8:45 am]

NOTICES

[7035-01-M]

INTERSTATE COMMERCE COMMISSION

INTERSTATE COMMERCE COMMISSION

(Finance Docket No. 28905 (Sub-Nos. 1F and 2F); No. MC-F-13810F)

CSX CORP.—CONTROL—CHESSIE SYSTEM, INC., AND SEABOARD COAST LINE INDUSTRIES, INC.

Railroad Operation, Acquisition and Construction; Initial Prehearing Conference Procedures

MARCH 7, 1979,


On February 15, 1979, the Commission published a notice in the Federal Register, 44 FR 9839, accepting the application in these proceedings. The notice also stated that an initial prehearing conference could be held on April 24, 1979, to discuss, among other things, disputes involving discovery and related matters.

Due to the time constraints under which the participants in these proceedings will be preparing their respective cases, this notice is being issued in advance of the prehearing conference in order to allow as much time as possible to prepare for the conference. While the deadline for filing comments in response to the applications is not until April 2, 1979, the procedures set forth in this notice will be applicable to all persons submitting comments on that date.

The prior Federal Register notice stated that discovery and related matters should be concluded prior to the prehearing conference to permit rulings at that time by the administrative law judge. Additional procedures relating to discovery are herein set out to insure that any disputes as to the production of information can be settled prior to the conference. In addition to procedures set forth in the prior notice, the parties shall observe the following:

1. On or before April 13, 1979, any person who seeks discoverable information from the applicants as to any then-pending application shall file requests for those forms of discovery permitted under the Commission's rules. Persons seeking information are advised that requests filed after April 13, 1979, will be considered only upon a showing of exceptional cause.

II. On or before April 23, 1979, counsel for applicants and those parties which have sought discovery shall meet and attempt to resolve outstanding discovery issues. The parties shall be prepared at the conference to inform the judge of the extent of these negotiations and of the extent to which outstanding discovery positions have not been satisfied and are being pressed. Copies of all inter-party correspondence relating to discovery shall be served on the judge.

April 16, 1979, is the date on or before which applicants must file their verified statements. Applicants shall identify and order those verified statements by placing in the upper right-hand corner of the cover page of each statement a two-letter prefix which identifies the applicant sponsoring the statement, followed by a number reflecting its position in the anticipated sequence of the introduction of statements at the oral hearing.

On or before April 23, 1979, each of the parties shall file with the Commission, and delivery to the judge, a summary statement of the following information: Interests, position, and relief sought; the specific issues in the proceeding; areas for stipulation and areas of possible dispute over material facts; areas of opinion or argument that would require presentation subject to cross-examination; and prospective areas of negotiation of protective conditions or other understandings between parties.

The following matters will be considered at the conference:

1. The position of participants;

2. Schedules and locations for hearings;

3. Procedures at hearing, e.g., use of verified statements for direct testimony and oral cross-examination; limitations on cross-examination; order and number of witnesses; consolidation of positions of parties; service of pleadings; nature and scope of preclusion orders;

4. Requests for discovery;

5. Types of evidence proposed to be submitted;

6. Stipulations as to labor protective and other conditions;

7. Identification of issues which are properly the subject of expert testimony;

8. Stipulations as to qualifications of expert witnesses proposed to be called at the oral hearing (applicants shall be prepared to submit written offers of proof at the conference);

9. Designation of liaison counsel by parties with common interests in the proceedings;

10. Traffic and operational data shall be submitted by all carrier parties: a. Copies of all existing preferential solicitation agreements, if any exist; b. Existing run-through train operations; described as to method of operation, participating carriers, and the market served;

11. Definition of terms;

FEDERAL REGISTER, VOL 44, NO. 48—FRIDAY, MARCH 9, 1979
12. Identification and simplification of the major issues in the proceeding:
13. Stipulation to the use of documents without objection, including but not limited to:
   b. Any report regularly made to the I.C.C. by any carrier pursuant to law or Commission regulations.
   c. All tariffs filed with the I.C.C. by, or on behalf of, any carrier.
   d. All regularly published publications of the Interstate Commerce Commission or its Offices or Bureaus.
   e. The Official Railway Guide.
   f. The Official Rail Equipment Register.
   g. Reports of the I.C.C. and courts of competent jurisdiction.
   h. Economic Reports of the President of the United States of America.
   i. Annual Reports of the Securities and Exchange Commission to the Congress of the United States of America.
   j. All regularly published reports of the United States Department of Transportation.
14. Stipulation to the use of the following items, as currently available, up to the close of the record, without challenge to their authenticity, but without agreement as to competency, relevancy or materiality:
   a. Annual reports to stockholders of any carrier or affiliate of a carrier subject to I.C.C. jurisdiction.
   b. Proxy statements issued to stockholders by the management of any carrier or affiliate of any carrier subject to I.C.C. jurisdiction, and statements of information in connection with exchange offers and other public stockholder solicitation material.
   e. Bank and Quotation Record, National News Service, Inc., Publisher.
   f. Other regularly published, readily obtainable statistical material.
   g. Parties and prospective parties in the presently pending application proceedings are notified that the failure of any party to appear at the prehearing conference shall be construed as a waiver of its right to participate further in the proceedings.
   h. On January 16, 1979, the commission served its decision on applicants' petition seeking waiver of certain provisions of the Commission's Consolidation Procedures, in Finance Docket No. 28905 CSX Corporation-Control-Cheesie System, Inc., and Seaboard Coast Line Industries, Inc. (not printed). Among the provisions which the Commission waived was that which requires applicants to file concurrently with their primary application all directly related applications. The Commission allowed applicants to file related trackage rights, abandonment and coordination project applications on or before May 20, 1979. It is possible that those persons to be effected by the prospective abandonments, as well as appropriate state agencies, may wish to participate in the prehearing conference. In order to protect the interests of these parties, applicants shall serve copies of this notice and of the notice published in Federal Register on February 15, 1979, on (a) those shippers who are significant users of the lines proposed to be abandoned, and (b) the Public Service Commission and designated state agency of each state in which all or part of any line sought to be abandoned is situated. Service shall be accomplished no later than 10 days from the service date of this notice.
   i. At the prehearing conference a service list and all decisions of the Commission related to these proceedings will be available. The admissibility of any late filed pleadings will be determined at the prehearing conference.
   j. The parties are advised that a tentative procedural schedule anticipates additional prehearing conferences on May 15, 1979 and June 5, 1979, with oral hearing on a consolidated record to commence June 25, 1979.

H. G. Homme, Jr.,
Secretary.
[FR Doc. 79-7376 Filed 3-8-79; 8:23 am]

[7035-01-M]
[AB 46 (SDM)]

CHICAGO, ROCK ISLAND & PACIFIC RAILROAD CO.

Amended System Diagram Map

Notice is hereby given that, pursuant to the requirements contained in Title 49 of the Code of Federal Regulations, Part 1121.23, that the Chicago, Rock Island and Pacific Railroad Company, has filed with the Commission its amended color-coded system diagram map in docket No. AB 46 (SDM).

The maps reproduced here in black and white are reasonable reproductions of that amended system diagram map and the Commission on February 2, 1979, received a certificate of publication as required by said regulation which is considered the effective date on which the system diagram map was filed.

Color-coded copies of the map have been served on the Governor of each state in which the railroad operates and the Public Service Commission or similar agency and the State designated agency. Copies of the map may also be requested from the office of the Commission, Section of Dockets by requesting docket No. AB 46 (SDM).

H. G. Homme, Jr.,
Secretary.
CHICAGO, ROCK ISLAND & PACIFIC RAILROAD COMPANY

LINE SUBJECT TO ABANDONMENT OR DISCONTINUANCE
OF OPERATION WITHIN THREE YEARS

VAN BUREN COUNTY, IOWA

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
CHICAGO, ROCK ISLAND & PACIFIC RAILROAD COMPANY

LINE SUBJECT TO ABANDONMENT OR DISCONTINUANCE OF OPERATION WITHIN THREE YEARS

LEE COUNTY, IOWA
NOTICES

CHICAGO, ROCK ISLAND & PACIFIC RAILROAD COMPANY

LINE SUBJECT TO ABANDONMENT OR DISCONTINUANCE OF OPERATION WITHIN THREE YEARS

WYANDOTTE COUNTY, KANSAS

AND

JACKSON COUNTY, MISSOURI

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
CHICAGO, ROCK ISLAND & PACIFIC RAILROAD COMPANY
LINE SUBJECT TO ABANDONMENT OR DISCONTINUANCE
OF OPERATION WITHIN THREE YEARS
FREEBORN COUNTY MINNESOTA
NOTICES

CHICAGO, ROCK ISLAND & PACIFIC RAILROAD COMPANY

LINE SUBJECT TO ABANDONMENT OR DISCONTINUANCE OF OPERATION WITHIN THREE YEARS

ALFALFA COUNTY, OKLAHOMA

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
NOTICES

Iowa

Terminals or Agency Stations: Lismore, M.P. 72.17; Alva, M.P. 103.79.

Kansas

Terminal Points or Agency Stations: Enid to Warren in Garfield and Major Counties

Missouri

Contractors:

Missouri

Terminal Points or Agency Stations: Enid to Alva in Garfield, Alfalfa and Woods Counties

Nebraska

Kansas City to Eldon in Wapello, Davis, and Lee Counties

Terminal Points or Agency Stations: Enid to Warren in Garfield and Major Counties

Oklahoma

Terminal Points or Agency Stations: Enid to Alva in Garfield, Alfalfa and Woods Counties

Texas

Terminal Points or Agency Stations: Pringle to Stinnett in Hutchinson County

Terminal Points or Agency Stations: Worthington, M.P. 254.70; Lismore, M.P. 275.71.

Arkansas

Category 1: Line Subject to Abandonment or Discontinuance of Operation Within 3 Years

Mesa-to-Des Arc in Prairie County

Terminal Points: Mesa, M.P. 1.00; Des Arc, M.P. 14.98.

Iowa

Category 1: Lines Subject to Abandonment or Discontinuance of Operation Within 3 Years

Woden to Titonka in Kosuth and Hancock Counties


Keokuk to Eldon in Wapello, Davis, Lee and Van Buren Counties

Terminal Points or Agency Stations: Keokuk, M.P. 3.20; Eldon, M.P. 65.90.

Washington to Keota in Washington and Keokuk Counties


Category 2: Lines for Which Abandonment or Discontinuance Application Is Pending

Royal to (but not including) Hartley in Clay and O'Brien Counties


Hancock to Avoca in Polk and Winnemucca County

Terminal Points: Hancock, M.P. 5.78; Avoca, M.P. -0.22.

Kansas

Category 1: Lines Subject to Abandonment or Discontinuance of Operation Within 3 Years

Troy to North Topeka in Doniphan, Atchison, Jackson and Shawnee Counties

Terminal Points or Agency Stations: Troy, M.P. 13.50; Horton, M.P. 68.00; North Topeka, M.P. 80.6 to E.P.S. 0 + 00, Kansas City, Kansas.

Kansas City to McAlester in Washington and Wyandotte Counties

Terminal Points: Kansas City, M.P. 68.70; Maple Island, M.P. 6.70.

Missouri

Category 1: Lines Subject to Abandonment or Discontinuance of Operation Within 3 Years

Kansas City to Eldon in Wapello, Davis, Lee and Van Buren Counties

Terminal Points or Agency Stations: Kansas City, M.P. 8.00; Kansas City, Missouri.

Nebroaska

Kansas City to Jackson County, in Central Industrial District

Terminal Points or Agency Stations: Kansas City, M.P. 8.00; Kansas City, Missouri.

Oklahoma

Kansas City to McAlester in Washington and Wyandotte Counties

Terminal Points: Kansas City, M.P. 8.00; Kansas City, Missouri.

Texas

Kansas City to McAlester in Washington and Wyandotte Counties

Terminal Points: Kansas City, M.P. 8.00; Kansas City, Missouri.

Terminal Points or Agency Stations: Pringle to Stinnett in Hutchinson County

Terminal Points: Pringle, M.P. 60.47; Stinnett, M.P. 56.82.

[FR Doc. 79-6539 Filed 3-6-79; 8:45 am]

[7035-01-M]

[Ex Parte No. 341, Rule 19, 57th Revised Exemption No. 90]

Aberdeen & Rockfish Railroad Co., et al.

Exemption Under Mandatory Car Service Rules

To all railroads:

It appearing, That certain of the railroads named except the railroad owning numerous 50-ft. boxcars; that under present conditions, there are substantial surpluses of these cars on their lines; that return of these cars to the owners would result in their being stored idle; that such cars can be used by other carriers for transporting traffic offered for shipments to points remote from the car owners; and that compliance with Car Service Rules 1 and 2 prevents such use of these cars, resulting in unnecessary loss of utilization of such cars.

It is ordered, That, pursuant to the authority vested in me by Car Service Rule 19, 50-ft. plain boxcars described in the Official Railway Equipment Register, I.C.C.-R.E.R., No. 410, issued by W. J. Trezise, or successive issues thereof, as having mechanical designation "XM", and bearing reporting marks assigned to the railroads named below, shall be exempt from provisions of Car Service Rules 1, 2(a), and 2(b).

Aberdeen and Rockfish Railroad Company

Reporting Marks: AR

Camino, Placeville & Lake Tahoe Railroad Company

Reporting Marks: CPLT

City of Prineville

Reporting Marks: COP

East Camden & Highland Railroad Company

Reporting Marks: ECH

Greenwood & Northern Railway Company

Reporting Marks: GNWR

Lake Superior & Ishpeming Railroad Company

Reporting Marks: LSI

Lenawee County Railroad Company, Inc.

Reporting Marks: LCRC

Louisiana Midland Railway Company

Reporting Marks: LOM

Millsboro & Welvey Railway Company

Reporting Marks: MRS

Manufacturers Railway Company

Reporting Marks: MRS

Federal Register, Vol. 44, No. 48—Friday, March 9, 1979
Middletown and New Jersey Railway Company, Inc.
Reporting Marks: MNJ

[EX PARTE No. 241, Rule 19, Exemption No. 192]
CHICAGO, MILWAUKEE, ST. PAUL & PACIFIC RAILROAD CO.
Exemption Under Mandatory Car Service Rules
Because of severe winter storms resulting in massive snow drifts blocking main tracks and yards, Chicago, Milwaukee, St. Paul, and Pacific Railroad Company (MILW) is unable to relocate empty cars to other stations for loading or to return them promptly to cars of Mexican or Canadian ownership. Consequently, MILW is unable to furnish cars of suitable ownership to shippers while at the same time similar cars of other ownerships stand idle because of the inability of MILW to return them to owners.

It is ordered, That pursuant to the authority vested in me by Car Service Rule 19:
(a) Chicago, Milwaukee, St. Paul and Pacific Railroad Company (MILW) is authorized to accept from shippers in the states of Wisconsin and Illinois general service freight cars described in paragraph (b) owned by other railroads listed in the Official Railway Equipment Register.
(b) This exemption is applicable to general service freight cars bearing reporting marks assigned to railroads listed in the Official Railway Equipment Register. This exemption shall not apply to cars of Mexican or Canadian ownership.

Effective February 15, 1979, and continuing in effect until further order of this Commission.


NOTICES

[FR Doc. 79-7119 Filed 3-8-79; 8:45 am]

[7035-01-M]

[Notice No. 39]
ASSIGNMENT OF HEARINGS

MARCH 6, 1979.

Cases assigned for hearing, postponement, cancellation or oral argument appear below and will be published only once. This list contains prospective assignments only and does not include cases previously assigned hearing dates. The hearings will be on the issues as presently reflected in the Official Docket of the Commission. An attempt will be made to publish notices of cancellation of hearings as promptly as possible, but interested parties should take appropriate steps to insure that they are notified of cancellations or postponements of hearings in which they are interested.

[FR Doc. 79-7118 Filed 3-8-79; 8:45 am]

[7035-01-M]

[Notice No. 40]
ASSIGNMENT OF HEARINGS

MARCH 6, 1979.

Cases assigned for hearing, postponement, cancellation or oral argument appear below and will be published only once. This list contains prospective assignments only and does not include cases previously assigned hearing dates. The hearings will be on the issues as presently reflected in the Official Docket of the Commission. An attempt will be made to publish notices of cancellation of hearings as promptly as possible, but interested parties should take appropriate steps to insure that they are notified of cancellations or postponements of hearings in which they are interested.

[FR Doc. 79-7121 Filed 3-8-79; 8:45 am]

[7035-01-M]

[Notice No. 41]
ASSIGNMENT OF HEARINGS

MARCH 6, 1979.

Cases assigned for hearing, postponement, cancellation or oral argument appear below and will be published only once. This list contains prospective assignments only and does not include cases previously assigned hearing dates. The hearings will be on the issues as presently reflected in the Official Docket of the Commission. An attempt will be made to publish notices of cancellation of hearings as promptly as possible, but interested parties should take appropriate steps to insure that they are notified of cancellations or postponements of hearings in which they are interested.

1 XXX Missouri-Kansas-Texas Railroad Company deleted.

1 This notice corrects hearing date for No. MC 128527 Sub-20.
NOTICES

[7035-01-M]  
(Notice No. 161)  
MOTOR CARRIER BOARD TRANSFER PROCEEDINGS

The following publications include motor carrier, water carrier, broker, and freight forwarder transfer applications filed under Section 212(b), 206(a), 211, 212(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 by April 9, 1979. Failure seasonally to file a protest will be construed as a waiver of opposition and participation in the proceeding. A protest must be served upon applicants' representatives(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.


H. G. HOMME, JR., Secretary.

[FR Doc. 79-7200 Filed 3-8-79; 8:45 am]

[7035-01-M]  
(Notice No. 36)  
MOTOR CARRIER TEMPORARY AUTHORITY APPLICATIONS

February 27, 1979.

The following are notices of filing of applications for temporary authority under Section 210(a) of the Interstate Commerce Act, or 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 officials noted 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.
NOTICES

MC 111 (Sub-14TA), filed February 1, 1979. Applicant: VIGENT MOTOR FREIGHT, INC., 6 Clafin Street, Boston, Mass. 02127. Representative: Joseph F. Siegelbaum, 17 Academy Street, Newark, N.J. 07102. Paper, printing paper, N.O.I., and materials, equipment and supplies used in the manufacture thereof between Gilman, VT, on the one hand, and on the other hand, points in NY, those points in PA on and east of Route 15 and East Brunswick, NJ. Restricted to the transportation of shipments originating at or destined to the facilities of Georgia Pacific Corporation at or near Gilman, VT 180 days. An underlying ETA seeks 90 days authority. Supporting shippers: Georgia Pacific Corporation, 800 Summer Street, Stamford, CT. Send protests to: Glenn A. Eady, Transportation Specialist, Interstate Commerce Commission, 150 Causeway Street, Room 501, Boston, MA 02114.

MC 170 (Sub-49TA), filed February 2, 1979. Applicant: PACIFIC INTER-MOUNTAIN EXPRESS CO., 25 N. Via Monte, Walnut Creek, CA 94595. Representative: Edgar E. Redick (same address as applicant), common carrier, regular routes: Railways or Locomotive Wheels, iron or steel, loose, or mounted on axles with, or without bearings, serving the facilities of Griffin Wheel Company at Keokuk, IA as an off-route point in connection with carrier's authorized regular route nationwide operations, for 180 days. An underlying ETA seeks 90 days authority. Supporting shippers: Griffin Wheel Company, Division of Amsted Industries, Inc., 200 West Monroe Street, Chicago, IL 60606. Send protests to: District Supervisor A. J. Rodriguez, 211 Main Street, Suite 500, San Francisco, CA 94106.

MC 200 (Sub-332TA), filed February 7, 1979. Applicant: RISS INTERNATIONAL CORPORATION, 903 Grand Avenue, Kansas City, Missouri 64106. Representative: Ivan E. Moody (same as applicant), Meat, 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 M.C.C. 209 and 766 (except hides and commodities in bulk), from the facilities of Hygrade Food Products Corporation at Starm Lake, IA to points in CT, DE, FL, GA, IL, IN, KY, IA, ME, MA, MD, MI, MO, MS, NE, NH, NJ, NY, NC, OH, OR, TX, UT, VT, WV, and DC restricted to traffic originating at the named origin for 180 days. An underlying ETA seeks 90 days authority. Supporting shippers: Hygrade Food Products Corporation, P.O. Box 4771, Detroit, MI 48212. Send protests to: Vernon V. Cable, District Supervisor, Interstate Commerce Commission, 600 Federal Building, 911 Walnut Street, Kansas City, Missouri 64106, a common carrier, by motor vehicle over regular routes, transporting general commodities, except those of unusual value, Glass, and B explosives, commodities in bulk, and those requiring special equipment, serving the facilities of Paoli Chair Company at or near Orleans, IN, as an off-route point in connection with an existing regular route operation over U.S. Hwy. 150 (also known as IN Hwy. 56), for 180 days. An underlying ETA seeks 90 days authority. Supporting shippers: Paoli Chair Company, P.O. Box 30, 524 E. Third St., Paoli, IN 47454. Send protests to: L.C.C., 313 Federal Office Bldg., 234 Summit St., Toledo, OH 43604.

MC 2000 (Sub-357TA), filed February 1, 1979. Applicant: RYDER TRUCK LINES, INC., P.O. Box 2408-R, Jacksonville, FL 32203. Representative: John Carter (same as applicant), Axle housings from Reading, PA, to VT, the facilities of Griffin Wheel Corporation, B&A II, or near Edgerton, WI, and Syracuse, NY, restricted to the transportation of shipments originating at the named origin and destined to named destinations, for 180 days. Supporting shippers: Ford Division, Dana Corp., P.O. Box 1422, Reading, PA 19603. Send protests to: G. H. Fauss, Jr., DS, ICC, Box 36086, 400 West Bay Street, Jacksonville, FL 32202.

MC 4405 (Sub-589TA), filed February 2, 1979. Applicant: DEALERS TRANSIT, INC., P.O. Box 1376, Tulsa, OK 74101. Representative: Leonard L. Bennett, P.O. Box 236, Tulsa, OK 74101. Lumber, lumber products, wood products and pallets, from points in GA to points in AL, FL, IL, IO, IA, MI, MN, MS, NC, OH, SC, TN, VA, WI, KY, and DC, for 180 days. An underlying ETA seeks 90 days authority. Supporting shippers: Culpepper Lumber Company, Inc., P.O. Box 216, Dearing, GA 30808. Send protests to: Connie Stanley, Transportation Assistant, Interstate Commerce Commission, Room 240 Old Office and Court House Bldg., 215 NW 3rd, Oklahoma City, OK 73102.

MC 14215 (Sub-21TA), filed January 2, 1979. Applicant: SMITH TRUCK SERVICE, INC., P.O. Box 1329, Steubenville, OH 43952. Representative: John L. Alden, 1396 West Fifth Avenue, Columbus, OH 43212. Iron and steel articles, (1) from plant sites of Wheeling-Pittsburgh Steel Corporation at Canfield, Martins Ferry, Mingo Junction, Steubenville and Yorkville, OH; Beech Bottom, Benwood, Follansbee and Wheeling, West Virginia; or Allenport and Monessen, PA; restricted to shipments originating at or destined to the above-named facilities, (2) From plant sites of Wheeling-Pittsburgh Steel Corporation at Allenport, PA, to points in IL, IN, and OH, for 180 days. An underlying ETA seeks 90 days authority. Supporting shippers: Wheeling-Pittsburgh Steel Corporation, P. O. Box 118, Pittsburgh, PA 15236. Send protests to: J. Niggemeyer DS, 416 Old P.O. Bldg., Wheeling, WV 26003.

MC 14314 (Sub-26TA), filed February 5, 1979. Applicant: DUFF TRUCK LINE, INC., P.O. Box 359, Broadway & Vine Streets, Lima, OH 45802. Representative: Barney Spurlock Co., L.P.A., 275 E. State St., Columbus, OH 43215. Authority sought to operate as a common carrier, by motor vehicle over regular routes, transporting general commodities, except those of unusual value, Glass, and B explosives, commodities in bulk, and those requiring special equipment, serving the facilities of Paoli Chair Company at or near Orleans, IN, as an off-route point in connection with an existing regular route operation over U.S. Hwy. 150 (also known as IN Hwy. 56), for 180 days. An underlying ETA seeks 90 days authority. Supporting shippers: Paoli Chair Company, P.O. Box 30, 524 E. Third St., Paoli, IN 47454. Send protests to: L.C.C., 313 Federal Office Bldg., 234 Summit St., Toledo, OH 43604.

MC 18738 (Sub-54TA), filed February 6, 1979. Applicant: SIMS MOTOR TRANSPORT LINES, INC., 610 W. 138th St., Riverdale, IL 60627. Representative: Eugene Cohn, 1 N. LaSalle St., Chicago, IL 60606. Iron and steel articles, between Portage, IN and points in the following WI counties: Milwaukee, Racine, Kenosha, Waukesha, Ozaukee and Washington for 160 days. An underlying ETA has been granted. Supporting shippers: Midwest Steel Division, National Steel Corp., Route 12, Portage, IN 66565. Send protests to: TA Annie Booker, 219 S. Dearborn St. Rm. 1386, Chicago, IL 60604.

MC 18738 (Sub-55TA), filed January 16, 1979. Applicant: SIMS MOTOR TRANSPORT LINES, INC., 610 W. 138th St., Riverdale, IL 60627. Representative: Eugene Cohn, 1 N. LaSalle St., Chicago, IL 60606. Iron and steel articles, from J & L Steel Company at or near East Chicago, IN to pts in Kenosha, Milwaukee, Racine, Waukesha, Washington and OZaukee Counties, WI for 180 days. An underlying ETA for 90 days has been granted. Supporting shippers: Youngstown Sheet and Tube Company, 3001 Dickey Road, East Chicago, IN 46312. Send protests to: TA Annie Booker, 219 S. Dearborn St. Rm. 1386, Chicago, IL 60604.

MC 22509 (Sub-13TA), filed February 7, 1979. Applicant: MISSOURI-NEBRASKA EXPRESS, INC., 5310 St. Joseph Avenue, St. Joseph, Missouri 64505. Representative: Harry Ross, 56 South Main Street, Winchester, Kentucky 40391. Metal Containers from LaPorte, IN to Des Moines and Sioux City, IA for 180 days. An underlying ETA seeks 90 days authority. Supporting shippers: Wheeling-Pittsburgh Steel Corporation, 8101 West Higgins Road, Chicago, Illinois 60631. Send protests to: Vernon V. Cable, District Supervisor, Interstate Commerce Commission, 600 Federal Building, 911 Walnut Street, Kansas City, Missouri 64106.

MC 35807 (Sub-25TA), filed January 29, 1979. Applicant: WELLS FARGO ARMORED SERVICE CORPORA-
NOTICES

TION, P.O. Box 4313, Atlanta, Georgia 30302. Representative: Steven J. Thatcher, P.O. Box 4313, Atlanta, Georgia 30302. Coin. Currency & securities between LA, NE, to points in MN for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Federal Reserve Bank of Atlanta, 104 Marietta Street, N.W., Atlanta, Georgia 30303. Send protests to: Mr. K. Davis, Jr., 1252 W. Peachtree St., N.W., Atlanta, Georgia 30309.


MC 48441 (Sub-30TA), filed January 22, 1979. Applicant: R.M.E. Inc., P.O. Box 418, Streator, IL 61364. Representative: E. Stephen Helsey, 805 McClehan Bank Building, 666 Eleventh Street, N.W., Washington, D.C. 20001. (1) Commodities dealt in by wholesale, retail and chain grocery stores and food house businesses and (2) Materials, equipment and supplies used in the manufacture, distribution and sale of the commodities named in (1) (except in bulk), between the facilities of Ralston Purina Co. at or near Clinton and Davenport, IA, on the one hand, and, on the other, points in IL, IN, OH and the lower peninsula of MI, for 180 days. An underlying ETA seeks authority for 90 days. Supporting Shipper(s): Ralston Purina Co., Checkboard Square, St. Louis, MO 63185. Supporting Shipper(s): TA Annie Booker, 219 S. Dearborn St. Rm. 1366, Chicago, IL 60604.

MC 51146 (Sub-676TA), filed February 1, 1979. Applicant: SCHNEIDER TRANSPORT INC., P.O. Box 2298, Green Bay, WI 54302. Representative: John R. Patterson, 2469 E. Commercial Blvd., Ft. Lauderdale, FL 33308. Plastic articles (except in bulk) from the facilities of Mobil Chemical Co., Plastics Div. at Franklin and Joliet, IL to points in IN, IA, KY, MI, MN, NE, OH & WI, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Mobil Chemical Co., Plastics Div., Macedon, NY 14502. Send protests to: Gulf Dura- lity, Transportation Asst., Interstate Commerce Commission, Bureau of Operations, U.S. Federal Building & Courthouse, 517 East Wisconsin Avenue, Room 619, Milwaukee, Wisconsin 53202.

MC 52465 (Sub-46TA), filed February 1, 1979. Applicant: GRAVES TRUCK LINE INC., 2130 South OH Street, Salina, KS 67401. Representative: William E. Underwood, P.O. Box 250, Topeka, KS 66603. 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, M.C.C. 209 and 766 (except hides and skins and commodities in bulk), from the facilities utilized by John Morrell & Co., at or near St. Louis, MO and its Corporation, commodities in bulk, from the AR-MS State line over MS 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): John Morrell & Co., 205 S. LaSalle St., Chicago, IL 60604. Send protests to: J. T. LaBene, ICC, 7256 Fed- eral Bldg. & U.S. Courthouse, Topeka, KS 66603.

MC 55896 (Sub-111TA), filed February 2, 1979. Applicant: R-W SERVICE SYSTEM INC., 20225 Goddard Rd., Taylor, MI 48180. Representative: E. M. Snyder, 22377 Migrant Rd., P.O. Box 400, Northville, MI 48187. Canned goods, from the facilities of Allen Canning Company located at or near Van Buren, Alma, Springdale, Siloam Springs, Lowell and Gentry, AR; Westville, Proctor, and Kansas, OK, to points in the States of IL, IN, OH, PA, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Allen Canning Company, P.O. Box 729, Siloam Springs, AR 72761. Send protests to: Tim Quinn, DS, ICC, 604 Federal Building and U.S. Courthouse, 231 W. Lafayette Blvd., Detroit, MI 48226.

MC 59467 (Sub-42TA), filed February 1, 1979. Applicant: SORENSEN TRANSPORTATION CO., INC., 6 Old Amity Road, Bethany, Connecticut 06525. Representative: Gerard A. Jose- loff, 80 State Street, Hartford, Connecticut 06103. Printed matter and products, materials, supplies used in the manufacture, distribution or sale of printed matter, (a) between Buffalo, NY on the one hand, and, on the other, Washington, DC, Bethany and Old Saybrook, CT; (b) from Newark Airport, Newark, NJ, LaGuardia and Kennedy Airport, NY; (c) from O'Hare International Airport, Chicago, and Bradley Field, Windsor Locks, CT to Buffalo, NY; (c) from Gallatin, TN to Bethany, CT and Edison and North Bergen, NJ; (d) from Old Saybrook, CT to Gallatin, TN; and (e) from Al- tanta, GA, to Chicago, IL, for 180 days. Supporting Shipper(s): Time, Inc., Time & Life Building, Rockefeller Center, New York, NY 10020. Send protests to: J. D. Perry Jr., DS, ICC, 135 High Street, Hartford, CT 06113.

MC 66746 (Sub-22TA), filed February 2, 1979. Applicant: SHIPPERS EXPRESS INC., 1651 Kerr Dr., P.O. Box 8308, Jackson, MS 39204. Representative: Harold D. Miller, Jr., P.O. Box 22657, Jackson, MS 39204. Common carrier: Ralston Purina Co. at or near Van Buren, Alma, Springdale, Siloam Springs, Lowell and Gentry, AR; Westville, Proctor, and Kansas, OK, to points in the States of IL, IN, OH, PA, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Ralston Purina Co., located at or near Pueblo, CO, and Jackson, MS; and, on the other, all points in that part of MS lying on and south of a line extending from the AR-MS State line over MS Hwy 4 to Senatobia, MS, then over U.S. Hwy 51 and/or I-55 to Jackson, MS, and return over the same route, serving all intermediate points south of and including Senato- bia, MS; and (2) between Memphis, TN and Jackson, MS; from Memphis, TN over U.S. Hwy 51 and/or I-55 to Jackson, MS, and return over the same route, serving all intermediate points to and including Senatobia, MS, then over U.S. Hwy 51 and/or I-55 to Winona, MS, then over U.S. Hwy 82 to the MS-Al State line (except Starkville, Columbus and Macon, MS). NOTE: Applic- ant proposes to serve all points within the commercial zones of points located on route (1) and join route (1) at Jackson, MS with existing regular routes between Jackson, MS and New Orleans, LA, for 180 days. Supporting Shipper(s): There are 47 statements in support attached to this application which may be examined at the I.C.C. in Washington, DC or copies of the same may be examined in the field office named below. Send protests to: Alan Tarrant, D/S, ICC, Rm. 212, 145 E. Amite Bldg., Jackson, MS 39201.

MC 73888 (Sub-94TA), filed February 2, 1979. Applicant: SOUTHERN TRUCKING CORPORATION, P.O. Box 7185, 1500 Orenda Avenue, Memphis, TN 38107. Representative: Robert E. Thie, P.O. Box 517, Ever- green, AL 36441. (1) Petroleum, petroleum products, vehicle body sealer and/or sound deadener compounds (except in bulk, in tank vehicles) and filters, from points in Warren County, MS to all points in the U.S. (except...
AK and HI; and (2) Petroleum, petroleum products, vehicle body sealer and/or sound deadener compounds, fillers, materials, supplies, and equipment as are used in the manufacture, sale, and distribution of the commodities named in Part I above (except in bulk, in tank vehicles), from points in AL, GA, IL, IN, KY, NY, OH, OK, PA, RI, SC, VA, and WV to points in Warren County, MS, for 180 days. Supporting shipper(s): Quaker State Oil Refining Corp., P.O. Box 989 Oil City, PA 16301. Send protests to: Floyd A. Johnson, District Supervisor, Interstate Commerce Commission, 100 North Main Building, Suite 2006, 100 North Main Street, Memphis, TN 38103.

MC 95607 (Sub-15TA), filed February 1, 1979. Applicant: RUCKER BROTHERS TRUCKING, INC., 1820 Stewart St., E., Tacoma, WA 98421. Representative: Michael D. Duppenthaler, 211 S. Washington St., Seattle, WA 98104. Lumber, lumber products, plywood, particleboard and laminated beams, between points in WA, OR, ID and MT, for 180 days. Supporting shipper(s): There are 25 shippers. Their statements can be examined at the office listed below and Headquarters. Send protests to: Shirley M. Holmes, T/A, ICC, 888 Federal Bldg., Seattle, WA 98174.

MC 100686 (Sub-429TA), filed February 2, 1979. Applicant: MEYER TRUCK LINES, INC., P.O. Box 7656, Shreveport, LA 71107. Representative: Wilburn L. Williamson, Suite 615-East, The Southwest Expressway, Oklahoma City, OK 73112. Lubricating oil and hydraulic fluid (except in bulk) from the facilities of Shell Oil Company at or near New Orleans, LA to points in TX and WA for 180 days. Applicant has filed an underlying ETA for 90 days operating authority. Supporting shipper(s): John Deere Company, Dallas Branch, P.O. Box 205958, Dallas, TX. Send protests to: Connie A, Gillory, ICC, T-9308 Federal Bldg., 701 Loyola Ave., New Orleans, LA 70113.

MC 102567 (Sub-21TA), Applicant: McNAIR TRANSPORT,' INC., 4295 Meadow Lane-P.O. Drawer 5357, Bossier City, LA 71111. Representative: James C. Day, Suite 130, Houston, TX 77040. Ethyl chloride and methyl chloride, in bulk, in tank vehicles from Baton Rouge, LA to points and places in the States of CA, CO, CT, GA, IL, KY, MD, MI, NJ, NY, OH, PA, TN, WV, TX, and WI for 180 days. Applicant has filed an underlying ETA seeking to 90 days. Supporting shipper(s): Ethyl Corporation, 511 Florida Blvd., Baton Rouge, LA 70802. Send protests to: Connie A, Gillory, I.C.C., T-9308 Federal Bldg., 701 Loyola Ave., New Orleans, LA 70113.

MC 10378 (Sub-28TA), filed January 2, 1979. Applicant: MARTEN TRANSPORT, LTD., Route 3, Mon- doul, WI 54455. Representative: Robert S. Lee, 1001 First National Bank Bldg., Minneapolis, MN 55402. (1) Feed; (2) feed ingredients; (3) commodities used in the manufacture of breads; (4) dessert preparations; and (5) agricultural commodities which are exempt from regulation under Section 203(b)(5) of the Interstate Commerce Act when moving at the same time and in the same vehicle with (1), (2), (3), and (4) above, from Appleton, Plover and Rothschild, WI, to points in AZ, CA, CO, ID, MO, MT, NV, NM, OR, UT, WA and WY, for 180 days. SUPPORTING SHIPPER(S): Foremost Foods Company, Industrial Foods Division, One Post Street, San Francisco, CA 94104. SEND PROTESTS TO: Delores A. Poe Transpt. Asst., ICC, 414 Federal Building & U.S. Court House, 110 South 4th Street, Minneapolis, MN 55401.

MC 106491 (Sub-61TA), filed January 4, 1978. Applicant: JOHNSON MOTOR LINES, INC., P.O. Box 31577, Charlotte, NC 28231. Representative: Roger W. Rash, P.O. Box 31577, Charlotte, NC 28231. (1) Canned goods, from the facilities owned or utilized by Campbell Soup Co., at or near Maxton, NC, to points in AL, FL, GA, NC, SC, TN, VA, and the District of Columbia; and (2) Materials, supplies and equipment, (except in bulk), between the facilities of the Miller Company, at or near Martin, TN on the one hand, and, on the other, points in the United States, for 180 days. NOTE: Applicant intends to tack the authority here applied for with authority held by it in MC-85970 and subtherewith. Applicant further intends to interline with other carriers: TN; NASHVILLE, TN; St. Louis, MO; Jackson, TN; Fulton, KY; Union City, TN; Alamo, TN; Trenton, TN and Dyersburg, TN.

SUPPORTING SHIPPER(S): The Miller Light Company, P.O. Box 605, Martin, TN 38237, SEND PROTESTS TO: Floyd A. Johnson, DS, ICC, 100 North Main Bldg., Suite 2006, 100 North Main Street, Memphis, TN 38103.

MC 85970 (Sub-17TA), filed January 4, 1979. Applicant: SARTAIN TRUCK LINE, INC., 1625 Brookwood Street, Dyersburg, TN 38101. Representative: Mr. William H. Pendleton (same address as applicant). Authority sought to operate common carrier by motor vehicle, over regular routes, transporting: Lighting fixtures and parts, attachments and accessories for lighting fixtures as are manufactured, processed or dealt in by manufacturers of lighting fixtures and lighting fixture products, (except commodities in bulk), between the facilities of the Miller Company, at or near Martin, TN on the one hand, and, on the other, points in the United States, for 180 days. NOTE: Applicant intends to tack the authority here applied for with authority held by it in MC-85970 and subtherewith. Applicant further intends to interline with other carriers: TN; NASHVILLE, TN; St. Louis, MO; Jackson, TN; Fulton, KY; Union City, TN; Alamo, TN; Trenton, TN and Dyersburg, TN.

SUPPORTING SHIPPER(S): The Miller Light Company, P.O. Box 605, Martin, TN 38237, SEND PROTESTS TO: Floyd A. Johnson, DS, ICC, 100 North Main Bldg., Suite 2006, 100 North Main Street, Memphis, TN 38103.

MC 107002 (Sub-542TA), filed January 31, 1979. Applicant: MILLER TRANSPORTERS, INC., P.O. Box 1123, Jackson, MS 39205. Representative: John J. Borth (same as applicant). Dry synthetic plastics, in bulk, in tank vehicles from a point in the State of GA to points in the State of FL, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Transbulk, Inc., Suite 407, 4616 Poplar St., Memphis, TN 38111. Send protests TO: Alan Price, 203(b)(6), ICC, Rm. 212, 145 E. Amite Bldg., Jackson, MS 39201.

MC 107515 (Sub-1203TA), filed February 1, 1979. Applicant: REFRIGERATED TRANSPORT CO., INC., P.O. Box 308, Forest Park, Georgia 30090. Receiving agent: P. M. Horses, Northern Division, Fifth Floor, Lenox Tower, South, 330 Peachtree Road, N.E., Atlanta, Georgia 30309. Frozen, inedible, meat, meat products and meat by-products (except commodities in bulk), from facilities of Lee Dog Food Co., at or near La Grange, KY to Alabaster, AL; Ocala and Tampa, FL; Muscatine, IA; Topeka, KS; Woburn, MA; St. Louis and St. Joseph, MO; Crete, NE; Columbus & Sebring, OH; and Allen...
NOTICES

FEDERAL REGISTER, VOL 44, NO. 48--FRIDAY, MARCH 9, 1979

13118
town, PA, and points in their respec-
tive commercial zones, for 180 days.

An underlying ETA seeks 90 days au-
dority. Supporting - Shipper(s): Lee
Dog Food Co., P.O. Box 205, La
Grange, KY 40031. Send protests to:
Sara K. Davis, T/A, ICC, 1265 West
Peachtree St., NW, Room 300, Atlanta,
Georgia 30309.

MC 107515 (Sub-1204TA), filed Feb-
uary 1, 1979. Applicant: REFRIGER-
ATED TRANSPORTATION CO., INC., P.O.
Box 308, Forest Park, Georgia 30090.
Representative: Alan E. Serby, Fifth
Floor, Lenox Towers, South, 3390
Peachtree Road, N.E., Atlanta, Geor-
gia 30326. Such commodities as are
sold in by drugstores, grocery, and
food business houses (except commodi-
ties in bulk), from the facilities of
Warner-Lambert Company and its de-
visions and subsidiaries at or near
Rockford, IL, to the facilities of
Warner-Lambert Company and its de-
visions and subsidiaries at Morrow,
GA, for 180 days. An underlying ETA
seeks 90 days authority. Supporting
shipper(s): Warner-Lambert Company,
201 Tabor Road, Morris Plains, NJ
07950. Send protests to: Sara K. Davis,
T/A, ICC, 1265 West Peachtree St.,
NW, Room 300, Atlanta, Georgia
30309.

MC 107743 (Sub-53TA), filed Novem-
ber 21, 1978, and published in the FR
issue of January 10, 1979, and repub-
lished as corrected this issue. Ap-
licant: SYSTEM TRANSPORT, INC.,
E. 11707 Montgomery, P.O. Box 3458
TA, Spokane, WA 99220. Repre-
sentative: James W. Hightower, 136
Wynnwood Professional Bldg.,
Dallas, TX 75224. Drilling mud, clay,
nickel and iron, except in bulk,
from MT, ND, SD, NV, WY, WY, TX,
OK, OR, WS, ID, CA, IL, IN, MO, PA,
OH, WI, MI, and IA, for 180 days. Sup-
porting shipper(s): Dresser Industries,
Inc., P.O. Box 6504, Houston, TX.
Send protests to: Hugh H. Chaffee DS,
ICC, 856 Federal Bldg., Seattle, WA
98174. The purpose of this republi-
cation is to correct the proper author-
sity.

MC 110144 (Sub-20TA), filed Dece-
ember 26, 1978. Applicant: JACK C.
ROBINSON, 65 ROBINS OF
FREIGHT LINES, 3600 Raper Mill
Road, P.O. Box 10234, Knoxville,
TN 37921. Representative: Warren A.
Goff, 2003 Clark Tower, Memphis,
TN 38137. General commodities, except.
Classes A and B explosives, household
goods (as defined by the Interstate
Commerce Commission, commodities
in bulk, and articles which require spe-
sial equipment. (a) Between Knoxville,
and Bristol, TN via U.S. Hwy. 11-E,
11-E, serving all intermediate points
between Johnson City and Bristol, includ-
ing Johnson City and Bristol; (b) Between
Knoxville and Bristol,
meal, from Lafayette, IN, to the States of Michigan, New York, Ohio, and Pennsylvania, for 180 days. Supporting shipper(s): Ralston Purina Company, Checkerdock Square, St. Louis, MO, 63188. Send protests to: Charles D. Little, Interstate Supervisor, Interstate Commerce Commission, 414 Leland Office Building, 527 East Capitol Avenue, Springfield, Illinois 62701.

MC 114890 (Sub-87TA), filed February 6, 1979. Applicant: COMMERCIAL CARTAGE CO., 343 Axminster Dr., Fenton, MO 63026. Representative: David L. Bachelor, President, Argus, 625 E. 3rd St., Springfield, Illinois 62704. Printing ink and printing ink ingredients, in bulk, in tank vehicles, from St. Louis, MO to points in AR, DE, IL, IN, KS, KY, MI, MN, NY, OH, PA, TN, VA and WI, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Crown Zellerbach Corp., 4150 Carr Lane Ct., Shrewsbury, MO 63377. Send protests to: P. E. Binder, ADS, ICC, Rm 1465, 210 N. 12th St., St. Louis, MO 63101.

MC 115162 (Sub-455TA), filed February 2, 1979. Applicant: POOLE TRUCK LINE, INC., P.O. Box (Drawer) 500, Evergreen, AL 36041. Representative: Robert E. Tate, same address as applicant. Zinc oxide, zinc dust, zinc slabs and zinc dust (except commodities in bulk in tank vehicles) from the facilities of St. Joe Zinc Company, at Josephtown, Potter Township, Beaver County, PA, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): St. Joe Zinc Company, Two Oliver Plaza, Pittsburgh, PA 15222. Send protests to: Mabel E. Holston, Transportation Asst., Bureau of Operation, ICC, Room 1616-2121 Building, Birmingham, AL 35203.

MC 115531 (Sub-483TA), filed January 29, 1979. Applicant: TRUCK TRANSPORT, INCORPORATED, 29 Clayton Hills Lane, St. Louis, MO 63131. Representative: Steve Vogt, 11040 Manchester Rd., St. Louis, MO 63122. Borate rock, crushed, in bulk in tank vehicles, from King's Creek, SC to Jackson, TN, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Owens-Corning Fiberglas Corporation, 500 Main St., Toledo, OH 43659. Send protests to: P.E. Binder, ADS, ICC, Rm 1465, 210 N. 12th St., St. Louis, MO 63102.

MC 115531 (Sub-484TA), filed February 6, 1979. Applicant: TRUCK TRANSPORT, INCORPORATED, 29 Clayton Hills Ln., St. Louis, MO 63131. Representative: J. R. Ferris, 11040 Manchester Road, St. Louis, MO 63122. (1) Beverages, carbonated or phosphated, non-alcoholic, in containers, from the facilities of Taylor Beverages at or near Hazelwood, MO, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Taylor Beverages, Inc., 555 Brown Rd., Hazelwood, MO 63042. Send protests to: P. E. Binder, DSS, ICC, Rm. 1465, 210 N. 12th St., St. Louis, MO 63101.

MC 115496 (Sub-113TA), filed February 1, 1979. Applicant: LUMBER TRANSPORT, INC., P.O. Box 11, Cochran, Georgia 31014. Representative: Virgil H. Smith, 1557 Phoenix Blvd., Atlanta, Georgia 30349. Expanded Urethane Panels and Expanded Plastic Materials from Dallas, TX and Greer, SC to points in the United States in and East of TX, AR, MO, IL, and WI, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Rmax, Inc., 13524 Welch Road, Dallas, Texas 75240. Send protests to: Sura K. Davis, T/A, Interstate Commerce Commission, 1252 W. Peachtree Street, N.W., Room 300, Atlanta, Georgia 30303.

MC 115651 (Sub-54TA), filed January 8, 1979. Applicant: KANEY TRANSPORTATION INC., 7222 Cumingham Road, Rockford, IL 61102. Representative: Robert D. Higgins, same address as applicant. Meat, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Kaney Transportation, 405 North 7th Street, St. Louis, MO 63102. Send protests to: Glenda Kuss, Representative: W. J. DIGBY, INC., 6015 East 58th Avenue, Commerce City, CO 80022. Representative: Howard Gore (same address as above). Meat, from Omaha, NE to points in CO, for 180 days. Underlying ETA seeks 90 days authority. Supporting shipper(s): Armour Foods Co., Greyhound Towers, Phoenix, AZ 85077. Send protests to: District Supervisor Herbert C. Ruoff, 492 U.S. Customs House, 721 19th Street, Denver, CO 80202.

MC 115826 (Sub-389TA), filed February 1, 1979. Applicant: W. J. DIGBY, INC., 6015 East 58th Avenue, Commerce City, CO 80022. Representative: Howard Gore (same address as above). Meat and packinghouse products, from facilities of Wilson Foods Corp., near Cedar Rapids, Iowa, Jackson, IN, Kansas City, MO, Fort Wayne, IN, and Memphis, TN to the facilities of Taylor Beverages at or near Hazelwood, MO, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Taylor Beverages, Inc., 555 Brown Rd., Hazelwood, MO 63042. Send protests to: Charles C. Davis, ETA, ICC, Rm. 1465, 210 N. 12th St., St. Louis, MO 63101.

MC 115841 (Sub-674TA), filed February 1, 1979. Applicant: COLONIAL REFRIGERATED TRANSPORTATION, INC., 9041 Executive Park Drive, Suite 110, Bldg. 100, Knoxville, TN 37919. Representative: D. R. Beeler (same address as applicant). Margarine, shortening, salad oils, bacon bits, powdered milk, and butter, from Omaha, NE to points in CO, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Collier Industries, Div. of Wilsey Foods, Inc., 915 East 5th St., Ft. Worth, TX 76102. Send protests to: Glenda Kuss, T/A, Interstate Commerce Commission, 1252 W. Peachtree Street, N.W., Room 300, Atlanta, Georgia 30303.
NOTICES

MC 116254 (Sub-249TA), filed February 2, 1979. Applicant: CHEM-HAULERS, INC., 118 East Mobile Plaza, Florence, AL 35630. Representative: Randy C. Luffman (same address as applicant). Chemicals, in bulk, from Marengo County, AL, to points in AL, GA, FL, MI, TN, AR, SC, NC, TX, LA, VA, NY, WI, Mi, OK, OH, MO, IN, IL, PA, MN, IA, KY, WV and MS, for 180 days. Supporting shipper(s): Borden Chemicals, division of Borden Co., Inc., 180 East Broad Street, Columbus, OH 43215. Send protests to: Mabel E. Holston, Transportation Asst., Bureau of Operation, ICC, Room 1616-2121 Building, Birmingham, AL 35203.

MC 116474 (Sub-42TA), filed February 1, 1979. Applicant: LEAVITT'S FREIGHT SERVICE, INC., 3 Kolinola Road, Springfield, OR 97477. Representative: David C. White, 2400 S.W. Fourth Avenue, Portland, OR 97201. Contract carrier—irregular routes; Treated poles, in tank vehicles, from the facilities of Orchard Grove Company at or near Lansing, MI to points in AL, GA, FL, MI, TN, AR, SC, NC, TX, LA, VA, NY, WI, MI, OK, OH, MO, IN, IL, PA, MN, IA, KY, WV and MS, for 180 days. Supporting shipper(s): Orchard Grove Company, 2701 East Michigan Ave., Lansing, MI 48912. Send protests to: Tim Quinn, DS, ICC, 604 Federal Building and U.S. Courthouse, 231 W. Lafayette Blvd., Detroit, MI 48226.

MC 117893 (Sub-239TA), filed February 5, 1979. Applicant: SUBLER TRANSFER, INC., 1 Vista Drive, P.O. Box 62, Versailles, OH 45380. Representative: Neil E. Hannan (same as applicant). Foodstuffs; except in bulk, from the facilities of Duffy-Mott Co., Inc., at Hamlin; Holley and Williamson, NY, to all points in the states of IL, IN, IA, KS, KY, MI, MN, MO, NE, OH and WI, for 180 days. Supporting shipper(s): Duffy-Mott Co., Inc., Frank Bozio, General Traffic Manager, 370 Lexington Ave., New York, NY 10017. Send protests to: Paul J. Lowry, DS, ICC, 5314 Federal Building, 550 Main St., Cincinnati, OH 45202.

MC 118086 (Sub-87TA), filed December 26, 1978. Applicant: ARNOLD BROS. TRANSPORT, LTD., 851 Legmodiere Blvd., Winnipeg, Manitoba, Canada R2K 3R4. Representative: Bernard J. Kemple, 10 South LaSalle Street, Suite 1600, Chicago, IL 60603. Such commodities as are dealt in, or used by, agricultural equipment, industrial equipment and lawn and leisure product dealers (except commodities in bulk), between the facilities of Deere & Company located in IL, WI and IA, on the one hand, and, on the other, points in and east of the United States and Canada located in MI, NY, VT, NH, and ME. Restriction: (1) The Transportation authorized herein is restricted to foreign commerce. (2) The transportation authorized herein is restricted to traffic originating at or destined to the facilities and/or dealers of John Deere Limited in the Provinces of Quebec, Prince Edward Island, Nova Scotia, New Brunswick and Newfoundland, Canada, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): John Deere Company, 100 Union Commerce Blvd., Cleveland, OH 44115. Send protests to: Gail Druggert, Transp. Asst., ICC, U.S. Federal Building and Courthouse, 517 East Wisconsin Avenue, Room 619, Milwaukee, WI 53202.

MC 119767 (Sub-347TA), filed January 3, 1979. Applicant: BEAVER TRANSPORT CO., P.O. Box 166, Pleasant Prairie, WI 53158. Representative: Michael V. Kaney (same address as applicant). Animal and vegetable oils, animal and vegetable oil products, and food seasoning or curing compounds, (except in bulk, in tank vehicles), from Chicago, IL, Louisville, KY and points in Will Co., IL to IL, IN, IA, KY, MI, MN, MO, OH, and WI for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): SCM Corporation, 900 Union Commerce Blvd., Cleveland, OH 44115. Send protests to: Call Druggert, Transp. Asst., ICC, U.S. Federal Building and Courthouse, 517 East Wisconsin Avenue, Room 619, Milwaukee, WI 53202.

MC 119912 (Sub-25TA), filed February 6, 1979. Applicant: SUNRISE TRANSPORTATION, INC., 8650 East 120th Street, Moline, IL 61265. Representative: Thomas M. Loughran, 100 Bush Street, 21st Floor, San Francisco, CA 94104. Lime, in bulk, in tank vehicles, from Arrowline, NV and Nelson, AZ to points in CA in or north of San Luis Obispo, Kern and Inyo Counties, for 180 days.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
An underlying ETA seeks 90 days authority. Supporting shipper(s): CENTRAL CONTRA COSTA SANITARY DISTRICT, POB 159, Walnut Creek, CA 94598 and the Flinthokie Lime Products Co., a Div. of The Flinthokie Company 4700 Ramona Boulevard, Monterey Park, CA 91754. Send protests to: District Supervisor A. J. Rodriguez, 211 Main Street, Suite 500, San Francisco, CA 94105.

MC 120908 (Sub-32TA), filed December 29, 1978. Applicant: UNTAH FREIGHTWAYS, 1030 South Redwood Road, Salt Lake City, UT 84104. Representative: Robert L. Bloomquist, 1030 South Redwood Road, Salt Lake City, UT 84103. Authority sought to operate as a common carrier, by motor vehicle, over regular routes, transporting General commodities, except commodities of unusual value, household goods and articles of like nature, except perishable food products and those requiring special equipment and articles of A and B explosives, between Vernal, UT, and Denver, CO; from Vernal, UT, over U.S. Highway 40 to Denver, CO, and return; and over irregular routes transporting Merchandise as is dealt in by wholesale, retail and chain grocery and food business houses, and in connection therewith, equipment, materials and supplies used in the conduct of such businesses, (excluding commodities in bulk), between the facilities of the Kroger Co., at or near Cincinnati, Springdale, Woodlawn, Blue Ash, Columbus, and Westerville, on the one hand, and, on the other, points in the states of OH, IN, IL, MO, AR, TX, TN, KY, GA, WA, WV, MI, PA, and FL, under a continuing contract or contracts, with the Kroger Co., restricted to operations conducted in vehicles equipped with mechanical refrigeration, for 180 days. An underlying ETA seeks 30 days authority. SUPPORTING SHIPPER(S): The Kroger Co., 1014 Vine Street, Cincinnati, OH 45201. SEND PROTESTS TO: Mr. Floyd A. Johnson, DS, ICC, 110 North Main Building, Suite 2008, 100 North Main Street, Memphis, TN 38103.

MC 140134 (Sub-11TA), filed January 3, 1979. Applicant: CALDARULO TRADING CO., 2840 South Ashland Avenue, Chicago, IL 60608. Representative: Richard A. Kerwin, 100 North Lake Shore Drive, Chicago, IL 60601. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting Foodstuffs, (except in bulk), from the facilities of Sanna Division, Beatrice Foods Co., located at 100 North Lake Shore Drive, Chicago, IL 60601, to points in AZ, CA, CO, ID, MT, NV, NM, ND, OR, SD, UT, WA and WY., restricted to the transportation of traffic originating at the named origins and destined to the named destination states, under a continuing contract, or contracts, with Sanna Division, Beatrice Foods Co., for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): James P. Zenzinger Transp. Mgr., Sanna Division, Beatrice Foods Co., P.O. Box 8046, Madison, WI 53708. SEND PROTESTS TO: Lois M. Stahl Transp. Asst., ICC, Room 3386, E. Main Street, Memphis, TN 38103. SEND PROTEST TO: Irene Carlos Transp. Asst., ICC, Room 1321 Federal Building, 300 North Los Angeles Street, Los Angeles, CA 90012.

MC 145435 (Sub-3TA), filed January 3, 1979. Applicant: WESTERN AG INDUSTRIES, INC., 2750 North Parkway, Fresno, CA 93771. Representative: Roland J. Mefford, 2750 No. Parkway, Fresno, CA 93771. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting Foodstuffs, from the site of Early California Foods at Visalla and Los Angeles, CA. on the one hand, to points in OR, WA, UT, CO, MO, IL, WI, IN, MI, OH, PA, NY, CT, MA, and GA, under a continuing contract or contracts, with Early California Foods, Inc., for 180 days. SUPPORTING SHIPPER(S): Early California Foods, Inc., P.O. Box 71, Visalla, CA 95377. SEND PROTESTS TO: Michael M. Butler, DS, 211 Main, Suite 500 San Francisco, CA 94105.

MC 145870 (Sub-3TA), filed January 5, 1979. Applicant: L-J-R HAULING, INCORPORATED, P.O. Box 699, Dublin, VA 24084. Representative: Wilmer B. Hill, Suite 805, 686 Eleventh St., N.W., Washington, DC 20001. Mining machinery and equipment, and parts thereof, and materials, equipment and supplies used in the installation thereof, (except in bulk), from Tazewell, VA, to points in KY, TN, WV, VA, IN, PA., IL and OH for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Kan Kan Foods, Inc., 3386 E. 44th Street, Vernon, CA 90058. Send protests to: District Supervisor A. J. Rodriguez, 211 Main Street, Suite 500, San Francisco, CA 94105.

MC 123501 (Sub-5TA), filed December 28, 1978. Applicant: CARDOSI CONTRACT REFRIGERATED EXPRESS, INC., 5885 Jetway Street, Arlington, TX 76002. Representative: Mr. Thomas A. Stroud, 2008 Clark Tower, 5100 Poplar Avenue, Memphis, TN 38137. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting Merchandise as is dealt in by wholesale, retail and chain grocery and food business houses, and in connection therewith, equipment, materials and supplies used in the conduct of such businesses, (excluding commodities in bulk), between the facilities of Foods, Inc., at or near Vernon, CA, and the facilities of Foods, Inc., at or near Amarillo, TX to points in California, Arizona, Colorado, Kansas, Missouri, and Nebraska, on the one hand, and, on the other, points in the states of CA, TX, OK, KS, MO, NE, and SD, under a continuing contract or contracts, with Foods, Inc., restricted to operations conducted in vehicles equipped with mechanical refrigeration, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Foods, Inc., 3386 E. 44th Street, Vernon, CA 90058. Send protests to: District Supervisor A. J. Rodriguez, 211 Main Street, Suite 500, San Francisco, CA 94105.
NOTICES

days authority. SUPPORTING SHIPPER(S): Metal-Craft, Inc., P.O. Box 862, Tazewell, VA 24651. SEND PROTESTS TO: Paul D. Collins, DS, ICC Room 10-502 Federal Building, 400 N. 8th Street, Richmond, VA.

MC 146007 TA, filed January 2, 1978. Applicant: MADISON AIR FREIGHT, INC., Dane County Regional Airport, 2300 Holmberg Street, Madison, WI 53704. Representative: James A. Spiegel, 6425 Odana Road, Madison, WI 53719. General commodities, except those of unusual value, Classes A and B explosives, household goods as defined by the Commission, commodities in bulk, commodities injurious or contaminating to other lading, and those requiring special equipment, restricted to traffic having a prior or subsequent movement by air, between Dane County Regional Airport on the one hand, and on the other hand points in Columbia, Dodge, Fond du Lac, Grant, Green, Green Lake, Iowa, Jefferson, Juneau, Lafayette, Marquette, Monroe, Richland, Rock, Sauk and Walworth Counties, for 180 days. SUPPORTING SHIPPER(S): There are approximately (38) statements of support attached to this application which may be examined at the Interstate Commerce Commission in Washington, D.C., or copies thereof which may be examined at the field office named below. SEND PROTESTS TO: Gail Daugherty Transp. Asst., ICC, U.S. Federal Bldg., & Courthouse, 517 East Wisconsin Avenue, Room 619, Milwaukee, WI 53202.

MC 146037 TA, filed January 4, 1979. Applicant: FREEMAN COLE AND BILLY G. HALL, d/b/a/ COLE AND HALL TRUCKING CO., P.O. Box 507, Camden, TN 38320. Representative: Mr. Abraham A. Diamond, 29 South La Salle Street, Chicago, IL 60603. Silica sand and natural bonded molding sand, in dump and tank vehicles, in bulk, from Benton County, TX, to points in AL, AR, FL, GA, IA, IL, IN, KS, KY, LA, MI, MO, MS, OH, PA, TN, TX and WI, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Hardy Sand Co., Hwy 70W, Camden, TN 38320. SEND PROTESTS TO: Floyd J. Johnson, DS, ICC 100 North Main Bldg., Suite 2008, 100 North Main Street, Memphis, TN 38103.

By the Commission.

H. G. HOMME, Jr.,
Secretary.

[FR Doc. 79-7203 Filed 3-8-79; 6:45 am]
### CONTENTS

<table>
<thead>
<tr>
<th>Items</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Civil Rights Commission</td>
<td>1</td>
</tr>
<tr>
<td>Commodity Futures Trading Commission</td>
<td>2</td>
</tr>
<tr>
<td>Equal Employment Opportunity Commission</td>
<td>3</td>
</tr>
<tr>
<td>Federal Election Commission</td>
<td>4</td>
</tr>
<tr>
<td>Federal Energy Regulatory Commission</td>
<td>5, 6</td>
</tr>
<tr>
<td>Federal Maritime Commission</td>
<td>7</td>
</tr>
<tr>
<td>Foreign Claims Settlement Commission</td>
<td>8</td>
</tr>
<tr>
<td>Nuclear Regulatory Commission</td>
<td>9, 10</td>
</tr>
<tr>
<td>Postal Rate Commission</td>
<td>11</td>
</tr>
<tr>
<td>Securities and Exchange Commission</td>
<td>12</td>
</tr>
<tr>
<td>Uniformed Services University of the Health Sciences</td>
<td>13</td>
</tr>
</tbody>
</table>

### [6335-01-M]

**COMMUNITY ON CIVIL RIGHTS.**

**DATE AND TIME:** Tuesday, March 13, 1979, 9 a.m.–1 p.m.

**PLACE:** Room 512, 1121 Vermont Avenue NW., Washington, D.C.

**STATUS:** Open to the public.

**MATTERS TO BE CONSIDERED:***

1. Approval of Agenda.
2. Approval of minutes from last meeting.
3. Staff Director’s Report:
   - A. Status of funds.
   - B. Personnel Report.
   - C. Office Directors’ reports.
   - D. Correspondence:
     - 1. Letter to Deputy Assistant Secretary of Defense Carpenter re rights of non-English speaking minority in the Armed Forces.
     - 2. Letter to OCR Director Tatel re higher education desegregation.
     - 3. Letter from LEAA Deputy Administrator Dogin re Native American Justice Issues in North Dakota.
     - 4. Letter from President Carter re Helsinki Final Act.
     - 5. Letter from Consumers Union Associate Director Braren re Media Update report.
4. Report on civil rights developments in the Western Region.
5. State Advisory Committee Re-Charters: (a) Colorado, (b) Delaware, (c) Indiana, (d) Kansas, (e) Maine, and (f) New Hampshire.
7. Review of Sears complaint.
8. Request from Asian Pacific Coalition re re-scheduling of May consultation.

**CONTACT PERSON FOR MORE INFORMATION:**

Barbara Brooks, Public Affairs Unit, 254-6697.

[IS-471-79 Filed 3-7-79; 3:59 pm]


### [6351-01-M]

**COMMODITY FUTURES TRADING COMMISSION.**

**TIME AND DATE:** 3 p.m., March 9, 1979.

**PLACE:** 2033 K Street NW., Washington, D.C., 8th Floor conference room.

**STATUS:** Closed.

**MATTERS TO BE CONSIDERED:**

- Long-term planning/budget and personnel.

**CONTACT PERSON FOR MORE INFORMATION:**

Jane Stuckey, 254-6314.

[IS-468-79 Filed 3-7-79; 10:39 am]


### [6570-06-M]

**EQUAL EMPLOYMENT OPPORTUNITY COMMISSION.**

**TIME AND DATE:** 9:30 a.m. (eastern time), Tuesday, March 13, 1979.

**PLACE:** Commission Conference Room, No. 5240, on the fifth floor of the Columbia Plaza Office Building, 2401 E Street NW., Washington, D.C. 20508.

**STATUS:** Part will be open to the public and part will be closed to the public.

**MATTERS TO BE CONSIDERED:**

1. Internal procedures for handling matters brought before EEOC for coordination under Executive Order 11296.
2. Report on Commission operations by the Executive Director.

**CLOSED TO THE PUBLIC**

1. Decisions on Recommendations on Requests to Appeal.
2. Litigation Authorization; General Counsel Recommendations; Matters closed to the public under the Commission’s regulations at 29 CFR 1012.13.

Note:—Any matter not discussed or concluded may be carried over to a later meeting.

**CONTACT PERSON FOR MORE INFORMATION:**

Marie D. Wilson, Executive Officer, Executive Secretariat, at (202) 634-6748.

This notice issued March 6, 1979.

[IS-461-79 Filed 3-7-79; 9:58 am]


### [6715-01-M]

**FEDERAL ELECTION COMMISSION.**

**DATE AND TIME:** Wednesday, March 14, 1979, at 10 a.m.

**PLACE:** 1325 K Street NW., Washington, D.C.

**STATUS:** Portions of this meeting will be open to the public and portions will be closed.

**MATTERS TO BE CONSIDERED:**

1. Portions Open to the Public
   - Setting of dates for future meetings.
   - Correction and approval of minutes.
   - Appropriations and budget.
   - Pending legislation.
   - 1980 elections and related matters.
   - Classification actions.
   - Routine administrative matters.

2. Portions Closed to the Public (Following Open Session)

**PERSONS TO CONTACT FOR INFORMATION:**

Mr. Fred S. Elland, Public Information Officer, telephone 202-523-4065.

Marjorie W. Emanuel, Secretary to the Commission.

[IS-470-79 Filed 3-7-79; 3:26 pm]


### [6740-02-M]

**FEDERAL ENERGY REGULATORY COMMISSION.**

**TIME AND DATE:** 2 p.m., March 7, 1979.

**PLACE:** 825 North Capitol Street NE., Washington, D.C. 20426, Room 8306.

**STATUS:** Closed.

**MATTERS TO BE CONSIDERED:**

1. Institution of a formal private investigation.
2. Proceedings relating to an investigation.
[6740-02-M]

6

FEDERAL ENERGY REGULATORY COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT:
44 FR 12330, published March 6, 1979.

PREVIOUSLY ANNOUNCED ITEM AND DATE OF MEETING: March 7, 1979, 10 a.m.

CHANGE IN MEETING: The following items have been added:

Item No., Docket No., and Company
CP-8. CNG Transmission Company.

KENNETH F. PLUMB,
Secretary.

[S-469-79 Filed 3-7-79; 3:12 p.m.]

[6730-01-M]

7

FEDERAL MARITIME COMMISSION.

TIME AND DATE: 10 a.m., March 14, 1979.

PLACE: Room 12125, 1100 L Street NW., Washington, D.C. 20573.

STATUS: Minutes of the 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
2. Proposed elimination of financial reporting by carriers of persons in the domestic offshore trade.

PORTIONS CLOSED TO THE PUBLIC
1. Order to Show Cause on sixteen conferences which are in noncompliance with General Order 7.

[6770-01-M]

8

(FWSC Meeting Notice No. 2-79—Revised)

FOREIGN CLAIMS SETTLEMENT COMMISSION.

ANNOUNCEMENT IN REGARD TO COMMISSION MEETINGS AND HEARINGS

The Foreign Claims Settlement Commission, pursuant to its regulations (45 CFR Part 504), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of open meetings and oral hearings for the transaction of Commission business and other matters specified, as follows:

Data, Time, and Subject Matter
Wednesday, March 7, 1979, at 10:30 a.m., Canceled.
Wednesday, March 14, 1979, at 10:30 a.m., Consideration of decisions involving claims of American Citizens against the German Democratic Republic.
Wednesday, March 21, 1979, at 10:30 a.m., Consideration of decisions involving claims of American Citizens against the German Democratic Republic.
Wednesday, March 28, 1979, at 10:30 a.m., Consideration of decisions involving claims of American Citizens against the German Democratic Republic.

Subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

All meetings are held at the Foreign Claims Settlement Commission, 1111 20th Street, NW., Washington, D.C. 20579: (202) 634-1155.


FRANCIS T. MAESTERSON,
Executive Director.

[S-459-79 Filed 3-7-79; 9:41 a.m.]

[7590-01-M]

9

NUCLEAR REGULATORY COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT:
44 FR 12331.

CONTACT PERSON FOR MORE INFORMATION:
Francis C. Hurney, Secretary, 202-523-5725.

[S-460-79 Filed 3-7-79; 9:41 a.m.]

TIME AND DATE: March 7 and 8, 1979.

PLACE: Commissioners' Conference Room, 1717 H St., N.W., Washington, D.C.

STATUS: Open/Closed (CHANGES).

MATTERS TO BE CONSIDERED:

WEDNESDAY, MARCH 7, 11 a.m. (APPROX)
1. Discussion of Legislative Proposals. (Approximately 1 hour—Public meeting) (Postponed from 3/1/79)

THURSDAY, MARCH 8, 11:30 a.m. (APPROX)
1. Additional Affirmation Item: Appointment of ABNS Member

THURSDAY, MARCH 8, 3:30 P.M.

CONTACT PERSON FOR MORE INFORMATION:
Roger M. Tweed, Office of the Secretary.

[S-467-79 Filed 3-7-79; 3:12 pm.]

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979

[7590-01-M]
The following additional items will be considered at the open meeting scheduled for Wednesday, March 7, 1979, at 10:00 a.m.:  
1. Consideration of whether to institute major changes in its approach to sales literature regulation: (1) withdrawing the Statement; (2) proposing the adoption of an interpretive rule which provides general guidelines but contains no specific requirements or prohibitions on the use of sales literature; (3) limiting staff comment on sales literature to avoid the appearance of “clearing” material; (4) reviewing sales literature after it is filed by “spot checking” and as part of inspections; and (5) publishing from time to time, as appropriate, staff advisory views on the content of sales literature in staff interpretive releases. For further information, please contact Anthony A. Vertuno at (202) 755-1192 or Sarah B. Ackerson at (202) 755-1792.  
2. Consideration of a proposed request for a waiver of certain provisions of the Commission’s Conduct Regulation (relating to outside practice and securities transactions) in connection with the temporary employment of Linda A. Wertheimer, Esquire. For further information, please contact Myrna Siegel at (202) 755-4329.  
3. Consideration of a request for a waiver of certain provisions of the Commission’s Conduct Regulation (relating to outside practice and securities transactions) in connection with the temporary employment of Linda A. Wertheimer, Esquire. For further information, please contact Myrna Siegel at (202) 755-4329.

SUNSHINE ACT MEETINGS

The following additional items will be considered at a closed meeting scheduled for Wednesday, March 7, 1979, at 10:00 a.m.:  
1. Consideration of whether to institute major changes in its approach to sales literature regulation: (1) withdrawing the Statement; (2) proposing the adoption of an interpretive rule which provides general guidelines but contains no specific requirements or prohibitions on the use of sales literature; (3) limiting staff comment on sales literature to avoid the appearance of “clearing” material; (4) reviewing sales literature after it is filed by “spot checking” and as part of inspections; and (5) publishing from time to time, as appropriate, staff advisory views on the content of sales literature in staff interpretive releases. For further information, please contact Anthony A. Vertuno at (202) 755-1192 or Sarah B. Ackerson at (202) 755-1792.  
2. Consideration of a proposed request for a waiver of certain provisions of the Commission’s Conduct Regulation (relating to outside practice and securities transactions) in connection with the temporary employment of Linda A. Wertheimer, Esquire. For further information, please contact Myrna Siegel at (202) 755-4329.  
3. Consideration of a request for a waiver of certain provisions of the Commission’s Conduct Regulation (relating to outside practice and securities transactions) in connection with the temporary employment of Linda A. Wertheimer, Esquire. For further information, please contact Myrna Siegel at (202) 755-4329.

TIME AND DATE: March 19, 1979, 8:00 a.m.

PLACE: Uniformed Services University of the Health Sciences, 4301 Jones Bridge Road, Bethesda, Maryland 20014 (Rooms A1024, A1017, and A2054).

STATUS: Open.

MATTERS TO BE CONSIDERED:

8:00 A.M.—MEETING, EDUCATIONAL AFFAIRS COMMITTEE

(1) Faculty Appointments; (2) Report—Graduate Program; (3) Report—Flexible Course/Clerkship Program—4th Year

8:00 A.M.—MEETING, ADMINISTRATIVE AFFAIRS COMMITTEE

(1) Report—Assistant Dean for Administration—Construction Update; (2) Report—Director Resource Management

8:45 A.M.—TOWN MEETING, BOARD OF REGENTS

9:15 A.M.—MEETING, BOARD OF REGENTS

(1) Report—Educational Affairs Committee; (2) Report—Administrative Affairs Committee; (3) Report—Acting President; (4) Report—Dean, School of Medicine; (5) Report—Admissions; (6) Report—1981-1985 Consolidated Guidance; (7) Report—Continuing Medical Education; (8) Report—Associate Dean, School of Medicine—a Status Report: Institutional Self-Study, (b) Acceptance Winslow Homer woodcuts; (9) Report—Departmental Program Review; Frederick J. Bollum, Ph. D., Chairman, Department of Biochemistry New Business

SCHEDULED MEETINGS: June 4, 1979.

CONTACT PERSON FOR MORE INFORMATION:

Frank M. Reynolds, Executive Secretary of the Board, 202/285-2111.

H. E. Lofahl

Deputy Director, Correspondence and Directives, Washington Headquarters Services, Department of Defense.

March 7, 1979.

[5-464-79 Filed 3-7-79; 11:20 a.m]

SECURITIES AND EXCHANGE COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENTS:

44 FR 11671

Two additional notices to be published.

STATUS: Closed meeting; open meeting.

PLACE: Room 825, 500 North Capitol Street, Washington, D.C.


CHANGES IN THE MEETING: Deletion; rescheduling; additional items.

The following item scheduled for consideration at a closed meeting on Thursday, March 1, 1979, immediately following the open meeting at 10:00 a.m., has been deleted.  
Institution and settlement of administrative proceedings of an enforcement nature.

The following item will not be considered at the closed meeting scheduled for Tuesday, March 6, 1979, at 10:00 a.m., but has been rescheduled for consideration on Tuesday, March 13, 1979, at 10:00 a.m.

Authorization to discuss settlement of possible enforcement action.
DEPARTMENT OF LABOR
Employment and Training Administration

COMPREHENSIVE EMPLOYMENT AND TRAINING ACT

Regulations Under Part A of Title IV of The Act
PROPOSED RULES

[4510–30–M]

DEPARTMENT OF LABOR

Employment and Training Administration

[20 CFR Part 680)

COMPREHENSIVE EMPLOYMENT AND TRAINING ACT

Regulations for Programs under Part A of Title IV of the Act

AGENCY: Department of Labor.

ACTION: Proposed rules.

SUMMARY: This document proposes new rules at 20 CFR Part 680, implementing provisions under Title IV—Youth Program, Part A of the Comprehensive Employment and Training Act (CETA) as enacted in the Comprehensive Employment and Training Act Amendments of 1978 (Public Law 95–524). The purpose of this publication is to request review and comments on the proposed rules.

DATES: Comments on the proposed rulemaking are due on or before April 9, 1979.

ADDRESS: Comments should be addressed to the Assistant Secretary for Employment and Training, U.S. Department of Labor, 601 D Street N.W., Washington, D.C. 20213. Attention: Robert Taggart, Administrator, Office of Youth Programs.

FOR FURTHER INFORMATION CONTACT:

Mr. Robert Taggart, Telephone: (202) 376–2646.

SUPPLEMENTARY INFORMATION:

The Youth Employment and Demonstration Projects Act (YEDPA) of 1977, Public Law 95–93 became effective on August 5, 1977. It amended the Comprehensive Employment and Training Act by adding several new programs for youth. The purpose of these new programs is to employ and increase the future employability of young persons, to help coordinate and improve existing career development, employment, and training programs, and to test different approaches in solving the employment problems of youth.

Title IV, Part A of CETA as reauthorized maintains the authority for the new youth programs authorized by YEDPA; they are: the Youth Incentive Entitlement Pilot Projects (YIEPP), designed to test the effect of a year-round structured work experience as an entitlement to encourage school completion; the Youth Community Conservation and Improvement Projects (YCCIP) designed to provide jobs and employment experience for youth in community betterment projects; and the Youth Employment and Training Programs (YETP) structured to make available to youth a broad range of employment and training services designed locally and adapted to local needs. The following Part 680, Subparts A, B and D sets forth the Federal regulations governing three of the Youth Programs, YETP, YCCIP, and YIEPP. These regulations are those regulations published on May 60, 1978, for YIEPP; and on September 26, 1978, for YETP and YCCIP, except for changes to references necessitated by the compilation of the new CETA regulations, and changes necessitated by the extension of YIEPP for an additional year are also being published. Several provisions that are duplicative of the CETA general administrative provisions contained in Parts 675 and 676 have been deleted.

The regulations in this document do not apply to Native American and migrant YETP and YCCIP programs; regulations for these programs will be published separately. These regulations also do not apply to the Secretary's YETP and YCCIP discretionary funds.

Accordingly, title 20 is proposed to be amended as follows:

PART 680—YOUTH PROGRAMS OPERATED BY PRIME SPONSORS UNDER THE COMPREHENSIVE EMPLOYMENT AND TRAINING ACT

Subpart A—Youth Employment and Training Programs

Sec.

680.1 Purpose.

680.2 Eligibility for funds under YETP.

680.3 Allocation of funds.

680.4 Program planning, planning and youth councils.

680.5 Description of the YETP annual plan subpart.

680.6 Activities and services.

680.7 Local educational agency agreements.

680.8 Eligibility for participation.

680.9 Eligibility for participation (extraordinary).

680.10 Participant compensation, benefits and working conditions.

680.11 Earnings disregard.

680.12 Maintenance of effort.

680.13 Substitution for Title II programs.

680.14 Academic credit.

680.15 Reallocation procedures.

680.16 Modifications.

680.17 Reporting requirements.

680.18 Governor's Statewide Youth Services Program.

Subpart B—Youth Community Conservation and Improvement Projects

Sec.

680.100 Purpose.

680.101 Eligibility for funds under YCCIP.

680.102 Allocation of funds.

680.103 Program planning, planning and youth councils.

680.104 Description of the YCCIP annual plan subpart.

680.105 Project planning process.

680.106 Project application content.

680.107 Project application submission.

Sec.

680.108 Project review.

680.109 Project prioritization.

680.110 Project activities.

680.111 Agreements with project applicants.

680.112 Program agent responsibility.

680.113 Limitation on use of funds.

680.114 Eligibility for participation.

680.115 Eligibility of participants.

680.116 Supervisory personnel.

680.117 Academic credits.

680.118 Substitution for Title II programs.

680.119 Common general provisions.

680.120 Review by the RA; redistribution.

Subpart D—Youth Incentive Entitlement Pilot Projects

Sec.

680.300 Scope and purpose of subpart.

680.301 Regulations governing entitlement; definitions.

680.302 Funding of entitlement projects.

680.303 Eligibility for funds.

680.304 Entitlement project application process (general).

680.305 (Reserved.)

680.306 Submittal of preapplications.

680.307 Preapplication specifications.

680.308 Selection of final applications.

680.309 Placing grants.

680.310 Final application process.

680.311 Program operation-related documentation.

680.312 Program budget: Estimated costs.

680.313 Agreements.

680.314 Assurances and certifications.

680.315 Review of final applications; selection of projects.

680.316 Eligibility of participants.

680.317 Worksites.

680.318 Allowable activities.

680.319 Participant benefits.

680.320 Academic credit.

680.321 Disregarding earnings.

680.322 Maintenance of effort.

680.323 Administrative provisions; hearing provisions; and limitations on use of funds.

AUTHORITY: Sec. 126 of the Comprehensive Employment and Training Act (29 U.S.C. 601 et seq.), unless otherwise noted.

Subpart A—Youth Employment and Training Programs

§ 680.1 Purpose.

(a) This subpart contains the regulations for the Youth Employment and Training Programs (YETP) under Title IV, Part A, Subparts 3 and 4 of the Act. The introductory and general provisions at Parts 675 and 676 of Title 20 also apply to YETP programs except as indicated in this subpart. To the extent the regulations set forth in this subpart conflict with other regulations promulgated under the Act, the requirements contained in this subpart shall prevail (sec. 447).

(b) It is the purpose of this program to enhance the job prospects and career opportunities of young persons, especially economically disadvantaged youth, to enable them to secure unsubsidized employment in the public

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
and private sectors of the economy. In addition, this program explores methods of dealing with the structural unemployment problems of youth and the immediate difficulties of youth in need of and unable to find jobs (sec. 431).

§ 680.2 Eligibility for funds under YETP.
Prime sponsors are eligible to receive funds under YETP (sec. 434).

§ 680.3 Allocation of funds.
Allocation of funds under YETP shall be in accordance with section 433 of the Act.

§ 680.4 Program planning, planning and youth councils.
(a) Planning. Each prime sponsor shall utilize the planning process and planning council as described in §§ 676.6 and 676.7 of this title, and the youth council described in paragraph (b) of this section (sec. 438(b)). In developing the annual plan subpart for YETP, the prime sponsor shall:
(1) Coordinate the YETP subpart with services and activities described in the annual plan subpart for Title III, but services to youth under Title III shall not be reduced because of the availability of YETP funds (sec. 438(a));
(2) Coordinate the services and activities funded under the other titles of CETA, including Job Corps, employment and educational services provided by local educational agencies, and post-secondary institutions; activities conducted under the Career Education Incentive Act; services offered by public employment service agencies; public assistance agencies; courts with jurisdiction over youthful offenders and status offenders; youth programs funded through other sources such as community-based organizations; and employment and educational activities of business, labor, apprenticeship programs, and nonprofit institutions in the community (sec. 438(a));
(3) Afford an opportunity to community-based organizations of demonstrated effectiveness in providing employment and training activities for youth to participate in the development of the YETP subpart as required by paragraph (c) of this section; and
(4) Afford an opportunity for appropriate labor organizations to comment on the YETP subpart consistent with the provisions of § 676.12 of this title.

(b) Youth Council. Each prime sponsor shall establish a youth council (sec. 438(b)).

(1) In consultation with the planning council, the prime sponsor shall make appointments to a youth council which includes individuals who are representative of the local vocational advisory council, post-secondary educational institutions, business, unions, apprenticeship community, the public employment service agencies, local government and nongovernment agencies which are involved in serving youth, the local community, and the prime sponsor. In addition, youth council members shall include youths (not less than two) who are participants in, or eligible for YETP (sec. 438(b)).
(2) The youth council may be either an entire separate council or a subcommittee or subcouncil to the planning council, or the prime sponsor may use existing youth councils created with respect to other programs under this Act if these councils meet the requirements set forth in this section. In all cases, the youth council shall report to the planning council (sec. 438(b)).
(3) The youth council shall make recommendations to the planning council for setting basic goals, policies and procedures for the YETP program. The youth council shall monitor and evaluate YETP and other CETA youth programs in the prime sponsor’s area for the purpose of improving the utilization and coordination of the delivery of such services (sec. 438(b)).
(4) The youth council shall review and make recommendations to the planning council with respect to the proposed agreements with local educational agencies under YETP (sec. 438(c)).

(c) Community-based organizations (CBO’s). Each prime sponsor shall involve CBO’s in the planning process as follows:
(1) Forty-five (45) days prior to submission of the proposed YETP subpart to the RA either the complete subpart or a summary of the proposed subpart shall be submitted to such CBO’s. Such organizations shall have 30 days for review and comment on the proposed YETP subpart. If a summary is submitted, it shall include at a minimum:
(i) Description of activities to be funded;
(ii) Proposed service deliverers and the services to be provided by each; and
(iii) A copy of the Youth Program Planning Summary and Youth Budget Information Summary.
(2) Any comments received must be considered prior to the submission of the YETP subpart to the RA and written responses will be made to comments from such CBO’s regarding selection of service deliverers and these comments and responses will be included when the YETP subpart is transmitted to the RA.

(d) Selection of service deliverers.
(1) In addition to the provisions of § 676.23 of this title, the following provisions apply to the selection of service deliverers for YETP, except for programs funded under the LEA agreements required in § 680.7 and when the prime sponsor chooses not to deliver program activities:
(i) Published criteria that will be used to evaluate applications; and
(ii) Written notification to each applicant of acceptance or non-acceptance with an explanation of the reasons for disapproval of funding.
(2) A prime sponsor may directly perform classroom training, on-the-job training or work experience as described in § 676.25 of this title, only if, after consultation with CBO’s, the prime sponsor determines that direct operation of the program will promote the purposes of this subpart (sec. 432(b)). The prime sponsor shall maintain documentation on the administrative and programmatic benefits of such direct operation.

§ 680.5 Description of the YETP annual plan subpart.
(a) Each prime sponsor shall submit a YETP subpart by a date established by the RA which, when approved, shall become part of the annual plan.
(b) The RA shall review and approve or disapprove the YETP subpart using the plan review procedures in § 676.14 of this title.
(c) Narrative description. The YETP subpart narrative shall contain:
(1) Objectives and needs for assistance.—(i) Program purpose. State the basic goal/purpose of the YETP program in the overall strategy for serving unemployed youth in the prime sponsor’s area.
(ii) Analysis of need. Identify the target groups within the eligible population that will receive services under the program and indicate the planned level of services to be provided to each group in terms of the percent each group will constitute of those to be served.
(iii) Results and benefits. Describe the benefits that will accrue to YETP participants and include:
(A) The quantifiable performance and placement goals for each program activity;
(B) The quantifiable performance and placement goals for each target group identified in the analysis of need.
(iv) If academic credit is received by YETP participants, the level of credit to be received, the activities for which credit will be received, and the agency awarding such credit. If credit other than academic credit is to be awarded, describe as indicated above (for example, cooperative credits, continuing education units, etc.).

PROPOSED RULES

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
PROPOSED RULES

(3) Approach.—(i) Program activities and services. Provide a description of the program activities and services and indicate the delivery agent, the duration and the target groups to be served by each activity.

(ii) Program coordination and linkage. (A) If not elsewhere in the Comprehensive Employment and Training Plan, describe the program linkage and coordination with the SESAs, local educational agencies (LEA's), courts with jurisdiction over youthful offenders, public assistance agencies, post-secondary institutions, labor organizations, private sector businesses, neighborhood and community organizations, the apprenticeship system, other CETA youth programs, and other programs for youth.

(B) Describe or attach a copy of the agreement that describes arrangement with Job Corps screening agency(s) for referral, selection, and placement of Job Corps youth.

(4) Management and administration. (i) Describe any significant differences in the administration, arrangement, and management (including organizational structure) of the YETP program from the information provided elsewhere in the Comprehensive Employment and Training Plan.

(ii) Describe the results or attach copies of any evaluation/assessment reports, conducted on last year's YETP program which were used to set priorities and/or determine the programmatic goals or purposes of YETP.

(iii) Attach copies, if any, of comments and recommendations received on the YETP subpart from the appropriate labor organizations, the youth council, the planning council, CBO's and LEA's.

(iv) If not included elsewhere in the Comprehensive Employment and Training Plan, describe the monitoring and evaluation process for the program.

(v) List each property item to be purchased which costs $1,000 or more by item, quantity, and price.

(vi) Attach a copy of the Youth Program Planning Summary and Youth Budget Information Summary on the YETP program.

(5) Assurances and certifications. The YETP assurances and certifications and detailed instructions for completing the requirements of the YETP subpart narrative are contained in the "Forms Preparation Handbook."

§689.6 Activities and services.

(a) Programs may include any type of employment and training activity specified in §676.25 of this title, except public service employment.

(1) Work experience activities may include a wide range of community betterment activities such as rehabilitation of public properties; assistance of weatherization of homes occupied by low-income families; demonstrations of energy-conserving measures, including solar energy techniques especially those utilizing materials and supplies available without cost, park establishment and upgrading; neighborhood revitalization; conservation and improvements; removal of architectural barriers to access, by handicapped individuals, to public facilities, and related activities. (sec. 432(a)).

(2) Productive employment and work experience opportunities may be funded in such fields as education; health care; neighborhood transportation services; crime prevention and control; environmental quality control (including integrated pest management activities); preservation of historic sites; and maintenance of visitor facilities. (sec. 432(a)).

(3) A written job description shall be developed and maintained for all work experience and on-the-job training positions funded under this subpart to provide a basis for determining their comparability to existing jobs of other individuals similarly employed.

(b) In-School programs. The in-school programs shall be designed to provide for either or both of the following two classifications of services. (Sec. 423(a):

1. Transition services

(i) These transition services shall be designed to prepare and assist youth to move from school to unsubsidized jobs in the labor market.

(ii) These services include:

(A) Outreach, assessment, and orientation;

(B) Counseling, including occupational information, apprenticeship information, and career counseling;

(C) Activities promoting education to work transition;

(D) Provision of labor market information;

(E) Services to youth to help them obtain and retain employment;

(F) Literacy training and bilingual training;

(G) Attainment of certificates of high school equivalency;

(H) Job sampling, including vocational exploration in the public and private sector;

(I) Institutional skills training;

(J) Transportation assistance;

(K) Child care and other necessary supportive services;

(L) Job restructuring to make jobs more responsive to the objectives of this subpart, including assistance to employers in developing job ladders or new job opportunities for youth, in order to improve work relationships between employers and youth;

(M) Provision of information regarding employment and training related opportunities;

(N) Job development, placement, and placement assistance to secure unsubsidized employment opportunities for youth to the maximum extent feasible and referral to employability development programs;

(O) Assistance in overcoming sex-stereotyping in job development, placement; and

(P) Outreach and other services to increase the labor force participation rate among males and females.

(2) Career employment experience. This activity is a combination of both well supervised employment (work experience or on-the-job training) and certain transition services including, at a minimum, career information, counseling, and guidance. Any work experience or on-the-job training must include those minimum ancillary transition services. Where work experience or on-the-job training is supported with funds serving in-school youth under agreements with local educational agencies, the ancillary transition services must also include placement services. Each prime sponsor shall assure that in-school youth participating in career employment experience need such participation in order to continue their education. (sec. 430).

(c) Special component. A prime sponsor may design a special component using up to 10 percent of its YETF funds for programs to serve a mixture of youth from families above and below the income level specified in §680.8(a)(3). The program shall test whether or to what extent income eligible youth benefit from participating in programs designed to serve youth from all economic backgrounds. (sec. 423). This special component shall:

(1) Have and follow a structured experimental design;

(2) Establish and use comparison groups;

(3) Provide for followup on participants;

(4) Provide in the Annual Narrative Report a followup on the experimental outcomes.

§689.7 Local Educational Agency agreements.

(a) Prime sponsors shall use at least 22 percent of their funds under this subpart to serve in-school youth in programs designed to enhance their career opportunities and job prospects (sec. 430(a)). The program shall test whether or to what extent income eligible youth benefit from participating in programs designed to serve youth from all economic backgrounds. (sec. 423). This special component shall:

(b) Agreements may be between the prime sponsor and one or more local educational agencies (LEA's) or a combination of LEA's represented by one LEA.

(c) Each agreement may be either a financial or nonfinancial agreement whichever is determined most appropriate by the prime sponsor and the LEA's, and shall:

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
PROPOSED RULES

(1) Provide a description of the activities and services to be provided to eligible participants; (2) The responsibilities of each party to the agreement for providing the activities and services which have been selected; (3) Contain provisions to assure that services provided and/or funds received pursuant to the agreement will not supplant existing services and/or State and local funds expended for the same purpose; and (4) Provide an assurance that the agreement has been reviewed by the youth council.

(a) Each person shall be at the time of enrollment, except as provided in § 680.9(b) and (c) (sec. 435): (1) Unemployed or underemployed, or in-school; (2) 16 through 21 years of age inclusive; and (3) A member of a family with a total family income at or below 85 percent of the lower living standard income level.

(b) Programs funded under YETP shall give preference to economically disadvantaged youth within the eligible population. Appropriate efforts shall be made to give service to those youth who have severe handicaps in obtaining employment, including but not limited to those who lack credentials (such as a high school diploma), those who require substantial basic and remedial skill development, those who are women and minorities, those who are veterans of military services, those who are offenders, those who are handicapped, those with dependents, or those who have otherwise demonstrated special needs as determined by the Secretary (sec. 444(a)).

(c) A youth may not be enrolled in full-time employment opportunities if: (1) The individual has not attained the age with respect to which the requirement of compulsory education ceases to apply under the laws of the State in which such individual resides; and (2) where employment is undertaken in cooperation with school-related programs awarding academic credit for work experience.

(2) The individual has not attained a high school diploma or its equivalent and it is determined by the prime sponsor that the youth dropped out of high school in order to participate in YETP (sec. 445(f)).

§ 680.9 Eligibility for participation (extraordinary).

(a) Individuals otherwise eligible under § 680.8 who are in school and who are 14 or 15 years old may participate in programs under YETP when the subpart specifies a youth development strategy which provides broad career exposure for these youths (sec. 435).

(b) Youth need not meet the income criteria if they participate in a special component, as described in § 680.6(e) (sec. 435).

(c) Youth, who do not meet the income criteria, and who are not in a special component, may be offered services which are limited to: (1) Counseling, including occupational information; (2) Occupational, education, and training information including information on apprenticeship training; (3) Placement services; (4) Job referral information through coordinated intake systems; and (5) Assistance in overcoming employment related sex-stereotyping in job development, placement, counseling, and guidance.

§ 680.10 Participants compensation, benefits, and working conditions.

(c) Youth, who do not meet the income criteria, and who are in school and are not in a special component, may be offered services which are limited to: (1) Counseling, including occupational information; (2) Occupational, education, and training information including information on apprenticeship training; (3) Placement services; (4) Job referral information through coordinated intake systems; and (5) Assistance in overcoming employment related sex-stereotyping in job development, placement, counseling, and guidance.

§ 680.10 Participants compensation, benefits, and working conditions.

Prime sponsors shall provide participants compensation, benefits and allowances as provided in §§ 676.25, and 676.27 of this title, except: (a) Wages. Participants receiving wages shall be paid no less than the highest of (sec. 442): (1) The wage rate set forth in section 6(a)(1) of the Fair Labor Standards Act. (see. 435): (2) Occupational, education, and training information including information on apprenticeship training; (3) Placement services; (4) Job referral information through coordinated intake systems; and (5) Assistance in overcoming employment related sex-stereotyping in job development, placement, counseling, and guidance.

§ 680.10 Participants compensation, benefits, and working conditions.

(c) Youth, who do not meet the income criteria, and who are in school and are not in a special component, may be offered services which are limited to: (1) Counseling, including occupational information; (2) Occupational, education, and training information including information on apprenticeship training; (3) Placement services; (4) Job referral information through coordinated intake systems; and (5) Assistance in overcoming employment related sex-stereotyping in job development, placement, counseling, and guidance.

§ 680.10 Participants compensation, benefits, and working conditions.

Prime sponsors shall provide participants compensation, benefits, and allowances as provided in §§ 676.25, and 676.27 of this title, except: (a) Wages. Participants receiving wages shall be paid no less than the highest of (sec. 442): (1) The wage rate set forth in section 6(a)(1) of the Fair Labor Standards Act. (see. 435): (2) Occupational, education, and training information including information on apprenticeship training; (3) Placement services; (4) Job referral information through coordinated intake systems; and (5) Assistance in overcoming employment related sex-stereotyping in job development, placement, counseling, and guidance.

§ 680.10 Participants compensation, benefits, and working conditions.

Prime sponsors shall provide participants compensation, benefits, and allowances as provided in §§ 676.25, and 676.27 of this title, except: (a) Wages. Participants receiving wages shall be paid no less than the highest of (sec. 442): (1) The wage rate set forth in section 6(a)(1) of the Fair Labor Standards Act. (see. 435): (2) Occupational, education, and training information including information on apprenticeship training; (3) Placement services; (4) Job referral information through coordinated intake systems; and (5) Assistance in overcoming employment related sex-stereotyping in job development, placement, counseling, and guidance.
should attempt to resolve the issue within 30 days after the agent has been informed of the job or projects in which the provisions of the Davis-Bacon Act, or any Federal law containing labor standards in accordance with the Davis-Bacon Act, or any Federal law 'contain-

(4) The prevailing wage determined by the Secretary under the Davis-Bacon Act (See 29 CFR parts 1, 3, 5, and 7) in the case of jobs in projects to which the provisions of the Davis-Bacon Act, or any Federal law containing labor standards in accordance with the Davis-Bacon Act, apply. However, in the case of such projects financed under YETP under $5,000, the em-
ployer, prime sponsor, and appropriate collective bargaining agent may agree to pay youth participants not less than the applicable minimum wage and not more than the wage rate of the entering apprentice in the most nearly comparable apprenticeable trade, and an appropriate ratio of journeymen to such partici-
pat ing youth to work on the project. If they cannot agree in 30 days, they may request a decision from the RA, or develop other jobs (sec. 442).

(b) Because most jobs will be short-
term and/or part-time work assign-
ments, and are designed to enhance the employability of individuals who are new entrants who have never worked, or individuals who are new entrants who have not been working in the competitive labor market, most jobs will be at entry level. Prime spon-
sors, therefore, are expected to pay wherever feasible the minimum rate required by this section, rather than a higher rate.

§ 680.11 Earnings disregard.
Wages and allowances received by any youth under YETP shall be disregarded in determining the eligibility of the youth's family for, and the amount of, any benefits that the youth's family may receive, under Federal or federally assisted programs (sec. 446).

§ 680.12 Maintenance of effort.
(a) The maintenance of effort provi-
sions of § 676.73 (a) of this title apply to all activities funded under YETP (sec. 443).
(b) The maintenance of effort provi-
sions for public service employment programs described in § 676.73 (b) and (c) of this title, shall apply to work ex-
périence activities under YETP.

§ 680.13 Substitution for Title II pro-
grams.
Programs funded under YETP shall be supplemental to but not replacing programs and activities for youth available under Title II of the Act (sec. 431).

§ 680.14 Academic credit.
Prime sponsors shall make appropriate efforts to encourage educational agencies and post-secondary institutions to award academic credit for the competencies participants gain from the program (sec. 445).

§ 680.15 Reallocation procedures.
(a) Reallocation procedures under § 676.47 of this title shall apply except as in paragraph (b) of this section (sec. 444(b)).
(b) If all proposed LFA agreements or certifications to existing agreements are not signed by the prime sponsor and the LEA(s) within 60 days after the initial submission of the YETP subpart to the RA for review and approval, the RA shall initiate reallocation procedures for those funds which were required to be cov-
ered under LFA agreements, except the RA may extend the 60 day period for a reasonable period of time when the RA determines that an agreement could not be reached because of circum-
stances beyond the control of the prime sponsor and LEA, for example, work stoppages. If the RA has initi-
at ed reallocation procedures, the RA shall mediate the dispute during the 30 day complaint period.

§ 680.16 Modifications.
(a) The procedures specified in § 676.16 of this title shall apply to modifying the YETP subpart.
(b) (1) When a collective bargaining agreement would be affected, the approp-
riate bargaining agent and the RA shall be notified in writing of all wage rate and job classification changes under the YETP program at least 15 calendar days prior to im-
plementing such changes.
(2) If the bargaining agent disagrees with the proposed changes in wage rates or job classifications, the dispute shall be resolved and the resolution re-
corded in writing prior to implementing such changes.

§ 680.17 Reporting requirements.
The reporting requirements under § 676.44 of this title shall apply to YETP. In addition, each prime spon-
sor shall, at the end of each fiscal year and on a date established by the Sec-
retary, submit an Annual Narrative Report. The report will include an as-

§ 680.18 Governor's Statewide Youth Serv-
ices Program.
(a) Activities and services. The Gov-
er shall use the funds allocated under section 433 of the Act to provide statewide youth services as the following:
(1) Expanded and experimental pro-
gress in apprenticeship arrangements, in conjunction with businesses, labor unions, State or Federal appren-
ticeship agencies;
(2) Special model employment and training programs and related services between appropriate State agencies and prime sponsors, with particular emphasis on experimental job training in the private sector;
(3) Providing labor market and occupa-
tional information for prime spon-
sors and local educational agencies without reimbursements;
(4) Fostering cooperative efforts be-
tween State and local institutions, in-
cluding (i) occupational and career guidance and counseling for students by relating education to placement services for in-school and out-of-school youth; and (ii) coordin-
ation of statewide activities carried out under the Career Education Incentive Act to improve the quality of educa-

tion and enhance career opportunities for students by relating education to their employment aspirations (see. 433(c)).

(b) Funding employment and training programs as defined in § 680.6 for eligible youth who are under the super-

(b) Eligibility for participation. Indi-
viduals participating in the Govern-
or's statewide youth services program shall meet the eligibility criteria provided in § 680.8 or 680.9 (sec. 435).
(c) Limitation of funds. (1) The overall 20 percent limitation of funds used for administration as set out in § 676.39 of this title shall not apply to the Governor's youth services program. (2) The provisions for pooling of adminis-
trative costs shall be optional for the Governor's youth services program.
(d) Governor's statewide youth ser-

§ 680.18 Governor's Statewide Youth Serv-
ices Plan. The Governor's youth services plan shall include the following information:
(1) The Governor may utilize the Master Plan developed for the Balance of State program or the Master Plan developed for the Governor's Special Grant as described in § 676.33 of this title, in lieu of developing a separate Master Plan for the Governor's statewide youth services program:
(2) A Request for Approval Letter;
(3) Application for Federal Assistance (standard form 424);
(4) The narrative description which shall include the following:
(d) Governor's statewide youth ser-

The Governor's youth services plan shall include the following information:
(1) The Governor may utilize the Master Plan developed for the Balance of State program or the Master Plan developed for the Governor's Special Grant as described in § 676.33 of this title, in lieu of developing a separate Master Plan for the Governor's statewide youth services program:
(2) A Request for Approval Letter;
(3) Application for Federal Assistance (standard form 424);
(4) The narrative description which shall include the following:

(A) Objectives and need for assistance.

(A) A description of the purpose or emphasis of the statewide youth serv-
ices plan, including how the Governor's youth services plan will enhance or expand the quality of youth employment and training services presently provided throughout the State. 

(B) A description of the target groups that will be served by the Governor's youth services plan, including an explanation of why the specific groups were selected, and the groups of youth that will be served who are under the supervision of the State.

(ii) Results and benefits. A description of the expected results and benefits to be derived by each target group that will be served.

(iii) Program activities and services. Identify each activity, including any experimental, demonstration, or model program, to be provided throughout the State; including any experimental, demonstration, or model program, to be provided. 

The Governor's youth services plan will enhance the skills to be learned. 

(iv) Management and administration. (A) Provide the organizational chart and staffing pattern for the plan, if not included in the master plan.

(B) Program coordination and linkage. Describe the coordination and program linkages, if not elsewhere described, with programs under Title II, Special Governor's grants; state or Federal apprenticeship agencies; statewide activities carried out under the Career Education Incentive Act; State courts with jurisdiction over youthful offenders and status offenders; public assistance agencies; State, local or post-secondary institutions including vocational education agencies.

(v) Management and administration. (A) Provide the organizational chart and staffing pattern for the plan, if not included in the master plan.

(B) Program coordination and linkage. Describe the coordination and program linkages, if not elsewhere described, with programs under Title II, Special Governor's grants; state or Federal apprenticeship agencies; statewide activities carried out under the Career Education Incentive Act; State courts with jurisdiction over youthful offenders and status offenders; public assistance agencies; State, local or post-secondary institutions including vocational education agencies.

(B) List any property item to be purchased if $1,000 or more by item, quantity, and price.

(C) Attach a Youth Program Planning Summary (YFPS) and a Youth Budget Information Summary (YBIS).

(D) Attach copies of any comments and recommendations received on the plan from the appropriate labor organizations, the State apprenticeship council, the Governor's youth council, and the State Employment and Training Council.

(E) The assurances and certifications for the Governor's youth services plan, the Governor shall establish a youth council as described in §680.4(b) which shall report to the State Employment and Training Council. The responsibilities of this council shall be those described in §680.4, except the reference to local agencies shall mean representatives of State agencies that represent statewide concerns.

(2) In submitting the Governor's youth services plan, the procedures specified in §676.12(a), (b) and (c) and §676.33(a)(5) of this title shall be followed.

(3) The approval procedures to be followed for the Governor's youth services plan are those specified in §676.14 of this title.

(4) The modification procedures specified in §676.16 of this title shall be used to modify the Governor's youth services plan under YETP.

Subpart B—Youth Community Conservation and Improvement Projects

§680.100 Purpose.

(a) This subpart contains the regulations for the Community Conservation and Improvement Projects (YCCIP) under Title IV, Part A, Subparts 2 and 4 of the Act. The introductory and general provisions at Parts 675 and 676 of Title II and the YETP regulations at Subpart A of this Part also apply to YCCIP program, except as indicated in this subpart. To the extent the regulations set forth in this subpart conflict with other regulations promulgated under the Act, the requirements contained in this subpart shall prevail (sec. 447).

(b) This program seeks to provide youth, experiencing severe difficulties in obtaining employment with well supervised work in projects that produce tangible benefits to the community.

§680.101 Eligibility for funds under YCCIP.

Prime sponsors are eligible to apply for YCCIP funds for projects in their area.

§680.102 Allocation of funds.

(a) Allocations. Allocation of funds under YCCIP shall be in accordance with section 423 of the Act.

(b) Program funding estimates. The Secretary will provide prime sponsors with program funding estimates based on their relative share of the State's unemployed population.

§680.103 Program planning, planning and youth councils.

(a) Planning. The prime sponsor shall utilize the planning process and planning council as described in §§675.6 and 676.7 of this title and the youth council established for YETP in developing its annual plan subpart for YCCIP (sec. 426(c)).

(b) Additional information. The PA may require that the additional information specified below be submitted at the same time as the Preapplication for Federal Assistance. Where such information is required, a decision concerning the adequacy of that information must be provided to the prime sponsor by five (5) working days after the submission date of the preapplication.

The prime sponsor will not be required to submit such information in its annual plan subpart. Such information includes a description of methods to:

(1) Solicit applications, particularly from neighborhood and community-based organizations, and solicit comments on the project applications from the planning and youth councils;

(2) Objectively select and rank project applications; and

(3) Involve appropriate labor organizations in the planning process.

§680.104 Description of the YCCIP annual plan subpart.

(a) Each prime sponsor shall submit a YCCIP subpart, due date established by the RA, which, when approved, shall become part of the annual plan.

(b) The RA shall review and approve or disapprove the YCCIP subpart using the procedures in §676.14 of this title.

(c) Narrative description. The narrative shall contain:

(1) Objectives and needs for assistance. Using the requirements for the YETP narrative, provide a description of the purpose of the YCCIP program and the target groups that will be served.

(2) Results and benefits. As described in the YETP narrative requirements, provide a description of the benefits that will accrue to the participants and to the community through the YCCIP program (sec. 426(b)).

(3) Approach. (i) Participant recruitment and eligibility. Describe, if not elsewhere described in the Comprehensive Employment and Training Plan, the methods that will be used to recruit eligible YCCIP youth.

(ii) Worksite supervision. (A) Describe the training for worksite supervisors and other worksite personnel involved with project participants. Indicate who will conduct this training (sec.425(b)(3)); and

(B) If the supervisor/worker ratio is less than 1:12, provide justification (sec. 425(b)(3)).

(iii) Program activities and services. (A) Describe the job training and skill development activities that will be available to participants. Indicate who will deliver the training, the duration of each training component, and the skills to be learned (sec. 426(b)(2)).

(B) Describe plans to coordinate the training and skill development activities with school-related programs (sec. 426(b)(2)).
PROPOSED RULES

(C) Pursuant to the requirements for YEIT, describe any activities or services, other than project activities, that will be funded under the program.

(iv) Linkages. If the linkages, including the Job Corps agreement, differ for YCCIP from those described in the YEIT narrative, then provide a description of these unique linkages (sec. 426(b)(1)).

(v) Project solicitation and selection. (A) If not included elsewhere in the Comprehensive Employment and Training Plan, describe the method used to solicit YCCIP project applications. Describe the efforts made to solicit applications from neighborhood and community-based organizations; and the method used by program agents to solicit applications, if different from the prime sponsor's (sec. 426(a)(1)).

(B) List or attach the criteria used to determine which project proposals are eligible for funding (sec. 426(a)(1)).

(C) Attach all project applications approved by the prime sponsor and the program agent and include a ranked listing of the approved project applications which total 100% of the prime sponsors funding estimate (sec. 426(a)(1)). Also include a ranked listing of any additional approved project applications above the funding estimate.

(D) Attach all project applications approved by program agents but not approved by the prime sponsor and describe why these project proposals were not approved by the prime sponsor (sec. 426(a)(1)).

(4) Management and administration. (i) Describe any significant differences in the administration, operation, and management (including organizational structure) of the YCCIP program from the information provided elsewhere in the Comprehensive Employment and Training Plan.

(ii) Describe the results or attach copies of any evaluation/assessment reports conducted on the last year's YCCIP program which were used to set priorities and/or determine the programmatic goals or purposes of YCCIP.

(iii) Attach copies, if any, of comments and recommendations received on the YCCIP plan subset from the appropriate labor organizations, the youth council, the planning council, CBO's and LEA's.

(iv) If not included elsewhere in the Comprehensive Employment and Training Plan, describe the monitoring and evaluation process for the program.

(v) List each property item to be purchased which costs $1,000 or more by item, quantity, and price.

(vi) Attach a copy of the Youth Program Planning Summary and Youth Budget Information Summary on the YCCIP program.

(5) Assurances and certifications. The Assurances and certifications and detailed procedures for completing the requirements of the YCCIP annual plan subpart are contained in the Forms Preparation Handbook.

§ 680.105 Project planning process.

(a) Program specifications. In developing the program specifications, prime sponsors may, after obtaining the approval of the planning and youth councils, limit the types of project activities by:

1. Establishing limitations on the size and duration of all projects;

2. Restricting projects to specified community needs; and

3. Identifying specific neighborhoods, if or geographically, in which projects may be conducted.

(b) Procedures. Each prime sponsor shall establish procedures for its own use and the use of any program agent(s) which will assure that potential prime sponsors, particularly neighborhood and community-based organizations, are notified of the project application process and the cut-off date for acceptance of project applications. The method of notification may be public hearings, public notices in the newspapers, bulletins, or other appropriate media.

§ 680.106 Project application content.

- All project applications must contain the following information:

(a) Agency. Name of agency or organization applying for project funds, type of agency (community-based organization, local educational agency) and type of agency (community-based or local educational agency) applying for project funds, and the program agent to which it was submitted;

(b) Description of project. (1) The need for the project in the area in which it will be conducted and how the project will meet the need;

(2) The types of Jobs youth are to perform;

(3) The full-time supervisor to youth ratio, or its equivalent and the reason for selecting the ratio;

(4) The qualifications of the supervisors in terms of necessary skills and experiences, or where these are not yet specifically identified, assurances that supervisors will be adequately trained in the skills needed to carry out the projects and in instructing participating youth and a description of the method for selecting supervisors; and

(5) The beginning and ending dates of the project;

(c) Participants. (1) Identify the number of participants to be enrolled and their expected duration of employment, not exceeding 12 months;

(2) List the target, groups to be served; and

(d) Costs of project activities. (1) Project costs shall be broken down into the following categories:

(a) Costs of wages and fringe benefits;

(b) Costs of materials, supplies and equipment used by participants on the job;

(c) Costs of supportive services for participants.

§ 680.107 Project application submission.

The project applicant shall submit applications to the program agent or to the prime sponsor, if there is no program agent, for its area.

§ 680.108 Project review.

(a) Criteria. The prime sponsor shall establish criteria to be used consistently by itself and any program agent for evaluating and approving project applications. These criteria are subject to review and comment by the youth and planning councils.

(b) Information. Each project, in order to be approved must:

(1) Provide tangibles output and measurable benefits which will accrue to the community;

(2) Provide benefits to participants in terms of work habits, skills, apprenticeship skills, and attainment of academic credit, where applicable;

(3) Be labor intensive;

(4) Ensure an adequate level of supervision, taking into account the complexity of the jobs to be created;

(FEDERAL REGISTER, VOL. 44, NO. 48--FRIDAY, MARCH 9, 1979)
PROPOSED RULES

§ 680.109 Project prioritization.
Each prime sponsor shall rank, in terms of their relative priority, approved project applications. Each prime sponsor shall submit:
(a) A primary listing of prioritized proposed projects not to exceed 100 percent of the program funding estimate; and
(b) If additional projects have been approved, a second listing to be considered for future funding. In instances where:
(1) Projects submitted within the 100 percent are not acceptable to the RA;
(2) A project is subsequently found to be nonproductive or is withdrawn; or
(3) Additional funds become available.

§ 680.110 Project activities.
(a) Each project shall provide participants with constructive work in terms of individual and community benefits in such areas as, the rehabilitation or improvement of public facilities (including removing of architectural barriers which limit the access to these facilities by handicapped individuals); neighborhood improvements; weatherization and basic repairs to low-income housing; energy conservation including solar energy projects, especially those utilizing materials and supplies available without cost; and conservation, maintenance, or restoration of natural resources of non-Federal publicly held lands (sec. 422).
(b) Training provided in YCCIP shall be directly related to the development of specific skills needed for the job.

§ 680.111 Agreements with project applicants.
(a) Prime sponsors or program agents shall enter into financial agreements with project applicants except as provided in paragraph (b) of this section.
(b) The prime sponsor or program agent may enter into a nonfinancial agreement with a project applicant if there is a written agreement that clearly identifies the administrative and programmatic benefits of such a nonfinancial agreement.

§ 680.112 Program agent responsibility.
A program agent under title II may elect to be a program agent under this subpart. Program agents shall approve or disapprove projects, administer the program in their areas, and be subject to the limitations of funds provided in § 680.113. The administrative responsibilities described in § 677.54(b) of this title shall apply to YCCIP program agents.

§ 680.113 Limitation on use of funds.
(a) Administrative costs. No more than 5 percent of the total funds may be used by the prime sponsor and program agent(s) for administrative costs. The remaining funds shall be made available for projects.
(b) Project funds. Of the project funds:
(1) At least 65 percent of the funds available shall be used for participant wages and fringe benefits, unless adequate justification is provided in the prime sponsor's YCCIP annual plan subpart.
(2) No more than 10 percent may be used by project applicants for administrative costs.
(3) Any remaining funds may be used for project related training of participants, project supervisors, service to participants, and for the acquisition, lease, or rental of materials, equipment, and supplies.

§ 680.114 Eligibility for participation.
(a) Each person shall, at the time of enrollment:
(1) Be 16 through 19 years of age, inclusive; and
(2) Be unemployed (sec. 422).
(b) Selection. In selecting eligible youth, prime sponsors shall give preference to the economically disadvantaged.
(1) Appropriate efforts shall be made to serve those eligible youths who have severe handicaps in obtaining employment (sec. 444(a)).
(2) A youth may not be enrolled in full-time employment opportunities if:
(I) The individual has not attained the age with respect to which the requirement of compulsory education ceases to apply under the laws of the State in which such individual resides, except: (A) during periods when school is not in session, and (B) where employment is undertaken in cooperation with school-related programs awarding academic credit for work experience;
(ii) The individual has not attained a high school diploma or its equivalent and it is determined by the prime sponsor that the youth dropped out of high school in order to participate in YCCIP (sec. 443(d)).
(c) Limitation. Each participant shall be limited to a maximum enrollment of 12 months with no more than two terminations and reenrollments, provided age eligibility is met at the time of each reenrollment.
Consistent with the provisions of § 676.30(c), every effort should be made to transition participants into unsubsidized jobs or other CETA opportunities upon completion of the 12 months enrollment (sec. 428).

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
§ 680.115 Earnings disregard.

Wages received by any youth under YCIPP shall be disregarded in determining the eligibility of the youth's family for, and the amount of, any benefits based on need under any Federal or federally assisted programs (sec. 446).

§ 680.116 Supervisory personnel.

Each project shall have an adequate number of skilled supervisors. There shall be at least the ratio of 1 full-time supervisor to every 12 youths, unless satisfactory justification for another ratio is provided in the prime sponsor's YCIPP annual plan-subpart. Supervisors shall have the skills needed to carry out the project and shall be able to instruct participants in those skills (sec. 425(b)).

§ 680.117 Academic credit.

Prime sponsors shall make appropriate efforts to encourage educational agencies and post-secondary institutions to award academic credit for competencies participants gain from their participation in the program (sec. 448(a)). If academic credit is not given for work experience in YCIPP projects, high school dropouts and potential dropouts shall be encouraged to return to or remain in school.

§ 680.118 Substitution for Title II programs.

Programs funded under YCIPP shall be supplementary to but not replace programs and activities for youth available under title II of the Act (sec. 421).

§ 680.119 Common general provisions.

The provisions governing modifications, reallocations, maintenance of effort, reporting, wages, benefits, and working conditions under YETIP shall apply to YCIPP programs.

§ 680.120 Review by the RA, redistribution.

(a) The RA may approve projects up to 100 percent of the prime sponsors program funding estimate.

(b) The RA shall disapprove any project application which does not meet the requirements of the Act, and the regulations. RA's shall review individual applications for outstanding disagreements between appropriate labor organizations, employers, and prime sponsors with respect to jobs that have been restructured. RA's shall provide in writing to the prime sponsor an explanation for any prioritized project applications that are rejected.

(c) Redistribution. If there are insufficient approved prioritized project applications to equal the prime sponsor's program funding estimate, the RA shall allow the prime sponsor 30 days in which to modify the prioritized project list. If the prime sponsor fails to submit revised project applications or submits revised project applications which are not approvable, the RA shall award the unused funds to other prime sponsors within the State for project applications approved by the RA. In States with only one prime sponsor or in States where no other prime sponsor will be able to spend these funds within a reasonable period of time, the RA shall initiate the reallocation procedures set forth in §676.47 of this title.

Subpart D—Youth Incentive Entitlement Pilot Projects

§ 680.300 Scope and purpose of subpart.

(a) This subpart contains the regulations governing the Youth Incentive Entitlement Pilot Projects (Entitlement Projects) under Title IV, Part A, Subpart I of the Act. The Youth Incentive Entitlement Pilot Projects were established by Title II of the Youth Employment and Demonstration Projects Act (YEDPA) of 1977.

(b) The basic purpose of the Entitlement Projects is to test the experimental idea of guaranteeing jobs, or in some cases a combination of jobs and training, to economically disadvantaged youth. The program will operate only on certain prime sponsor areas, or portions of prime sponsor areas, chosen by the Department of Labor. Within those areas during the school year, otherwise unavailable part-time employment, or a combination of part-time employment and training, will be guaranteed to those economically disadvantaged youth between the ages of 16 to 19 inclusive, who are in secondary school, who are in a program leading to a certificate of high school equivalency. In addition, in those same areas during the summer, otherwise unavailable full-time employment, or a combination of part-time employment and training, will be guaranteed to economically disadvantaged youth between the ages of 16 to 19 inclusive, who are in a secondary school or who are in a program leading to a certificate of high school equivalency. (Sec. 418(a)).

(c) Congress mandated that the entitlement approach be rigorously tested under varying geographic, economic, and other circumstances. Because of the high cost of guaranteeing year-round jobs to all in-school disadvantaged youths, only a limited number of demonstrations can be undertaken with available funds. In order to test whether jurisdictions can feasibly implement substantial programs, only a limited number of Tier I projects will be implemented. These will cover entire jurisdictions or neighborhoods. In order to test a number of innovative approaches authorized by the Act and to get a wider geographic spread, a somewhat larger number of Tier II projects will be funded, demonstrating specific innovative entitlement approaches. These projects might cover only the area served by a particular school or small school district.

(d) To make sure that Entitlement Projects would be selected and operated as a national experiment, with the necessary flexibility to develop and test new and improved ideas, Congress did not authorize the Secretary to allocate funds to CFTEA prime sponsors by formula. Instead, the Secretary of Labor is required to determine how many Entitlement Projects are to be established and where they should be located.

§ 680.301 Regulations governing entitlement projects; definitions.

(a) The regulations governing Entitlement Projects shall be those in this subpart. The general provisions at Part 676 of this title shall also apply to Entitlement Projects. However, to the extent a regulation in this subpart conflicts with a regulation at Part 676 of this title, the regulations in this subpart shall prevail.

(b) Definitions for terms used in this subpart may be found at §676.4 of this title, except as stated within this subpart.

§ 680.302 Funding of entitlement projects.

(a) Of the funds available under this subpart, the Secretary shall reserve a portion of the funds for research, technical assistance, consultants, and other appropriate purposes.

(b) The Secretary shall use the remaining funds under this subpart to fund selected Entitlement Projects.

§ 680.303 Eligibility for funds.

All prime sponsors under Title II of the Act shall be eligible to apply for Entitlement Project funds.

§ 680.304 Entitlement project application process (general).

(a) The Entitlement Project application consists of two steps, a preapplication procedure and a final application procedure.

(b) Selected projects have been financed to start in January 1978.

§ 680.305 [Reserved]

§ 680.306 Submittal of preapplications.

(a) Prime sponsors planning to submit a preapplication for an Entitlement Project are requested to send a letter of such intent to the Employment and Training Administration (ETA) national office. A copy of the
PROPOSED RULES

letter shall be sent to the appropriate Regional Administrator.

(b) The prime sponsor's preapplication is to be submitted as follows:

(1) Five copies are to be sent to the Regional Administrator of the appropriate ETA regional office (one need to have original signatures).

(2) One signed original and 14 copies are to be sent to the ETA national office.

§ 680.307 Preapplication specifications.

This section sets forth the types of information and data to be provided in the prime sponsor's preapplication. The preapplication should clearly indicate whether it is for Tier I or Tier II project.

(a) The following information, which may be obtained from the approved Master Plan, shall be provided with respect to the prime sponsor:

(1) (i) Geographic and political boundaries;

(ii) Most recent population survey data, by age, race, and sex;

(iii) Most recent data on poverty levels in the area, by age, race, and sex;

(iv) Labor force data including employment and unemployment figures by age, race, and sex; and

(v) Principal characteristics of the labor market (size of major industries, growth, trends, etc.)

(2) Information on the following items should be based on the prime sponsor's best estimates using the 1970 census and updates, the Office of Education Survey of Income and Education, and local school data.

(i) The size of the eligible youth population (16-19 years old, economically disadvantaged as defined in 680.316(a)(4) with no high school diploma or equivalent).

(ii) Breakdown of the eligible youth population showing those currently in school and out-of-school, and for each of these groups, the total employed (part-time, full-time), unemployed, and not in the labor force.

(b) Proposed Entitlement Area.—(1) General. Preapplications must identify the geographic area to be designated as the Entitlement Area. The Entitlement Area must be a discrete geographic area which can be delineated by a single set of boundaries on a map.

(ii) The Entitlement Area for Tier I projects must contain at least 3,500 and no more than 12,000 eligible youth. For Tier II projects, the Entitlement Area must include 1,500 or less eligible youth. Prime sponsors may propose to administer an Entitlement Area that is not contiguous to Tier I in an area with more than 12,000, or under Tier II in an area with more than 1,500 eligible youth provided they promise to finance 100 percent of the extra costs.

(iii) For Tier I projects, it is preferable that the geographic boundaries of the Entitlement Area coincide with the boundaries of the public secondary school system or an identifiable subpart of that system to minimize the number of eligible youth residing in the Entitlement Area who attend public schools located outside the Entitlement Area.

(iv) In designating the Tier I Entitlement Area, prime sponsors should consider locating primarily in that area, for example, by including low-residential commercial districts as part of the Entitlement Area.

(2) Information requested. If the Entitlement Area is different from the prime sponsor's jurisdictional area, the information requested in paragraph (a) of this section should also be submitted for the Entitlement Area.

(c) Estimated Job Demand in the Entitlement Area.—(1) General. Since employment opportunities must be provided to all eligible youth in the Entitlement Area, it is critically important to estimate the number of eligible youth who seek jobs. The estimate must consider not only unemployed in-school youth, but those not looking for jobs who would take them if available, those who would choose in-school project jobs over possible employment alternatives, and those not currently in school who would return.

(2) Information Requested. Estimate, by the best available data, the number of youth who will seek entitlement jobs. Describe the estimation methodology.

(d) Schools in Entitlement Area.—(1) General. The pre-application shall describe the public and private secondary school systems attended by project eligible youth residing in the proposed Entitlement Area.

(2) Information Requested. For each public and private school system, provide:

(i) A description of the organization and administration of the secondary school system;

(ii) An identification of the proportion of the Entitlement Area's eligible secondary school population who are attending schools in the Entitlement Area;

(iii) A list of the names and addresses of the secondary schools (Grades 9-12) located in the Entitlement Area, and for each such secondary school:

(A) Identification of the most recent and reliable data on total pupil population, total pupil population of youths eligible for the Entitlement Project and school dropout rates. The information on dropout rates should be as detailed as possible and describe the method by which these rates were calculated;

(B) A description of current formalized workstudy, cooperative and special career-education programs, and the numbers enrolled; and

(C) A description of notable special programs already being undertaken for economically disadvantaged youth to promote retention in, return to, and completion of school, including alternative education and programs; and

(iv) One or more maps of the proposed Entitlement Area which are marked in order to clearly:

(A) Delineate the geographic boundaries for each school system in the Entitlement Area;

(B) Identify the street location of each public and private secondary school in that area; and

(C) Show the attendance zone for each public secondary school.

(e) Description of Existing Youth Programs. Each pre-application shall:

(1) Describe the prime sponsor's existing Part 677 programs for the 16-19 year-old youth population. The description should include funding levels and numbers of youth served for Fiscal Year 1978 and planned for Fiscal Year 1979.

(2) To the degree possible, also describe the programs to be funded and number of youth to be served under subparts A and B of this Part.

(3) Provide the best possible dollar estimates of CETA youth program operations in the Entitlement Area in Fiscal Year 1977 and the level in Fiscal Year 1978 not counting Entitlement funds.

(4) Describe how current CETA youth program will complement and be integrated with the Entitlement Project, and

(5) Describe any innovative or model program in the prime sponsor area which would indicate a unique capacity to fulfill responsibilities under the Entitlement Project.

(1) Innovative Approaches.—(1) General. Prime sponsors may test a variety of innovative employment and training approaches within the larger context of the Entitlement program. These approaches should not cover an entire Tier I project, of which the basic purpose is to test the Entitlement notion itself, but may be used as a component of Tier I projects. Tier II
projects should include one or more of the following innovative approaches:  
(A) The use of subsidies to private for-profit employers to encourage such employers to provide employment and training opportunities;  
(B) Arrangements with unions to enable eligible youth to enter into apprenticeship training as part of the employment entitlement;  
(C) Inclusion of economic disadvantages faced by the youth under the jurisdiction of the juvenile or criminal justice system with the approval of the appropriate authorities.  
(ii) The Department of Labor is especially interested in receiving proposals concerning the use of Entitlement funds to promote completion of high school by young unwed mothers.  
(iii) Prime sponsors may propose to undertake other innovative approaches provided adequate justification is provided in their pre-applications.  
(2) Information Requested. Pre-applications shall describe innovative approaches, identify how these will be implemented and administered, describe the area in which these would be implemented, and estimate the size of the eligible population that would be involved.  
(e) Project Organization and Administration.—(1) General. (i) Because of the size and complexity of the Entitlement Projects, a single governmental, private, nonprofit, or educational agency should be designated to assume overall management responsibility for program operations, including coordinating participant recruitment, site development, work-site development, and the relationships among schools, training activities and support services, program monitoring, report preparation, and maintenance of management information. The prime sponsor may delegate this responsibility.  
(ii) For the Entitlement Project, the entire youth participant payroll shall be centrally administered by the prime sponsor or its delegatee management agency. Finally, since this is a demonstration project, extensive research, monitoring, and evaluation must be carried out by the prime sponsor under the supervision of the Department of Labor.  
(2) Information Requested. (i) Identify the responsible management agency and describe its proposed staffing structure for the Entitlement Project, its previous experience with employment and training programs, its specific capabilities for managing the Entitlement Project, and, if other than the prime sponsor, its relationship to the prime sponsor.  
(ii) Indicate whether the prime sponsor or a prime sponsor will administer the payroll and explain the rationale for the choice.  
(iii) Indicate procedures which will be used for monitoring program operations.  
(iv) Provide an assurance from the prime sponsor that it will cooperate fully in the design, implementation, and evaluation of the Entitlement Project.  
(b) Recruitment.—(1) General. The "Entitlement" concept can only be meaningfully tested if eligible youth are aware of the program. Therefore, prime sponsors should provide information and do active outreach with respect to potential participants.  
(2) Information Requested. The procedures for informing, referring, recruiting, and determining eligibility of participants (both in-school and out-of-school) should be detailed, including identification of the private and/or public agencies to be utilized for this purpose. Particular reference should be made to the proposed role of the State Employment Service with respect to these functions. Special efforts shall be made to recruit youth from families receiving public assistance (Sec. 418(a)(4)(D)).  
(i) Work-Site Development.—(1) General. (i) The employment or combination of employment and training guaranteed under this program is intended to be year-round with no limitation on the period of enrollment. However, this guarantee shall not exceed 20 hours per week for each youth employed during the school year nor 40 hours per week during the summer. During the school year, the guarantee must be maintained for at least 6 months and during the summer for at least 8 weeks. This guarantee shall not be provided to each youth for less than 10 hours per week during the school year and not less than 30 hours per week during the summer. Prime sponsors may also allow youths to work 40 hours a week during school year break of 5 consecutive school days or more. However, the minimum paid program time guarantee does not apply to school year breaks of 5 consecutive days or more.  
(ii) The opportunities guaranteed may take any of the forms specified in Section 417 of the Act, and are guaranteed to an eligible youth only so long as the youth remains enrolled in high school or in a certified or approved high school equivalency program. Out-of-school youth must return to school or enter an equivalency program in order to be eligible for the employment guarantee.  
(iii) Based on estimates of the number of eligible youth who will seek employment in the Entitlement Project, the prime sponsor should plan for a larger number of jobs as a cushion in case the estimates are too low. The concept of an entitlement must be maintained; therefore, make work jobs for unexpected numbers of applicants not permissible. In Tier I projects, jobs must be primarily located in the Entitlement Area.  
(iv) Emphasis in work site development shall be placed on jobs having careful supervision and which provide youth with structured, productive work settings. Jobs shall be designed to introduce youth to the habits of work. Prime sponsors should make every effort to create new and different job classifications, occupations, and restructured jobs; (See 418(a)(3))  
(2) Information Requested. (i) The types and locations of jobs;  
(ii) What phase-in, if any, would be necessary.  
(iii) Anticipated work site (hiring and training projects) administration and supervisory structure for its role in Entitlement;  
(iv) Types of hiring agencies (government, nonprofit, education institution, private); and  
(v) Procedures to assure that restructured job proposals will be discussed with appropriate labor organizations for existing jobs.  
(j) Training Support Services.—(1) General. (i) The basic intent of Entitlement Projects is to provide employment, training and support services, however, may be provided. For the purpose of planning, it should be assumed that a participant will spend most of paid program time engaged in direct job performance at the worksite.  
(ii) Any training that is conducted during paid program time should be directly related to the participant's specific needs, and  
(iii) Participants are to be paid for time spent in training in accordance with § 676.26.  
(iv) Participants shall not be paid for time spent in supportive services (as defined in § 676.25(a)(3))  
(v) Prime sponsors are discouraged from paying for staff and overhead costs for training and support services out of Entitlement funds. Prime sponsors should use funds from other sources to cover these costs.  
(2) Information Requested. Identify and describe the nature and extent of any proposed training and services, how these will relate to the proposed jobs, and the organizations and funds that will provide them.  
(k) Entitlement Project-School Relationship. Each pre-application shall:  
(1) Describe planned cooperation between public and private secondary school system officials and the prime

**PROPOSED RULES**

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
PRPOSED RULES

13199

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979

sponsor. At a minimum, the application should include written statements from school officials indicating their agreement to:

1. Avoiding participant (including dropout) recruitment and eligibility determinations;

2. Cooperate in the ongoing monitoring of enrollment and academic and attendance requirements; and

3. Provide necessary information for effective project management and evaluation;

(2) Describe special procedures and actions that will be taken to facilitate the return of school dropouts.

(3) Identify with all agencies which offer high school equivalency programs and provide agreements comparable to those described above for school systems.

(i) Commitment of Local Institutions and Organizations.—(1) General

(i) Prime sponsors shall consult with the appropriate labor organizations in developing restructured and/or newly classified jobs during the pre-application stage.

(ii) Describe data systems reports, if applicable, the managing agency's previous experience in administering in-school employment programs and

prime sponsor management purposes, but which differ from the regular reports on program and financial performance required by the CETA regulations for CETA programs; indicate the frequency of their production.

(iii) Describe the currently operating data collection systems used by the secondary school systems in the proposed Entitlement Area with respect to student enrollment, attendance, performance and dropouts.

(n) Budget—(1) General. Costs shall be estimated for the period January 1978, through June 1979 (or the end of the 1978-79 school year, whichever comes first). Prime sponsors should commit funds available under other programs (in particular, funds under Titles II and IV of the Act) to the Entitlement Project.

(2) Information Requested. The pre-application shall specify separately the amount of Entitlement funds and non-Entitlement funds proposed to be used, broken down by the following cost categories:

(I) Administration:

(A) Personnel; and

(B) Nonpersonnel;

(ii) Allowances;

(iii) Wages:

(A) School year; and

(B) Summer;

(iv) Fringe benefits;

(v) Worksite supervisor salaries:

(A) School year; and

(B) Summer;

(vi) Worksites expenses:

(A) Equipment; and

(B) Supplies;

(vii) Training; and

(viii) Services

§630.308 Selection of final applicants.

(a) Pre-Application review criteria.

(I) The following basic criteria shall be used to evaluate both Tier I and Tier II pre-applications:

(i) Quality and thoroughness of documentation required by §630.307;

(ii) Managerial, administrative, operating, and fiscal capability of the prime sponsor and, if applicable, the designated management agency;

(iii) Level of commitment of other resources to the Entitlement Project, especially funds under Titles II and IV of the Act;

(iv) Degree to which the Entitlement project will be integrated with local educational career development, and employment and training programs for economically disadvantaged youth;

(v) Commitment of cooperation and participation from local school systems, labor organizations, and other local groups;

(vi) The prime sponsor's and, if applicable, the managing agency's previous experience in administering in-school employment programs and

career education and special programs for dropouts;

(vii) Proposed total cost, unit cost; and

(viii) Basis for data and ability to satisfy the data needs required by the research and demonstration character of the Entitlement program; and

(xi) Commitment of cooperation from appropriate local labor organizations, the private sector, and the State Employment Service. Arrangements should be made with all appropriate groups during the pre-application period to obtain their assistance in implementing the program.

(2) Information Requested. The pre-application should contain letters of intent to cooperate from appropriate labor organizations, government officials, the State Employment Service, and other local organizations, associations or agencies involved with the eligible youth population.

(c) Overall Collection System.—(1) General. It is anticipated that the national evaluation of Entitlement Projects will rely heavily on existing CETA and school system data collection systems. Effectively operating systems, therefore, are of great importance.

(2) Information Requested. (i) Describe the currently operating prime sponsor data collection and processing systems, indicating whether the system is automated or manual, the types and availability of information kept on individual participants, and the typical lag-time between a participant's enrollment or status change and the availability of that information in the data system.

(ii) Describe data system reports, if any, which may be appropriate for the Entitlement program that are used for

prime sponsor's past performances and cost structure; — and

(v) Commitment of other such factors designed to test the efficacy of a youth job entitlement in urban and rural variations, size and socio-economic and regional circumstances such as different unemployment rates, school dropout rates, urban and rural variations, size and other such factors designed to test the efficacy of a youth job entitlement in urban and rural variations and circumstances (Sec. 418(a)(11)). Pre-applicants not selected shall be notified in writing of their nonselection, the reasons therefor, and that further docu-
§ 680.309 Planning grants.

(a) The Assistant Secretary shall notify selected final applicants in writing of the reasons for their selection, emphasizing the particular experimental aspects of their pre-applications which the Assistant Secretary judged especially meritorious.

(b) The Assistant Secretary shall award planning grants to the final applicants so that they can develop their grant applications along the lines initially set out in the approved pre-application.

(c) If, at the time of the planning grant, or during the planning phase, the final applicant determines that it is unable to develop its final application along the authorized lines, the final applicant shall notify the Assistant Secretary in writing immediately.

§ 680.310 Final application process.

(a) Every final application shall contain, in detail the information required by §§ 680.311-680.314.

(b) Only those prime sponsors which are selected to receive planning grants under § 680.309 shall be eligible to submit final applications.

§ 680.311 Program operation-related documentation.

Each final application shall include the following items:

(a) Descriptions of all additions, changes, and clarifications to the materials submitted in the preapplications, especially those materials requested by ETA as a result of its review of the preapplication;

(b) Descriptions of which of the following groups of youth will be considered by the prime sponsor to “reside” in the Entitlement Area and therefore be eligible (if otherwise eligible) for program participation;

(1) Youths confined in prisons or other correctional institutions in the area;

(2) Youths in area hospitals, drug rehabilitation centers, half-way houses, etc.; and

(c) How the enrollment eligibility criteria and procedures will be applied to any of these or other groups of youth in institutional “residences” selected to be included in the program. Each such institutional “residence” included in the program shall be listed and briefly described;

(d) The procedures for verification and revalidation of eligibility criteria and the method by which these will be implemented, and how the eligibility criteria and verification procedures will be explained to participants at the time of enrollment;

(e) Proposed policies for defining good cause for the rejection of a job or other nonparticipation by a participant; proposed procedures and timetables for making another job offer in such cases; and proposed procedures for the resolution of grievances;

(f) In detail, proposed standards for determining satisfactory performance, including policies on attendance and lateness on the job or at training, suspension and termination policies and procedures; and the procedures and staff responsibilities for monitoring program performance;

(g) Agreements obtained from participating schools and high school equivalency (GED) programs indicating their willingness to provide a monthly status report for each participant certifying the participant’s compliance or noncompliance with the school’s or GED program’s minimum academic and attendance requirements, including, from each participating secondary school or GED program a description of the standards and policies for determining its minimum academic and attendance requirements;

(h) All worksites, proposed wages, and proposed employment and training opportunities;

(i) Proposed procedures for complying with the Family Education Rights and Privacy Act; include agreements with school systems with respect to this item; and

(j) (1) Payroll, audit, and other fiscal procedures;

(2) The current prime sponsor accounting and reporting system, with attention to the requirements of this subpart; and the current system for allocating personnel charges to multiple funding sources;

(3) The system used to requisition for periodic advances or reimbursements for existing DOL funded programs. If the system is a Letter of Credit, indicate the average number and amounts of cash requests for the last 6 months; and

(4) The fiscal organization and staffing, internal controls, and other procedures for fiscal integrity and accountability. Attach:

(i) A copy of any Management Agency’s last certified Financial Statement;

(ii) A copy of the last DOL audit, of the Prime Sponsor along with response and further documentation regarding the outcome of open items; and

(iii) Copies of payroll accounting, and financial forms relevant to the Entitlement program.

§ 680.312 Program budget: Estimated costs.

Each final application shall describe program expenses whether proposed to be paid from Entitlement, other CETA, or other funds in sufficient detail and with sufficient justification to show the basis and rationale for the estimates and calculations. All budgetary material shall be organized by four categories of expense: Program Management, Participant Costs (wages and allowances), Work Site Supervision and Expenses, and Training. Each of these major categories shall be subdivided into personnel and nonpersonnel costs. With respect to each major category and subcategory, the final application shall indicate which of the estimated costs are to be paid directly by the Prime Sponsor or its designee management agency, and which are to be paid under agreements with subcontractors and vendors.

§ 680.313 Agreements.

Each final application shall include all agreements which the prime sponsor has entered into for the purpose of the Entitlement program. These agreements shall include:

(a) All grant agreements entered into pursuant to § 680.109(a); (b) An agreement with the State Employment Service agency;

(c) Agreements with every public, private nonprofit, and private-for-profit school in the Entitlement project area which is attended by eligible youths, and, to the extent feasible and appropriate, with every such school outside the Entitlement Project area which eligible youths from the Entitlement Project area attend;

(d) Agreements with all agencies, schools, and institutions in the Entitlement Project area which will offer, under the program, courses which result in a certificate of high school equivalency, and to the extent possible and appropriate, with similar entities outside the Entitlement Project area which are open to eligible youths from the Entitlement Project area;

(e) All on-the-job training, employment guarantee, and grant agreements entered into with private nonprofit and for-profit employers;

(f) Any agreements with unions with respect to apprenticeship training; and

(g) Any other agreements entered into in order to run the Entitlement program.

§ 680.314 Assurances and certifications.

Each application shall contain an assurance that the prime sponsor, in operating its Entitlement Project, will comply with the Master Plan including Assurances and Certifications in the Master Plan and with the following additional assurances:

(a) Compliance with Title IV, Part A; subpart 1 of the Act with other applicable provisions of the Act, and
with the regulations in this subpart; and

(b) Compliance with the Hazardous Occupations Orders issued pursuant to the Fair Labor Standards Act and set forth at 29 CFR 570.50 et seq., with respect to the employment of youths under 18 years of age.

§ 680.315 Review of final applications; Selection of Projects.

(a) The review of final applications will take into account the requirements of sec. 418(a)(1) of the Act that prime sponsors selected to operate Entitlement projects be “from areas with differing socioeconomic and regional circumstances such as differing unemployment rates, school dropout rates, urban and rural variations, size, and other such factors * * *”.

(b)(1) To implement sec. 418(a)(1), the Tier I final applications shall be separated into three classifications:

(i) Classification No. 1—Metropolitan cities where the Entitlement Area encompasses only a portion of one or more local political jurisdictions (units of general local government)

(ii) Classification No. 2—Non-metropolitan areas (primarily rural areas) where the Entitlement Area encompasses a number of complete local political jurisdictions (units of general local government)

(iii) Classification No. 3—Metropolitan cities or counties where the Entitlement Area encompasses one or more complete local political jurisdictions (units of general local government).

(2) Each Tier I final application shall be reviewed only in competition with others within its classification. Within each classification, each application will be ranked against the others in the classification with respect to each of the Tier I project criteria described in paragraph (d) of this section.

A composite of the separate rankings with respect to each criterion shall be used to determine the final overall ranking of applications in each classification.

(c) Overall ranking will be made of all Tier II final applications using the Tier II project criteria described in paragraph (d) of this section.

(d) Final applications shall be reviewed against the following criteria. The first four criteria, equally weighted, shall be used to review Tier I projects. All five criteria, equally weighted, shall be used to review Tier II projects.

Management capability, feasibility and commitment. This criterion will take into account:

(i) Managerial, administrative, and operating capability of the designated management agency;

(ii) Operational and management feasibility of the proposed Entitlement Area;

(iii) Commitment of cooperation and participation from local schools, GED programs, labor organizations, and other interested local groups.

(2) Operational plans. This criterion will take into account:

(i) Prime sponsor’s estimated youth participation rate and plans for recruiting the eligible population, including procedures for verifying eligibility criteria;

(ii) Nature and quality of worksites, including proposed supervisory structure;

(iii) Procedures for review, control, and coordination of all operational components.

Financial system and program data system quality and commitment. This criterion will take into account:

(i) Quality of procedures and systems to be used to comply with pay-roll, fiscal and accounting requirements;

(ii) Commitment and ability to satisfy data collection and reporting needs required by the research demonstration character of the Entitlement program.

(iii) Quality of budget and resources commitment. This criterion will take into account:

(i) Analysis of proposed budget in terms of total cost, unit cost, and cost structure;

(ii) Level and nature of commitment of other local resources to the program, including the degree to which the Entitlement program will be integrated with existing local programs.

Innovative features. This criterion will take into account the quality and feasibility of the innovative approaches of the Tier II Entitlement projects.

(e) Each ETA regional office shall review the final applications submitted by prime sponsors in its region to identify (1) any inaccuracies in estimates concerning planned use of other local funding resources, and (2) any mistakes of fact.

(f) The Assistant Secretary for Employment and Training may utilize a review panel to consider the Tier I and Tier II final applications, the results of onsite reviews and regional office assessments. If a panel is used, the panel shall provide rankings to the Department of Labor as described in this section, and shall make Entitlement project recommendations to the Assistant Secretary based on these rankings and the requirements of sec. 418(a)(1) of the Act.

(g) The Assistant Secretary has made final selection of the Entitlement projects as of January 10, 1978, based on the specifications set forth in paragraphs (a), (b), (c), (d), and (e) of this section and on the recommendations of the panel. Final Tier I selections will include not more than two Classification No. 1 areas, one Classification No. 2 area, and two or three (depending on available resources) Classification No. 3 areas as described in paragraph (b) of this section. The number of final Tier II selections has depended on the cost of selected projects in relation to the available resources. Applicants shall be notified in writing of their selection. Those who will have not been selected shall also be notified and justification for nonselection will be available upon request.

§ 680.316 Eligibility of participants.

(a) Every youth who resides in the geographic area of the Entitlement Project shall be entitled to participate in the program provided that, at the time of application and selection, the youth provides documented evidence which shows that:

(1) The youth is aged 16-19 inclusive, unless the Department has authorized the prime sponsor to administer an Entitlement Project for youths between 19 and 25 years of age;

(2) The youth has not received a high school diploma or certificate of high school equivalency;

(3) The youth has resided in the Entitlement Project area for 30 days. Newly discharged veterans however, are exempt from the 30 day residency requirement;

(4) The youth is economically disadvantaged. For purposes of this subpart, economically disadvantaged shall mean that the youth:

(i) Either constitutes a family of one, or is a member of a family;

(ii) And receives cash welfare payments under a Federal, State or local program, or whose income is at or below the poverty level as determined by the Office of Management and Budget (OMB).

For the purposes of this paragraph, a “family” is as defined in § 675.4 of this title, and the term “family income” is as defined in § 675.40 of this title. Family income shall be computed pursuant to § 675.4 of this title except that earnings received by a youth under Title IV shall be disregarded in computing family income. In the case of newly discharged veterans, income received while in military service shall be disregarded in computing family income.

(5) The youth is:

(i) Enrolled in and attending a State-certified secondary school program leading to a high school diploma, or enrolled in such a program scheduled to begin within 30 days of the Youth’s Entitlement program enrollment; or

(ii) Enrolled in and attending a certified or approved program leading to a certificate of high school equivalency.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
PROPOSED RULES

(GED), or enrolled in such a program scheduled to begin within 30 days of the Youth's Entitlement program enrollment.

(b) If the youth is under the juvenile or criminal justice system, the appropriate authorities must approve the youth's participation or continued participation in writing.

(c) The citizenship provisions of § 676.3(b) of this title shall apply to the Entitlement program.

(d) (1) No otherwise eligible youth shall be excluded from participation because of any mental or physical handicap unless a qualified physician or psychologist certifies that the youth is mentally or physically incapable of obtaining a high school diploma or certificate of high school equivalency.

(2) All otherwise eligible mentally or physically handicapped youths who are not certified as provided in paragraph (d)(1) of this section, are entitled to participate in the program. The prime sponsor must take every step necessary to insure that such youths can participate. The prime sponsor may not segregate such youths from regular program activities, but must redesign these activities to ensure participation.

(e) Section 418(a)(4)(I) of the Act prohibits a youth from taking a job under this subpart if his or her relative has responsibility for hiring persons into that job. Therefore, prime sponsors shall assure that eligible youths are not placed in jobs by their relatives.

(f) Since jobs during the school year must last at least 6 months, and jobs in the summer must last at least 8 weeks, no youth may be enrolled in the program if the grant will end before the youth can complete the required period of employment unless there are sufficient funds to maintain that youth for the minimum guaranteed period of employment.

(g) A participant reaching 20 years of age while in the program may remain in the program only until the participant completes either 8 weeks of full-time summer employment or 6 months part-time school-year employment. If upon reaching the 20th birthday the participant has already completed either 8 weeks of full-time summer employment or 6 months of part-time school-year employment, the participant shall be immediately terminated from the program. For projects that are serving youth 19-25, this requirement applies to youth reaching 25 years of age.

(h) A participant must continue to be economically disadvantaged as defined in § 680.316(a)(4) and to reside within the Entitlement Area or be terminated from the program. The prime sponsor shall re-verify participant economically disadvantaged status and residency between the seventh and twelfth month following enrollment and annually thereafter. In re-verifying economically disadvantaged status, however, wages and allowances received under the Entitlement program shall not be included when computing family income.

(i) A participant must meet minimum academic and attendance requirements of the secondary school or high school equivalency program in which the participant is enrolled or be terminated from the Entitlement program. The secondary school or GED program must provide monthly assurances that the participant is meeting minimum academic and attendance requirements.

(j) A participant who receives a high school diploma or a certificate of high school equivalency while in the program may remain in the program until the completion of either 8 weeks of full-time summer employment or 6 months of part-time school-year employment.

(k) A participant who has been found by the prime sponsor, after notice and an opportunity for a hearing, to be otherwise refusing to participate in the program without good cause, shall be terminated from the program. The participant shall be given a termination notice which states that the participant may appeal the termination to the appropriate ETA regional office. Upon receipt of such an appeal the regional office shall process it as a complaint pursuant to Part 676.

(l) Except as provided below, any participant who has been terminated from the Entitlement program may re-enroll at any time provided the participant meets the eligibility criteria in this section. Participants who have been terminated for failure to participate without good cause must wait 60 days before they apply for re-enrollment. Re-enrollment of such participant after the 60 day period shall be subject to the discretion of the prime sponsor, based on the determination that the participant will properly participate.

§ 680.317 Work sites.

(a) Work sites shall:

(1) Not detract from or interfere with the educational curriculum of the participants and, whenever possible, shall complement that curriculum;

(2) Be primarily in the Entitlement Area or easily accessible, and in reasonable proximity to the residences of eligible youth;

(3) Be developed and committed in such a manner as to minimize the time between enrollment and assignment to a work site of any participant.

(b) Participants shall spend a majority of paid program time on the work site engaged in direct job performance. Training may be provided during the remaining time, provided the training is directly related to the specific work assignment.

§ 680.318 Allowable activities.

The Entitlement project may include any type of employment or training activity authorized under Title II, Part B of the Act.

§ 680.319 Participant benefits.

(a) The wage provisions of § 680.10 shall apply to the Entitlement program. In addition:

(1) In Entitlement projects in which employment with private-for-profit employers is authorized, up to 100 percent of the wages may be paid. (i) However, in such cases, prime sponsors must submit acceptable plans for reducing the level of wage subsidy over the period of participation of the participant.

(2) No additional payments shall be provided by the Entitlement program to any such for-profit organization.

(b) In the case of participants working at jobs and/or engaged in training provided by private-for-profit organizations wages (and/or allowances) shall be paid, as in all cases, by the central payroll facility required by § 680.307(g)(1)(d).

(c) Each participant shall spend the majority of his/her paid time in the Entitlement program in either work or training which is directly related to the assignment. Consequently, participants should be paid wages for both work time and training time, except when more than 50 percent of scheduled program time is spent in training. In such cases, allowances shall be paid in accordance with § 676.26 for the period spent in training.

(b) No funds under the Entitlement program may be used for retirement benefits or costs.

§ 680.320 Academic credit.

Prime sponsors shall make appropriate efforts to encourage educational agencies to award academic credit for the competencies participants gain in the Entitlement program.

§ 680.321 Disregarding earnings.

The provisions of § 680.11 of this Part shall apply to the Entitlement program (Sec. 446).
§ 680.322 Maintenance of effort.

The provisions of §§ 680.12 and 680.13 shall apply to the Entitlement program.

§ 680.323 Administrative provisions; hearing provisions; and limitations on use of funds.

(a) All the provisions of Part 676 of this title shall apply to the Entitlement program except to the extent they conflict with the regulations in this subpart.

(b) To the extent that the research, demonstration, and informational requirements of this subpart conflict with the regulations contained in Part 676, the regulations in this subpart shall prevail. In order to determine whether a conflict exists, grantees shall consider both the regulations in this subpart and the terms of the Entitlement grants which implement the regulations in this subpart. For example, the regulations throughout this subpart contain requirements that the grantee submit detailed information not required by the regulations in Part 676. Because of the research and demonstration nature of the Entitlement program such information is essential. As a result, the Entitlement grants, which implement the regulations contained in this subpart, contain reporting and other requirements which are both different from and more detailed than those in Part 676. In such cases, the grantees shall follow the Entitlement grant requirements. Other specific examples of such conflicts are as follows:

(1) Since under the regulations in this subpart, the Entitlement program is administered by the national office the terms regional office and Regional Administrator in Part 676 mean for purposes of this subpart national office and Grant Officer respectively; and

(2) To the extent that Entitlement grants require the use of categories for allocating costs for reporting purposes which are different from or more detailed than the allocable cost categories in § 676.41, the grantee shall allocate costs pursuant to the categories in the Entitlement grant.

(c) Questions regarding the applicability of specific provisions of Part 676 which may appear to conflict with the regulations or grant shall be addressed to the Grant Officer.

(d) No funds under the Entitlement program may be used to pay for time spent in the Entitlement program in excess of 20 hours a week during the school year or 40 hours per week during the summer. The minimum paid program time guaranteed for each employed youth shall be 10 hours per week during the school year and 30 hours per week during the summer. Prime sponsors may also allow youths to work 40 hours a week during school year breaks of 5 consecutive school days or more. However, the minimum paid program guarantee does not apply to school year breaks of 5 consecutive school year days or more.

(e) Prime sponsors may use program funds under both Title II and Title IV, Part C of the Act for the Entitlement Project. Funds under Title IV, Part A, Subparts 2 and 3 of the Act may also be used provided modifications are obtained for those grants. Funds received under Title IV, Part C shall be integrated with funds received under this Subpart. Therefore, the regulations under this subpart shall apply to such funds. Title II funds and other Title IV funds, however, may not be integrated, but must be separately accounted for. The regulations appropriate to each program shall apply to such funds when conflicts occur between those regulations and the Entitlement regulations. Thus, for example, Entitlement Project wages and allowances paid for with Title II funds, shall be paid at the wage rates and allowance rates set forth in the Title I regulations.

Signed at Washington, D.C. the 1st day of March 1979.

RAY MARSHALL,
Secretary of Labor.

[FR Doc. 79-6538 Filed 3-8-79; 8:45 am]
DEPARTMENT OF LABOR
Employment Standards Administration

MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION
General Wage Determination Decisions
NOTICES

MODIFICATIONS AND SUPERSEDEAS DECISIONS TO GENERAL WAGE DETERMINATION DECISIONS

This is to advise all interested parties that the Department of Labor intends to withdraw 30 days from the date of this notice the following General Wage Determinations applicable to Residential Constructions consisting of single family homes and garden type apartments up to and including 4 stories: TX77-4027-Brazoria, Fort Bend, Galveston, Harris, Matagorda, Montgomery & Walker Counties, dated February 18, 1977 in 42 FR 10276; TX78-4029-Armstrong, Carson, Castro, Childress, Collingsworth, Dallam, Deaf Smith, Donley, Gray, Hansford, Hartley, Hemphill, Hutchinson, Lipscomb, Moore, Ochiltree, Oldham, Potter, Randall, Roberts, Sherman, Swisher and Wheeler Cos., Texas, dated April 14, 1978 in 43 FR 16113; TX79-4012-Bastrop, Blanco, Caldwell, Fayette, Hays, Lee, Travis, & Williamson Cos., Texas, dated January 5, 1979 in 44 FR 1085; TX79-4013-Tarrant County, Texas, dated January 5, 1979 in 44 FR 1086.

Signed at Washington, D.C. this 2nd day of March 1979.

DOROTHY P. COME,
Assistant Administrator,
Wage and Hour Division.
### NOTICES

#### DECISION #AL79-1001 - Mod. #1
(44 FR 5601 - January 26, 1979)
Statewide Alabama

**CHANGE:**

<table>
<thead>
<tr>
<th><strong>Electrical</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone 1</td>
</tr>
<tr>
<td>Zone 2</td>
</tr>
</tbody>
</table>

**FOOTNOTE:**
- Plus fringe benefits of 3.5% Health and Welfare, 3% 40 Pension and 5% Apprentice training

#### DECISION #AL79-1015 - Mod. #1
(44 FR 6653 - February 2, 1979)
Hudson County, Alabama

**CHANGE:**

<table>
<thead>
<tr>
<th>Laborers</th>
<th>$5.55</th>
<th>.35</th>
<th>.50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laborers, Mason tenders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Air tool op. (jackhammer, vibrators), mortar mixer</td>
<td>5.80</td>
<td>.35</td>
<td>.50</td>
</tr>
</tbody>
</table>

#### DECISION #G379-5100 - Mod. #2
(43 FR 8482 - February 9, 1979)
Statewide Arizona

**Changes:**

| Elevator Constructors          | $12.05 | .895 | .69  | 3% + a | .03 |
| Elevator Constructors' Helpers | 9 695  | 895  | 69   | 3% + a | .03 |
| Elevator Constructors' Helpers (Prob.) | 6 925  |      |      |        |    |
| Ironworkers                    |        |      |      |        |    |
| Central and Southern Areas     | 12.30  | 1.34 | 2.47 |        |    |
| Northern Area                  | 14.43  | 1.34 | 2.47 |        |    |

**Tucson and Yuma Areas:**

<table>
<thead>
<tr>
<th>Zone At 0-30 miles from Stone and Congress in Tucson and from the County Courthouse in Yuma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brush</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Zone A</td>
</tr>
<tr>
<td>Zone B</td>
</tr>
</tbody>
</table>

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
### DECISION #A379-5100 (Cont'd)

#### Change (Cont'd):

<table>
<thead>
<tr>
<th>Painters (Cont'd): Tucson and Yuma Areas (Cont'd)</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone B (Cont'd):</td>
<td>Basic Hourly Rates</td>
</tr>
<tr>
<td>Swing Stage, over 40 ft</td>
<td>Brush</td>
</tr>
<tr>
<td></td>
<td>Spray</td>
</tr>
<tr>
<td></td>
<td>Structural Steel and</td>
</tr>
<tr>
<td></td>
<td>Tanks:</td>
</tr>
<tr>
<td></td>
<td>Brush</td>
</tr>
<tr>
<td></td>
<td>Spray and Sandblaster</td>
</tr>
<tr>
<td>Zone D: 51 miles and</td>
<td></td>
</tr>
<tr>
<td>from Tucson and from</td>
<td></td>
</tr>
<tr>
<td>Yuma:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Brush</td>
</tr>
<tr>
<td></td>
<td>Spray</td>
</tr>
<tr>
<td></td>
<td>Swing Stage, under 40 ft</td>
</tr>
<tr>
<td></td>
<td>Brush</td>
</tr>
<tr>
<td></td>
<td>Spray</td>
</tr>
<tr>
<td></td>
<td>Structural Steel and</td>
</tr>
<tr>
<td></td>
<td>Tanks:</td>
</tr>
<tr>
<td></td>
<td>Brush</td>
</tr>
<tr>
<td></td>
<td>Spray and Sandblaster</td>
</tr>
</tbody>
</table>

#### Tucson and Yuma Areas (Cont'd)

| Zone D (Cont'd):        | Basic Hourly Rates       | H & W | Pensions | Vacation | Education and/or Appr Tr |
| Swing Stage, over 40 ft | Brush                    | $12.46| 67       | 40       | 06       |
|                         | Spray                    | 12.96 | 67       | 40       | 06       |
|                         | Structural Steel and     |       |          |          |          |
|                         | Tanks:                   |       |          |          |          |
|                         | Brush                    | 12.71 | 67       | 40       | 06       |
|                         | Spray and Sandblaster    | 12.21 | 67       | 40       | 06       |

### DECISION No. DF78-3080 - Mod. 92

(42 FR 51267 - November 3, 1976)

State of Delaware

### Add:

<table>
<thead>
<tr>
<th>Line Construction (Railroad Only)</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linemen</td>
<td>10.82</td>
<td>45</td>
<td>3%</td>
<td>a</td>
<td>75%</td>
</tr>
<tr>
<td>&quot;y&quot; Equipment Operator</td>
<td>10.82</td>
<td>45</td>
<td>3%</td>
<td>a</td>
<td>75%</td>
</tr>
<tr>
<td>&quot;y&quot; Equipment Operator</td>
<td>9.47</td>
<td>45</td>
<td>3%</td>
<td>a</td>
<td>75%</td>
</tr>
</tbody>
</table>

### Paving and Incidental Grading Payments

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefit Payments</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
</tr>
<tr>
<td>Electricians</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paving and Incidental Grading (District of Columbia only)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asphalt Shoveler</td>
<td>11 70</td>
<td>70</td>
</tr>
<tr>
<td>Asphalt Raker</td>
<td>7 30</td>
<td>32</td>
</tr>
<tr>
<td>Asphalt Tamper</td>
<td>7 50</td>
<td>32</td>
</tr>
<tr>
<td>Cement Masons</td>
<td>7 60</td>
<td>32</td>
</tr>
<tr>
<td>Concrete Saw Operators</td>
<td>7 50</td>
<td>32</td>
</tr>
<tr>
<td>Concrete Shoveler</td>
<td>7 40</td>
<td>32</td>
</tr>
<tr>
<td>Form Setter</td>
<td>7 75</td>
<td>32</td>
</tr>
<tr>
<td>Laborer</td>
<td>7 25</td>
<td>32</td>
</tr>
<tr>
<td>Jackhammer</td>
<td>7 45</td>
<td>32</td>
</tr>
<tr>
<td>Hand Burner Operator</td>
<td>7 40</td>
<td>32</td>
</tr>
<tr>
<td>Power Equipment Operators:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Concrete Spreader Operator, Finishing Machine, Roller, (tough), Compressor, Rubber-tired Loader (1/4 cu yds or less)</td>
<td>7 30</td>
<td>27</td>
</tr>
<tr>
<td>Asphalt Plant Mixer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loader Operator Tanks (5 cu yds or less), Burner Planer, Bulldozer, Mechanic or Welder, Rubber-tired Loader (over 1/4 cu yds)</td>
<td>7 70</td>
<td>27</td>
</tr>
<tr>
<td>Asphalt Spreader, Hydraulic Backhoe (1 cu yd or less)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asphalt Plant Engineer, Asphalt Roller Operator, Concrete Breaker (machine)</td>
<td>7 75</td>
<td>27</td>
</tr>
<tr>
<td>Crane Operator, Concrete Paving Operator</td>
<td>7 90</td>
<td>27</td>
</tr>
<tr>
<td>Shovel Operator</td>
<td>8 00</td>
<td>27</td>
</tr>
<tr>
<td>Grader Operator (1/4 cu yds or less), Motor Grader, Operator Tracks (over 24 cu. yds)</td>
<td>8 65</td>
<td>.27</td>
</tr>
<tr>
<td>C-1000 Grader Operator (over 1/4 cu yds)</td>
<td>8 90</td>
<td>.27</td>
</tr>
</tbody>
</table>

### Tractor Drivers Payments

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefit Payments</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
</tr>
<tr>
<td>Power Broom, Oilier</td>
<td>7 40</td>
<td>27</td>
</tr>
<tr>
<td>Sand Setter</td>
<td>7 70</td>
<td>27</td>
</tr>
<tr>
<td>Truck Drivers:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Truck Drivers (standard)</td>
<td>7 25</td>
<td>27</td>
</tr>
<tr>
<td>Tandem</td>
<td>7 37</td>
<td>27</td>
</tr>
<tr>
<td>Tractor trailer (capable of moving heavy equipment)</td>
<td>7 50</td>
<td>27</td>
</tr>
</tbody>
</table>

### Decision #1075-1080

MODIFICATIONS P 7

(Decision #78-2160-Mod. #1)

ILL-1-PEO-1-2-3

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions*</th>
<th>Vacation</th>
<th>Education and/or Approx Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>CLASS I</td>
<td>$12.40</td>
<td>.75</td>
<td>.75</td>
<td>08</td>
</tr>
<tr>
<td>CLASS II</td>
<td>12.30</td>
<td>.75</td>
<td>.75</td>
<td>08</td>
</tr>
<tr>
<td>CLASS III</td>
<td>12.10</td>
<td>.75</td>
<td>.75</td>
<td>08</td>
</tr>
<tr>
<td>CLASS IV</td>
<td>8.00</td>
<td>.75</td>
<td></td>
<td>1.08</td>
</tr>
</tbody>
</table>

**POWER EQUIPMENT OPERATORS:**

**CLASS I - Master Mechanic**

**CLASS II - Utility Operator**

**CLASS III - Power Cranes, Draglines, Derricks, Shovels, Graders, Mechanics, Concrete Mixers with Skip, Tournanixor, Two Drum Machine, One Drum Hoses, Tower or Boom, Cableways, Tower Machines, Hoist Patrol, Boom Crane, Boom or Mover Truck, Winch or Hydraulic Boom Truck, Truck Crane, Tournaspli, Tractor Operating Scoops, Bulldozer, Push Tractor, Asphalt Planer, Finishing Machine on Asphalt, Large Rollers on Earth, Rollers on Asphalt Mix, Ross Carvings or similar Machine, Gravel Processing Machine, Asphalt Plant Engineer, Paver Operator, Farm Tractor with half yard Bucker and/or Backhoe Attachment, Dredging Equipment or Dredge Operator, Central Mix Plant Engineer, CD or similar type machine, Concrete Pump, Truck or Skid Mounted, Tower Crane, Engine or Rock Crusher Plant, Concrete Plant Engineer, Ditching Machine with dual attachment, Tractor-Mounted Loaders, Cherry Picker, Hydraulic Crane, Standard or Dinko Locomotives, Scoopmobiles, Rodi Loaders, Soil Cement Machine, Back Filler, Elevating Machine, Power Blade, Drilling Machines, Inc., Weld Testing, Caisson, Shaft or any similar type drilling machines, Motor Driven Paint Machine, Pipe Cleaning Machine, Pipe Wrapping Machine, Pipe Bending Machine, Airco Paver, Boring Machine, (Oleo Equipment Greaser), Barber-Crome Loaders, Formless Fuser, (Bell Point System), Concrete Spreader, Hydra Ax, Rosco Concrete Saw, Marine Scoops, Brush Barber, Brush Barrier, Brush Planer, Tree Mover, Helicopter Crew (3), Piledriver - Skid or Crawler, Stump Remover, Root Rake, Tug Boat Operator, Refrigerating Machine, Freezing Operator, Chair Cart - Self-Propelled, Hydra Seeder, Draw Blower, Power Sub Grader, Roll Float, Finishing Machine, Self-Propelled Pavement Breaker (Backhoe attached), Lilt (or similar type machine), Two Air Compressors, Compressors hooked in Manifold, Overhead Crane, Chip Spreader, Mud Cat, Sull-Air

**CLASS IV - Concrete Mixers without Skips, Rock Crusher, Ditching Machine under $5, Curbing Machine, One Drum Machines without Tower or Boom, Air Tugger, Self-Propelled Concrete Saw, Machine Mounted Post Hole Digger, two to four Generators, Water Pumps, or Welding Machines, within 400 feet, Air Compressor 600 cu. ft and under, Rollers on Aggregate and Seal Coat Surfaces, Fork Lift, Concrete and Blacktop Curb Machine, Farm Tractor with less than half yard Bucket, One Water Pump, Oilers, Air Valves or Steam Valves, One Welding Machine, Truck Jack, Hub Jack, Gunite Machine, House Elevators when used for hoisting Material, Engine Tenders, Fireman, Wagon Drill, Flex Plane, Conveyor, Scraper, Filter and Pulsation, Switchman, Fireman on Pile Pots, Fireman on Asphalt Plants, Distributor Operator on Trucks, Tamper, Self-Propelled Power Broom, Stripping Machine (motor driven), Form Tamper, Seaman Tiller, Bulk Cement Plant Equipment Greaser, Deck hands, Truck Crane, Oiler Driver, Cement Blimp, Form Grader, Temporary Heat, Throttle Valve, Farm Tractor

NOTICES

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
MODIFICATIONS P. 9

DECISION 69A72-6001 - Mod. 53
(44 FR 1634 - January 5, 1979)
Statewide Louisiana

Changes:
Carpenters (Building Construction):
Zone 10 - Carpenters & soft floor layers 9.00 .60 .35 .05
Millwrights 10.90 .60 .35 .05
Pile drivers 10.50 .60 .35 .05
Electricians:
Zone 4 - Electricians 12.35 70 .3% 2/10%
Cable splicers 12.35 70 .3% 2/10%
Zone 8 - Electricians 12.35 3% 1/2%
Cable splicers 12.60 3% 1/2%
Elevator Constructors:
Zone 1 - Mechanics 10.27 .765 56 4%/4b .025
Helpers 705JR .765 56 4%/4b .025
Helpers (Prob.) 505JR
Zone 2 - Mechanics 10.025 .895 69 4%/4b .035
Helpers 705JR .895 69 4%/4b .035
Helpers (Prob.) 505JR
Line Construction:
Zone 4:
Linemen, Equipment Operators 12.35 70 .3% 1/2%
Groundmen 505JR .70 .3%
Zone 5:
Linemen & equipment operators 12.35 3% 1/2%
Groundmen 607JR 3% 1/2%

DECISION 69A79-6002 - Mod. 42
(44 FR 1650 - January 5, 1979)
Bossier, Caddo & Calcasieu Parishes, Louisiana

Changes:
Elevator Constructors:
Bossier & Caddo Parishes:
Mechanics 10.025 .895 .69 4%/4b .035
Helpers 705JR .895 .69 4%/4b .035
Helpers (Prob. 505JR
Calcasieu Parish:
Mechanics 10.27 .745 .56 4%/4b .025
Helpers 705JR .745 .56 4%/4b .025
Helpers (Prob.) 505JR

Fringe Benefits Payments

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/ or Appr Tr</th>
</tr>
</thead>
</table>

DECISION 69J38-5129 - Mod. 59
(43 FR 50744 - October 17, 1978)
Washoe County, Nevada

Changes:
Elevator Constructors 8.16 70 .75 .02
Elevator Constructors Help 11.46 895 .69 3% + a .03
Elevator Constructors Help (Prob.) 8.15
Painters:
Brush and Roller 13.43 70 .75 .02
Brush - swing stage, up to 40 ft; Brush - steel?
Sandalst 13.70 70 .75 .02
Spray Tower Painters 13.95 70 .75 .02
Spray - swing stage, up to 40 ft; Spray - steel
Refriger 14.20 70 .75 .02

Add:
Line Construction (Railroad Only)
Linemen 10.74 7% 7% 3/4%
Lineman 10.72 7% 7% 3/4%
Groundmen 6.68 7% 7% 3/4%

Add:
Hunterson, Middlesex, Somerset, Union (up to Wack Ave south of Cranford) and Warren Counties from Zone 1 for Truck Drivers

Add:
Truck Drivers:
Boscowon, Middlesex, Somerset, Union (up to Wack Ave south of Cranford), and Warren Counties (Classification Definitions are as listed on page 20 of the above referenced decision.)

Group 1 9.12 88 975 1k
Group 2 9.35 88 975 1k
Group 3 9.40 88 975 1k
Group 4 9.50 88 975 1k
Group 5 9.60 88 975 1k

FEDERAL REGISTER, VOL. 44, NO. 48-FRIDAY, MARCH 9, 1979

13211
**NOTICES**

**DECISION FN78-3047 - Mod. #3**
(63 FR 26235 - June 16, 1978)
Atlantic City, Burlington, Camden, Cape May, Cumberland, Gloucester, Mercer, Monmouth, Ocean, and Salem Counties, New Jersey

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
</tr>
<tr>
<td>Line Construction - Railroad only</td>
<td>Line Construction - Railroad only</td>
</tr>
<tr>
<td>Lineman</td>
<td>10</td>
</tr>
<tr>
<td>Groundman</td>
<td>6.60</td>
</tr>
</tbody>
</table>

**Change:**

<table>
<thead>
<tr>
<th>Truck Drivers:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone 3</td>
</tr>
<tr>
<td>Group 1</td>
</tr>
<tr>
<td>Group 2</td>
</tr>
<tr>
<td>Group 3</td>
</tr>
<tr>
<td>Group 4</td>
</tr>
<tr>
<td>Group 5</td>
</tr>
</tbody>
</table>

**DECISION FPN78-3054 - Mod. #2**
(63 FR 35868 - August 11, 1978)
Bucks, Chester, Delaware, Montgomery and Philadelphia Counties, Pennsylvania

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
</tr>
<tr>
<td>Lineman</td>
<td>10.94</td>
</tr>
<tr>
<td>&quot;A&quot; equipment operator</td>
<td></td>
</tr>
<tr>
<td>&quot;B&quot; equipment operator</td>
<td></td>
</tr>
<tr>
<td>Footnote: d. Paid Holidays: New Year's Day, Decoration Day; Independence Day; Labor Day; Thanksgiving Day; Christmas Day and Good Friday</td>
<td></td>
</tr>
</tbody>
</table>

**DECISION NO. PR78-2002 - Mod. #1**
(43 FR 51587 - November 3, 1978)
Puerto Rico, Island Wide

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
</tr>
<tr>
<td>Laborers</td>
<td>2.80</td>
</tr>
<tr>
<td>Mortar Mixers</td>
<td>2.80</td>
</tr>
</tbody>
</table>

**Change:**

<table>
<thead>
<tr>
<th>Laborers:</th>
</tr>
</thead>
<tbody>
<tr>
<td>$2.90</td>
</tr>
</tbody>
</table>

**DECISION NO. PR78-3019 - Mod. #1**
(43 FR 13738 - March 31, 1978)
Puerto Rico, Island Wide

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
</tr>
<tr>
<td>Ironworkers, Rebars</td>
<td>2.80</td>
</tr>
<tr>
<td>Laborers, Unskilled</td>
<td>2.80</td>
</tr>
<tr>
<td>Painters</td>
<td>2.80</td>
</tr>
<tr>
<td>Truck Drivers</td>
<td>2.80</td>
</tr>
</tbody>
</table>

**DECISION NO. PR78-3005 - Mod. #1**
(43 FR 51587 - November 3, 1978)
Puerto Rico, Island Wide

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
</tr>
<tr>
<td>Laborers</td>
<td>2.80</td>
</tr>
<tr>
<td>Air Tool Operator</td>
<td>2.80</td>
</tr>
<tr>
<td>Painters</td>
<td>2.80</td>
</tr>
<tr>
<td>Tile Setters</td>
<td>2.80</td>
</tr>
</tbody>
</table>

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979

**DECISION NO. PR78-3009 - Mod. #1**
(43 FR 51587 - November 3, 1978)
Puerto Rico, Island Wide

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
</tr>
<tr>
<td>Laborers</td>
<td>2.80</td>
</tr>
</tbody>
</table>

**NOTICES**

**DECISION FN78-3047 - Mod. #3**
(63 FR 26235 - June 16, 1978)
Atlantic City, Burlington, Camden, Cape May, Cumberland, Gloucester, Mercer, Monmouth, Ocean, and Salem Counties, New Jersey

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
</tr>
<tr>
<td>Line Construction - Railroad only</td>
<td>Line Construction - Railroad only</td>
</tr>
<tr>
<td>Lineman</td>
<td>10</td>
</tr>
<tr>
<td>Groundman</td>
<td>6.60</td>
</tr>
</tbody>
</table>

**Change:**

<table>
<thead>
<tr>
<th>Truck Drivers:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zone 3</td>
</tr>
<tr>
<td>Group 1</td>
</tr>
<tr>
<td>Group 2</td>
</tr>
<tr>
<td>Group 3</td>
</tr>
<tr>
<td>Group 4</td>
</tr>
<tr>
<td>Group 5</td>
</tr>
</tbody>
</table>

**DECISION FPN78-3054 - Mod. #2**
(63 FR 35868 - August 11, 1978)
Bucks, Chester, Delaware, Montgomery and Philadelphia Counties, Pennsylvania

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
</tr>
<tr>
<td>Lineman</td>
<td>10.94</td>
</tr>
<tr>
<td>&quot;A&quot; equipment operator</td>
<td></td>
</tr>
<tr>
<td>&quot;B&quot; equipment operator</td>
<td></td>
</tr>
<tr>
<td>Footnote: d. Paid Holidays: New Year's Day, Decoration Day; Independence Day; Labor Day; Thanksgiving Day; Christmas Day and Good Friday</td>
<td></td>
</tr>
</tbody>
</table>

**DECISION NO. PR78-2002 - Mod. #1**
(43 FR 51587 - November 3, 1978)
Puerto Rico, Island Wide

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
</tr>
<tr>
<td>Laborers</td>
<td>2.80</td>
</tr>
<tr>
<td>Mortar Mixers</td>
<td>2.80</td>
</tr>
</tbody>
</table>

**Change:**

<table>
<thead>
<tr>
<th>Laborers:</th>
</tr>
</thead>
<tbody>
<tr>
<td>$2.90</td>
</tr>
</tbody>
</table>

**DECISION NO. PR78-3019 - Mod. #1**
(43 FR 13738 - March 31, 1978)
Puerto Rico, Island Wide

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
</tr>
<tr>
<td>Ironworkers, Rebars</td>
<td>2.80</td>
</tr>
<tr>
<td>Laborers, Unskilled</td>
<td>2.80</td>
</tr>
<tr>
<td>Painters</td>
<td>2.80</td>
</tr>
<tr>
<td>Truck Drivers</td>
<td>2.80</td>
</tr>
</tbody>
</table>

**DECISION NO. PR78-3005 - Mod. #1**
(43 FR 51587 - November 3, 1978)
Puerto Rico, Island Wide

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
</tr>
<tr>
<td>Laborers</td>
<td>2.80</td>
</tr>
<tr>
<td>Air Tool Operator</td>
<td>2.80</td>
</tr>
<tr>
<td>Painters</td>
<td>2.80</td>
</tr>
<tr>
<td>Tile Setters</td>
<td>2.80</td>
</tr>
</tbody>
</table>

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
## Truck Drivers:

<table>
<thead>
<tr>
<th>Category</th>
<th>Basic Hourly Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to but not including 1½ tons</td>
<td>7.05</td>
</tr>
<tr>
<td>1½ to but not including 3 tons</td>
<td>7.25</td>
</tr>
<tr>
<td>3 tons but not including 5 tons</td>
<td>7.50</td>
</tr>
<tr>
<td>5 tons and over including special equipment</td>
<td>7.65</td>
</tr>
<tr>
<td>Heavy Duty — off the road trucks</td>
<td>7.75</td>
</tr>
</tbody>
</table>

Welders, riggers, riveters — receive rate prescribed for craft performing operation to which welders, riggers, and riveters are incidental.

## Paid Holidays:

- A-New Year’s Day
- B-Memorial Day
- C-Independence Day
- D-Labor Day
- E-Thanksgiving Day
- F-Christmas Day

## Footnotes:

- a 6 paid holidays: A through F
- b Employer contributes 8% of regular hourly rate to Vacation Pay Credit for employees who have worked in business more than 5 years. Employer contributes 6% of regular hourly rate to Vacation Pay Credit for employees who have worked in business less than 5 years.

## Laborers:

<table>
<thead>
<tr>
<th>Group</th>
<th>Basic Hourly Rate</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>6.00</td>
<td>.35</td>
<td>40</td>
<td>03</td>
</tr>
<tr>
<td>B</td>
<td>6.75</td>
<td>.35</td>
<td>40</td>
<td>03</td>
</tr>
<tr>
<td>C</td>
<td>6.70</td>
<td>.35</td>
<td>40</td>
<td>03</td>
</tr>
<tr>
<td>D</td>
<td>6.65</td>
<td>.35</td>
<td>40</td>
<td>03</td>
</tr>
<tr>
<td>E</td>
<td>7.05</td>
<td>.35</td>
<td>40</td>
<td>03</td>
</tr>
<tr>
<td>F</td>
<td>7.50</td>
<td>.35</td>
<td>40</td>
<td>03</td>
</tr>
<tr>
<td>G</td>
<td>7.45</td>
<td>.35</td>
<td>40</td>
<td>03</td>
</tr>
<tr>
<td>H</td>
<td>7.35</td>
<td>.35</td>
<td>40</td>
<td>03</td>
</tr>
<tr>
<td>I</td>
<td>7.20</td>
<td>.35</td>
<td>40</td>
<td>03</td>
</tr>
<tr>
<td>J</td>
<td>8.15</td>
<td>.35</td>
<td>40</td>
<td>03</td>
</tr>
</tbody>
</table>

- Group A: All or electrical tool operators and asphalt rakers.
- Group B: Vibrator operators, chain saw ops of mechanical equipment which replaces (wheelbarrows or buggies), power mowers, mortar mixers, pipe layers, concrete, and other hand tools.
- Group C: Pile drivers, excavators, and other similar laborers.
- Group D: Mason tenders, building laborers.
- Group E: Burners on demolition, wagon drill operators and tunnel laborers.
- Group F: Powermen.
- Group G: Electricians (10' Dia).
- Group H: Tunnel miners.
- Group I: Pneumatic concrete gun operators and nozzlemen.
- Group J: Chuck tenders.
- Group K: Oxen operators.
### POWER EQUIPMENT OPERATORS

<table>
<thead>
<tr>
<th>GROUP</th>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>GROUP A</td>
<td>10.04</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>GROUP B</td>
<td>9.51</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>GROUP C</td>
<td>9.44</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>GROUP D</td>
<td>10.74</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>GROUP E</td>
<td>10.03</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>GROUP F</td>
<td>8.57</td>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>

- **GROUP A**: Asphalt plant, boom tractor, bulldozer, cabalovers, corkscrew, compressors (2 or more), crane-orchard-tractor, derrick, forklift, front end loader, grade, heavy duty machinery, hoist (1 drum or more), mixers, push tractor, scrapers, shears, trenching machine (and all similar equipment), winch trucks, motor graders, concrete pump, piledriver, rotary drill.

- **GROUP B**: Air compressor (over 125), asphalt spreaders, blade graders (pull type), boat operator, conveyor (2 or more up to 4), crawler tractors, distributors, bituminous surfacing, farm tractors, finishing machine, pumps over 4 inches, rollers, welding machine (1 or more).

- **GROUP C**: Air compressor (125 & under), oilers-fienecon, conveyor (1) tended by oilers), pumps (under 4 inches), welding machines (3 or under).

- **GROUP D**: On steel erection: Crane, dragline, derrick, hoist, piledriver, winch truck, forklift, tower cranes, climbing cranes, cherry picker, mechanics, locomotives, tugboat.

- **GROUP E**: Tractors, welding machine, gas or diesel driven welding machine (1 or more), air compressors over 125 (2 or less), power generating units (gas or diesel).

- **GROUP F**: Gas or diesel driven welding machine (3 or less), air compressors over 125 (2 or less), oilers, fienecon, small boat.

### FRINGE BENEFITS PAYMENTS

<table>
<thead>
<tr>
<th></th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic Hourly Rates</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education and/or Appr Tr</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

### ASBESTOS WORKERS

<table>
<thead>
<tr>
<th></th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic Hourly Rates</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### DECISION NO A279-5104

#### Page 2

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
</tr>
</tbody>
</table>

**Painters:**
- **Zone A:** 0-30 miles from Tucson
  - Post Office
- **Zone B:** 31-40 miles from Tucson
  - Post Office
    - Structural Steel, Brush: 11.46, H & W: 67, Pensions: 40, Vacation: 06
  - Zone C: 41-50 miles from Tucson
    - Post Office
      - Brush: 11.21, H & W: 67, Pensions: 40, Vacation: 06
      - Structural Steel, Brush: 12.21, H & W: 67, Pensions: 40, Vacation: 06
  - Zone D: 51 miles and over from Tucson Post Office

**Plasterers:**
- **Zone A:** 0-30 miles from Tucson
  - Post Office: 8.57, H & W: 35, Pensions: 60
  - Zone B: 30-40 miles from Tucson
    - Post Office: 9.07, H & W: 35, Pensions: 60
  - Zone C: 40-50 miles from Tucson
  - Zone D: 50 miles and over from Tucson Post Office
    - 10.07, H & W: 35, Pensions: 60
  - Zone E: 60 miles and over from Tucson Post Office
    - 10.16, H & W: 85, Pensions: 85

**Plasterers' Tenders:**
- 10.07, H & W: 35, Pensions: 60

---

### DECISION NO A279-5104

#### Page 3

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
</tr>
</tbody>
</table>

**Plumbers; Steamfitters:**
- **Free Zone 0-15 miles**
  - Zone 1: 0 miles from the stated base points in Flagstaff, Yuma, Tucson and Douglas
  - Zone 2: 15-30 miles from the stated base point
  - Zone 3: 30-40 miles from the stated base point
  - Zone 4: 40 miles and over from the Phoenix and Tucson basing points

- **Roofers:**
  - Zone A: 0-44 miles from Tucson
    - Zone B: 44 miles from Tucson
  - Zone C: 40-50 miles from Tucson
  - Zone D: 50 miles and over from Tucson Post Office

**Sheet Metal Workers:**
- **Free Zone 0-22 miles from Tucson**
  - Zone 1: 0-22 miles from Tucson
  - Zone 2: 22-45 miles from Tucson
  - Zone 3: Over 45 miles from Tucson

**Soil Floor Layers:**
- 9.07, H & W: 35

**Sprinkler Fitters:**
- 12.20, H & W: 65

**Terra Cotta Workers; Tile Setters; Marble Setters:**
- 9.27, H & W: 90

---

**Footnote:**
- Employer credits 4% basic hourly rate of employee with over 5 years' service.

**Paid Holidays:**
- A: New Year's Day; B: Memorial Day; C: Independence Day; D: Labor Day; E: Thanksgiving Day; F: Christmas Day.
<table>
<thead>
<tr>
<th>Group</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Apprenticeship</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LABORERS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>8.75</td>
<td>92</td>
<td>98</td>
<td>98</td>
<td>10.0</td>
</tr>
<tr>
<td>Group 2</td>
<td>8.75</td>
<td>92</td>
<td>98</td>
<td>98</td>
<td>10.0</td>
</tr>
<tr>
<td>Group 3</td>
<td>8.75</td>
<td>92</td>
<td>98</td>
<td>98</td>
<td>10.0</td>
</tr>
<tr>
<td>Group 4</td>
<td>8.75</td>
<td>92</td>
<td>98</td>
<td>98</td>
<td>10.0</td>
</tr>
<tr>
<td>Group 5</td>
<td>8.75</td>
<td>92</td>
<td>98</td>
<td>98</td>
<td>10.0</td>
</tr>
<tr>
<td>Group 6</td>
<td>8.75</td>
<td>92</td>
<td>98</td>
<td>98</td>
<td>10.0</td>
</tr>
<tr>
<td>Group 7</td>
<td>8.75</td>
<td>92</td>
<td>98</td>
<td>98</td>
<td>10.0</td>
</tr>
</tbody>
</table>

**POWER EQUIPMENT OPERATORS**
(Except PileDriving and Steel Friection)

| Group 1 | 8.75           | 92   | 98       | 98       | 10.0                          |
| Group 2 | 8.75           | 92   | 98       | 98       | 10.0                          |
| Group 3 | 8.75           | 92   | 98       | 98       | 10.0                          |
| Group 4 | 8.75           | 92   | 98       | 98       | 10.0                          |
| Group 5 | 8.75           | 92   | 98       | 98       | 10.0                          |
| Group 6 | 8.75           | 92   | 98       | 98       | 10.0                          |
| Group 7 | 8.75           | 92   | 98       | 98       | 10.0                          |

**TRUCK DRIVERS**

| Group 1 | 8.75           | 92   | 98       | 98       | 10.0                          |
| Group 2 | 8.75           | 92   | 98       | 98       | 10.0                          |
| Group 3 | 8.75           | 92   | 98       | 98       | 10.0                          |
| Group 4 | 8.75           | 92   | 98       | 98       | 10.0                          |
| Group 5 | 8.75           | 92   | 98       | 98       | 10.0                          |
| Group 6 | 8.75           | 92   | 98       | 98       | 10.0                          |

**FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979**

---

**LABORERS**

- **Group 1**: All Helpers not herein separately classified; Cesspool diggers and installers; Crash box men; Checkers, tool dispatcher; Concrete dump man; pipe and/or hose men; Pumpers and/or repairmen; Fence builder, guard rail builder, highway; Farm strippers; Labor, general or construction; Landscape gardener and nurseryman; Paving, road crew and gangs; Riprap stone men; Astro turf layer; Cleanup, Bull gang; Trackman—railroad

- **Group 2**: Cement finisher tender. Concrete curer (impervious membranes); Cutting torch operator; Fine grader (highway, engineering and sewage work only); Kettleman—Tarman. Power type concrete bugy

- **Group 3**: Rander, Chucktender (except tunnel); Creecote tlemian; Guinea chaser; Powderman helper; Rip—rip stone paver; Sandblaster (pot tender); Spiker and wrencher

- **Group 4**: Cement dumper (skip-type mixer or handling bulk cement); Chain saw machines (on cleaning and grubbing); Concrete vibrating machines; Grubber and shaker (except tunnel); Floor sanders; Concrete: Hydraulic jacks, and similar mechanical tools not separately classified herein; Operators and tenders of pneumatic and electric tools; Pipe人脸er and/or backup man (pipeline); Pipe wrapper; Pneumatic gopher; Rigger/Signalman (pipeline)

- **Group 5**: Air and water wash-out nozzle man; Asphalt rakers and irone; Driller; Grade setter (pipelines); and guided trencher and similar operated equipment; Jackhammer and/or pavement breakers; Pipelayers (including but not limited to non-metallic, transite and plastic pipe, water pipe, sewer pipe, drain pipes, underground tile and conduit); Rock sledger; Sander (using both hand bars or safety belt); Tamper (mechanical—all types); Precast manhole erecter

- **Group 6**: Concrete Cutting Torch; Concrete saw (hand guided); Driller, core, diamond, wagon or air track; Drill doctor and/or air tool repairman; Gunman and miserman (gunite); Sandblaster (nozzle)

- **Group 7**: Concrete road form setter; Gunite nozzle man or rodman; Drillers, Oxy/Hydrogen, PA 140, 220 Gardner-Denver, Hydroscopic; Powderman; Sander (drillers); Welders and/or pipelayers installing process piping; Form setter and/or builder
POWER EQUIPMENT OPERATORS (Except Piledriving and Steel Erection)

Group 1: Air compressor operator; Field equipment servicemen; Heavy duty repair helper; Heavy duty welder helper; Oiler Pump operator

Group 2: Conveyor operator; Generator operator - portable; Power grizzly operator; Self-propelled chip spreading machine - conveyor operator; Watch fireman; Welding machine operator - gasoline and diesel power

Group 3: Concrete mixer operator - skip type; Dinky operator - (under 20 tons wt); Driver-motor paver, Slurry seal machine, and similar type equipment; Motor crane driver; Power awesoper operator - self-propelled; Hose carrier or fork lift operator; Skip loader operator - all types with rated capacity 1-1/2 cu yds or less; Wheel type tractor operator (Ford, Ferguson, or similar type) with attachments such as fresno, push blade, post hole auger, mower, etc., excluding compacting equipment

Group 4: A-frame boom truck or winch truck operator; Asphalt plant fireman; Elevator hoist operator - (including Tunkey hoist or similar type); Grade checker - (excluding civil engineer); Multiple power concrete saw operator; Pavement breaker, mechanical compactor operator, power propelled; Roller operator - all types - except as otherwise classified; Scree operator; Self-propelled chip spreading machine operator - (including Slurry seal machine operator) Stationary pipe-wrapping and cleaning machine operator; Tagger operator

Group 5: Aggregate plant operator (including crushing, screening and sand plants, etc.); Asphalt plant mixer operator; Beltconcrete machine; Boring machines operator; Concrete mechanical tamp, spreading or finishing machine (including Clark, Johnson or similar types); Concrete pumper operator; Concrete batch plant operator; all types and sizes; Conductor, brokeman, or handler; Drilling machine, including water wells; Elevating grader operator - all types and sizes (except as otherwise classified); Field equipment serviceman; Highline cableway signalman; Holman bolt loader operator or similar, with belt width 48" or over; Locomotive engineer (including Dinky - 20 tons wt. and over); Motor-paver and similar type equipment operator; Operating engineer rigger; Pneumatic-tired scraper operator (Turnpulp, Euclid, Cat, D-W, Hancock and similar equipment) up to and including 12 cu yds; Power jumbo form setter operator; Pressure grout machine operator (as used in heavy engineering construction); Road oil mixing machine operator; Roller operator - on all types asphalt pavements; Self-propelled compactor, with blade; Skip loader operator - all types with rated capacity over 14 but less than 4 cu yds; Slip form operator (power driven lifting device for concrete forms); Soil cement road mixing machine operator - single pass type; Stationary central generating plant operator rated 300 KW or more; Surface heater and planer operator; Traveling Pipe-wrapping machine operator

POWER EQUIPMENT OPERATORS (Cont'd)

Group 5A: Heavy duty mechanic and/or welder; Pneumatic-tired scraper, all sizes and types over 12 cu yds up to and including 45 cu yds; HCC (Turnpul, Euclid, Cat, D-W, Hancock and similar equipment); Tractor operator (Pusher, Bulldozer, Scraper) up to 400 net horsepower rating; Trenching machine operator

Group 6: Auto-grade machine (CMI and similar equipment); Boring Machine operator (including Moil, Badger and similar type); Concrete Mixer Operator - paving type, and mobile mixer; Concrete Pump operator with boom attachment (truck mounted); Crane Operator - crawler and pneumatic type, under 100 ton capacity HCC; Crawler type tractor operator - with boom attachment; Derrick operator; Forklift operator for hoisting personnel; Grade-all operator; Helicopter hoist; Highline cableway operator (less than 20 tons rated capacity); Mass excavator operator (John Bucyrus Erie and similar types); Mechanical hoist operator (two or more drums); Motor grade operator - any type power blade; Motor grade operator with elevating grader attachment; Hacking machine operator; Overhead crane operator; Piledriver engineer (portable, stationary or skid rig); Pneumatic-tired scraper operator - all sizes and types (Turnpul, Euclid, Cat, D-W, Hancock and similar equipment over 45 cu yds); HCC - Power driven ditch lining or ditch trimming machine operator; Skip loader operator - all types with rated capacity 4 cu yds, but less than 8 cu yds; Slip form paving machine operator (including Gunner, Zimmermann and similar types); Specialized power digger operator - attached to wheel-type tractor; Tower crane (or similar type) operator; Tractor operator (Pusher, Bulldozer, Scraper (400 net horsepower and over)); Tagger operator (two or more); Universal equipment operator - Shovel, Backhoe, Dragline, Clamshell, etc., up to 8 cu yds

Group 7: Crane Operator - pneumatic or crawler (100 ton hoisting capacity and over HCC rating); Helicopter pilot - FAA qualified when used in construction work; Highline cableway operator, over 20 ton rated capacity and using traveling head and tail tower; Remote control earth moving equipment operator; Skip loader operator - all types with rated capacity of 8 cu yds or more; Universal equipment - Shovel, Backhoe, Dragline, Clamshell, etc., 8 cu yds and over
TRUCK DRIVERS

Group 1: Teamsters; Pickups; Station Wagon; Manhaul driver

Group 2: Dump or flatrack (2 or 3 axle); Water truck (under 3500 gallons); Duggymobile (1 cu yd or less); Tireman; Bus driver, ambulance driver, self-propelled street sweeper; Warehousemen

Group 3: Dump or flatrack (4 axle); Dump or dumpster (less than 7 cu yds); Water truck (2500 gallons but less than 4000 gallons)

Group 4: Dumpster or dumpster (7 cu yds but less than 16 cu yds); Dump or flatrack (5 axle); Water truck (4000 gallons and over); Slurry type equipment or leverman; Flaherty spreader or similar type equipment or leverman; Transit mix (8 cu yds or less)

Group 5: Dump or flatrack (6 axle); Transit mix (over 6 cu yds but less than 10 5 cu yds); Rock truck (1 or Dart, Euclid, and other similar type end dumps, single unit less than 16 cu yds)

Group 5A: Oil Tanker or Spreader and/or Boomman, Retortman or Leverman

Group 6: Transit mix (over 10.5 cu yds but less than 14 cu yds); Road carrier, Rock lift or lift truck; Hydro lift, Swedish crane Iowa 300 and similar types; Concrete pump (when integral part of transit mix truck); Dump or flatrack (7 axle)

Group 7: Dump or Flatrack (8 axles)

Group 8: Off-highway equipment driver including but not limited to; 2 or 4 wheel power unit, 1, 5, Cat, 24 Series, Euclid, International and similar type equipment, transporting material when top loaded or by external means including pulling water tanks, fuel tanks or other applications under Teamster Classification; Rock trucks (Dart, Euclid, or other similar end dump types) 16 cu yds and over; Excavator; Dumpster or dumpster (16 cu yds and over); Dump or flatrack (9 axles)

Group 8A: Heavy duty mechanic/welder; Body and fender man

Group 8B: Field equipment serviceman or fuel truck driver

Group 8C: Heavy duty mechanic/welder helper

SUPERSSEAS DECISION

STATES: Georgia, North Carolina, South Carolina, Virginia, and Washington, D.C. and in Florida, all counties on the Atlantic coast and the Gulf coast west to the Apalachicola River and all tributary Waterways.

DECISION NUMBER: CA79-1062

DATE: Date of Publication Superseded Decision No. CA-78-1015 dated March 10, 1976 in 43 FR 10166

DESCRIPTION OF WORK: Dredging Projects

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
</tr>
<tr>
<td>HYDRAULIC DREDGES 20&quot; AND OVER</td>
<td></td>
</tr>
<tr>
<td>Leverage</td>
<td>$8.16</td>
</tr>
<tr>
<td>Engineer</td>
<td>8.00</td>
</tr>
<tr>
<td>Mate</td>
<td>7.17</td>
</tr>
<tr>
<td>Helper</td>
<td>7.43</td>
</tr>
<tr>
<td>Derrick Operator</td>
<td>7.73</td>
</tr>
<tr>
<td>Spill barge operator</td>
<td>7.55</td>
</tr>
<tr>
<td>Spill barge operator</td>
<td>7.55</td>
</tr>
<tr>
<td>Tug master</td>
<td>7.10</td>
</tr>
<tr>
<td>Carpenter</td>
<td>7.68</td>
</tr>
<tr>
<td>Tug mate</td>
<td>6.74</td>
</tr>
<tr>
<td>Electrician</td>
<td>7.88</td>
</tr>
<tr>
<td>Machinist</td>
<td>7.61</td>
</tr>
<tr>
<td>Stevedore</td>
<td>6.09</td>
</tr>
<tr>
<td>Oilman &amp; Fireman</td>
<td>5.87</td>
</tr>
<tr>
<td>Deckhand &amp; tug deckhand</td>
<td>5.44</td>
</tr>
<tr>
<td>Shoreman</td>
<td>5.22</td>
</tr>
<tr>
<td>Second cook</td>
<td>5.44</td>
</tr>
<tr>
<td>Headman</td>
<td>5.32</td>
</tr>
<tr>
<td>HYDRAULIC DREDGES UNDER 20&quot;:</td>
<td></td>
</tr>
<tr>
<td>Leverage</td>
<td>7.38</td>
</tr>
<tr>
<td>Engineer</td>
<td>6.97</td>
</tr>
<tr>
<td>Welder</td>
<td>7.10</td>
</tr>
<tr>
<td>Mate</td>
<td>6.23</td>
</tr>
<tr>
<td>Oilman and Fireman</td>
<td>5.80</td>
</tr>
<tr>
<td>Lauchman</td>
<td>5.87</td>
</tr>
<tr>
<td>Shoreman</td>
<td>5.22</td>
</tr>
<tr>
<td>Spill barge operator</td>
<td>6.41</td>
</tr>
<tr>
<td>Spill barge operator</td>
<td>6.41</td>
</tr>
<tr>
<td>Deckhand</td>
<td>5.44</td>
</tr>
<tr>
<td>CLAMSHELL DREDGES</td>
<td></td>
</tr>
<tr>
<td>Operator</td>
<td>8.09</td>
</tr>
<tr>
<td>Engineer</td>
<td>7.58</td>
</tr>
<tr>
<td>Welder</td>
<td>7.32</td>
</tr>
<tr>
<td>Mate</td>
<td>7.01</td>
</tr>
<tr>
<td>Fireman &amp; Oiler</td>
<td>5.87</td>
</tr>
<tr>
<td>Deckhand</td>
<td>5.44</td>
</tr>
<tr>
<td>Launchman</td>
<td>5.87</td>
</tr>
<tr>
<td>Seaman</td>
<td>5.54</td>
</tr>
</tbody>
</table>

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
### Decision No. GA79-1042

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
<td>Pensions</td>
</tr>
</tbody>
</table>

#### Dipper Dredges:
- Operator: 8.19, 73, 60, a
- Craneoperator: 7.77, 73, 60, a
- Engineer: 7.96, 73, 60, a
- Welder: 7.43, 73, 60, a
- Mate: 7.17, 73, 60, a
- Fireman & Oiler: 5.87, 73, 60, a
- Deckhand: 5.44, 73, 60, a
- Tugmaster: 7.25, 73, 60, a
- Tugmate: 6.82, 73, 60, a
- Snowman: 5.54, 73, 60, a

#### Tugs (Tending Dipper & Clamshell Dredges):
- Tug master: 7.25, 73, 60, a
- Tugmate: 6.82, 73, 60, a
- Engineer: 7.25, 73, 60, a
- Assistant engineer: 6.66, 73, 60, a
- Deckhand: 5.35, 73, 60, a
- Cook: 5.54, 73, 60, a

#### Stewart Department – on Dipper and Clamshell Dredges and on Hydraulic Dredges 20” and Under:
- Cook: 5.80, 73, 60, a
- Mess cook: 5.39, 73, 60, a
- Messman & janitor: 5.29, 73, 60, a

#### Drillboats:
- Driller: 8.06, 73, 60, a
- Blaster: 8.06, 73, 60, a
- Operator engineer: 8.06, 73, 60, a
- Helper: 5.87, 73, 60, a

#### Notes:
- **Paid Holidays:** A-New Year’s Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day
- a Six paid holidays, A through F, plus vacation contribution of 73% of straight time pay

---

###備考

- **Air Conditioning and Heating Mechanics:** $5,77
- **Bricklayers:** 7.00
- **Carpenters:** 6.12
- **Cement Masons:** 7.29
- **Electricians:** 6.84
- **Insulators:** 5.50
- **Laborers:** 5.06
- **Painters:** 5.82
- **Plumbers:** 6.10
- **Roofers:** 6.00
- **Sheet Metal Workers:** 8.88
- **Tile Setters:** 8.00
- **Truck Drivers:** 8.03
- **Power Equipment Operators:**
  - Backhoes: 9.09
  - Bulldozers: 9.10
  - Front End Loaders: 9.33
  - Graders: 9.10

---

**FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979**
### SUPPLEMENT DECISION

**STATE:** Nevada  
**COUNTY:** Clark County (does not include the Nevada Test Site)  
**DECISION NUMBER:** NV78-5102  
**Supersedes Decision No:** NV78-5018 dated March 17, 1976, in 43 FR 11447  
**DESCRIPTION OF WORK:** Residential Construction consisting of single family homes and garden type apartments up to and including 4 stories.

| Basic Hourly Rates | Fringe Benefits Payments |  
|--------------------|--------------------------|---
|                     | H & W  | Pensions | Vacation | Education and/or Appr Tr |
| **ASBESTOS WORKERS** | $14.46 | $1.10 | $1.30 |  |
| **BOILERMAKERS** | 14.36 | 1.875 | 1.00 | 1.00 | 0.03 |
| **BRICKLAYER; Stonemason** | 12.97 | 0.90 | 60 |  |
| **CARPENTERS:**  
  Zone 1: Area within the City limits of Henderson, Nevada, and Boulder City, Nevada; area within a 10 mile radius of Las Vegas, Nevada; In Clark County, the present fenced area of Nellis Air Force Base, as well as that area adjacent to Nellis Air Force Base bounded on the north by the Nellis spur track and on the west by the train line of the Union Pacific Railroad.  
  Carpentry  
  Floor Layers; Patent Scaffold Erectors; Power Saw Operators  
  Pile drivers  
  Millwrights  
  Zone 2: Area outside of Zone 1 and not more than 20 miles from the communities described above  
  Carpentry  
  Floor Layers; Patent Scaffold Erectors; Power Saw Operators  
  Pile drivers  
  Millwrights  
  Zone 3: Area over 20 miles and not more than 40 miles from the communities described in Zone 1  
  Carpentry  
  Floor Layers; Patent Scaffold Erectors; Power Saw Operators  
  Pile drivers  
  Millwrights  
  Zone 4: Area over 40 miles from the communities described in Zone 1  
  Carpentry  
  Floor Layers; Patent Scaffold Erectors; Power Saw Operators  
  Pile drivers  
  Millwrights |  |  |  |  |

**NOTICES**

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
### Electricians:

- **Electricians; Technicians:** $15.26, 98, 36,155, 08
- **Cable Splicers:** 15.59, 98, 36,155, 08
- **Elevator Constructors, Helpers:** 10.53, $0.05, 60, 33,060, 03
- **Elevator Constructors' Helpers:** 10.17, $0.05, 60, 33,060, 03

### Ironworkers:

- **Fence Erectors:** 11.11, 1.29, 2.57, 1.65, 07
- **Structural:** 12.00, 1.29, 2.57, 1.65, 07
- **Layher:** 10.60, 7.00, 1.00, 1.00, 16
- **Marble, Terrazzo, Tile Finishers:** 12.97, 0.90, 60, 06
- **Wiremen; Steamfitters:** 9.65, 0.70, 60, 06

### Painters:

- **Brush; Roller:** 13.64, 75, 35, 06
- **Paperhangers; Spray; Steel; Swing Stage; Sandblasters; Tapers:** 13.99, 75, 35, 06

### Plaster Tenders:

- **Plasterers:** 11.92, 66, 1.35
- **Framers; Steamfitters:** 12.18, 1.00, 1.00, 08
- **Roofers:** 11.53, 1.25, 2.32, 1.85, 08
- **Sheet Metal Workers:** 14.75, 80
- **Sofa Floor Layers:** 14.71, 1.14, 1.61, 17
- **Sprinkler Fitters:** 13.47, 65
- **Terra Cotta Workers, Tilers:** 13.50, 75, 1.05, 08

### Footnotes:

- Employer contributes 4% basic hourly rate for over 4 years' service and 24% basic hourly rate for 6 months' to 5 years' service as Vacation Pay.
- Credit: Six Paid Holidays; A through K.

### Paid Holidays:

- A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day

### Laborers:

- **Group 1:** $9.95, 66, $1.53
- **Group 2:** 10.16, 66, 1.53
- **Group 3:** 10.26, 66, 1.53
- **Group 4:** 10.35, 66, 1.53
- **Group 5:** 10.45, 66, 1.53

---

**Laborers:**

- Group 1: Cutting Torch Operator (demolition); Dry packing of concrete and filling of form-bolt holes; Fine Grader, highway and street paving; airport runways and similar type heavy construction; Flagman, spotter, debris handler and dumper; Gas and oil pipeline laborer; Guinea chaser; Laborer, demolition (cleaning of bricks, lumber, etc.); Laborer, general or construction; Laborer, packing rod steel and pans; Laborer, temporary water lines (portable type); Landscape Gardner and Nurseryman; Tarman and Mortman, Rattke man, Potman and Man; Asphait, Lay-kold creosote, lime and similar type materials; "Applying" means applying, dipping, brushing or handling of such materials for pipe wrapping and waterproofing; Underground Laborer, including Caisson Bellowers; Window Cleaner.

- Group 2: Asphalt Raker, Ironer, Spreader, Luteman; Buggymobile Man; Cement Blower (on one yard or larger mixers and handling bulk cement); Cesspool Digger and Installer; Chucktender (except tunnels); Concrete Core Cutter; Concrete Curer, Impervious membrane and oiler of all materials; Concrete Saw Man, excluding tractor type, cutting, scoring old or new concrete; Gas and Oil Pipeline Wrappacre, Pot Tender and Form Man; Making and Caseling of all non-metallic Pipe Joints; Operators and Tenders of pneumatic and electric tools; Vibrating machines, hand-propelled trenching machines; impact wrench multple and similar mechanical tools not separately classified herein; Operator of cement Grinding Machine; Riprap Stonemower; Roto-scrapers; Sandblaster (pot tender); Scaele Ber; Septic Tank Digger and Installer (lead man); Tank Scaler and Cleaner; Tree Climber, Faller, chain saw operator, Pittsburgh Chipper and similar type brush shredders.

- Group 3: Gas and Oil Pipeline Wrappacre, 6 in pipe and over; Jackhammer and/or pavement breaker; Laying of all non-metallic pipe, including sewer pipe, drain pipe and underground tile; Oversize concrete vibrator operator; 70 lbs and over; Rock Slinger; Scalev (using box 'n chain or safety belt or power tools).

- Group 4: Cribber or Shorer, Lagging, sheeting, trench bracing, hand guided lagging hammer; Head rock slinger; Powderman - blaster, all work of loading holes, placing and blasting of all powder and explosives of whatever type, regardless of method used for such loading and placing; Sandblaster (noseleman); Steel Headerboard Man.

- Group 5: Driller (core, diamond or wagon), Joy Driller Model Tw-N-2A, Gardner-Denver Model DH 143 and similar type drills.
POWER EQUIPMENT OPERATORS
(Except Pile driving and Steel Erection)

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
<th>Group 4</th>
<th>Group 5</th>
<th>Group 6</th>
<th>Group 7</th>
<th>Group 8</th>
<th>Group 9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic Hourly Rates</td>
<td>$11.10</td>
<td>$11.30</td>
<td>$11.67</td>
<td>$11.61</td>
<td>$11.03</td>
<td>$11.14</td>
<td>$11.26</td>
<td>$11.43</td>
</tr>
<tr>
<td>Fringe Benefits Payments</td>
<td>$1.10</td>
<td>$1.10</td>
<td>$1.10</td>
<td>$1.10</td>
<td>$1.10</td>
<td>$1.10</td>
<td>$1.10</td>
<td>$1.10</td>
</tr>
<tr>
<td>H &amp; W Pensions</td>
<td>$2.30</td>
<td>$2.30</td>
<td>$2.30</td>
<td>$2.30</td>
<td>$2.30</td>
<td>$2.30</td>
<td>$2.30</td>
<td>$2.30</td>
</tr>
<tr>
<td>Vacation</td>
<td>70</td>
<td>70</td>
<td>70</td>
<td>-70</td>
<td>70</td>
<td>70</td>
<td>70</td>
<td>70</td>
</tr>
<tr>
<td>Education &amp;/or Apps</td>
<td>14</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

POWER EQUIPMENT OPERATORS
(Except Pile driving and Steel Erection)

Group 1: Brakefitter, Compressor Operator, Engine Filler, Generator Operator, Heavy Duty Repairman Helper, Pump; Signalman, Switchman

Group 2: Concrete Mixer Operator, Skip Operator, Belt Tensioner; Conveyor Operator, Fireman, Hydrostatic Pump Operator, Oiler, Crusher (asphalt or concrete plant); Plant Operator, generator, pump or compressor; Rotary Drill Helper (oilfield); Skiploader - wheel type up to 3/4 yd., with attachments; Soil Field Technician; Tar Pot Fireman, Temporary Heating Plant Operator, Trenching Machine Operator, Truck Crane Operator

Group 3: A-Frame or Winch Truck; Elevator Operator (Inside), Equipment Greaser (reel), Ford Ferguson (with dregtype attachments), Helicopter Radioman (ground); Power Concrete Curing Machine, Power Concrete Saw; Power Driven Jumbo Form Setter, Rove Carrier, Stationary Pipe Wrapping and Cleaning Machine

Group 4: Asphalt Plant Fireman, Boring Machine, Boxman or Mixerman (asphalt or concrete), Bridge Type Unloader and Turntable Operator Chip Spreading Machine, Concrete Pump (small portable), Dinky Locomotive or Motorman (up to and including 10 tons), Equipment Greaser (grease truck), Helicopter Boats, Highline Cables, Signallman, Hydrohammer-Aero Stoper; Power Sweeper, Roller (compacting), Screed (asphalt or concrete), Trenching Machine (up to 6 ft.)
POWER EQUIPMENT OPERATORS (Cont'd)
(Except Piledriving and Steel Erection)

Group 7: Crane (over 25 tons up to and including 100 tons H & R C); Derrick Barge, Dual drum mixer; Hoist, stiff legs, guy derrick, or similar type, up to and including 100 tons; Hoist or similar type except brick (9 cat); Rubber-tired earth moving equipment (single engine over 50 yds struck); Rubber-tired earth moving equipment (multiple engine, bulldozer, Caterpillar and similar) (over 25 yrs and up to 50 cu yds struck); Tractor loader operator (crawler and wheel type over 6% yrs); Tower crane repairman; Shovel, backhoe, dragline, clamshell operator (over 5 cu yds); Woods mixer and similar pugmill equipment; Heavy duty repairman - welder combination.

Group 8: Auto grader; Automatic slip-form; Crane (over 100 tons); Hoist stiff legs, guy derrick or similar type (250 cu yds); Mechanical finishing machine; Mobile form traveler; Motor patrol (multiple engine); Pipe mobile machine; Rubber-tired earth moving equipment (multiple engine, bulldozer, Caterpillar and similar type over 50 cu yds struck); Rubber-tired self loading scraper (paddle wheel-super type self-loading) (2 or more units); Tandem equipment (2 units only); Tandem tractor (quad 6 or similar type); Tunnel hole boring machine; Rubber-tired Scraper (pushing without push cat, push-pull) (500 per hour additional).

Group 9: Canal Liner; Canal trimmer; Helicopter pilot; Highline cableway; Wheel excavator (over 750 cu yds); Remote controlled earth moving equipment ($1.00 per hour additional to base rate).

TRUCK DRIVERS

<table>
<thead>
<tr>
<th>Basic</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>$9 97</td>
<td>SI 70</td>
<td>SI 70</td>
<td>SI 70</td>
</tr>
<tr>
<td>Group 2</td>
<td>10 08</td>
<td>SI 70</td>
<td>SI 70</td>
<td>SI 70</td>
</tr>
<tr>
<td>Group 3</td>
<td>10 13</td>
<td>SI 70</td>
<td>SI 70</td>
<td>SI 70</td>
</tr>
<tr>
<td>Group 4</td>
<td>10 29</td>
<td>SI 70</td>
<td>SI 70</td>
<td>SI 70</td>
</tr>
<tr>
<td>Group 5</td>
<td>10 47</td>
<td>SI 70</td>
<td>SI 70</td>
<td>SI 70</td>
</tr>
<tr>
<td>Group 6</td>
<td>10 97</td>
<td>SI 70</td>
<td>SI 70</td>
<td>SI 70</td>
</tr>
</tbody>
</table>

TRUCK DRIVERS

Group 1: Dump Trucks (less than 12 yds); Trucks (legal payload capacity less than 15 tons); Water and fuel trucks (under 2500 gal); Pickups; Service; Repairman helper; Drivers of busses (on jobsite used for transportation of up to 25 passengers); Steamers equipment (highest rate for dual craft operation).

Group 2: Dump trucks (12 yds but less than 16 yds); Trucks (legal payload capacity between 15 and 20 tons); Water and fuel trucks (2500 to 4000 gal); Truck drivers working on gas and oil pipeline (including winch truck and all sizes of trucks); Truck greasers and triemen; Drivers of busses (on jobsite used for transportation of more than 25 passengers); Bootman.

Group 3: Dumpers (less than 6% yds); Transit-mix (less than 15); Warehouse Clerk.

Group 4: Dump trucks (16 yds up to and including 22 yds); Trucks (legal payload capacity 20 tons but less than 30 tons); Water and fuel trucks (4000 gal but less than 6000 gal); Dumpers (6% yds and over); Transit-mix (3 yds but less than 6 yds); Euclid-type spreader trucks; Dumpster; Fork lift; Ross carrier - highway; Road oil spreading truck; time spent spreading oil.

Group 5: Dump trucks (over 22 yds); Trucks (legal payload capacity 20 tons and over); Water and fuel trucks (6000 gal and over); Transit-mix (6 yds and over); Truck repairman.

Group 6: D W and similar-type equipment, D W and 10 and D W 20; Euclid-type equipment, LeTourneau Pulls, Terra Cobras and similar types of equipment; also P 90 and similar-type trucks when performing work within jammer jurisdiction, regardless of types of attachment including power units pulling off highway belly dumps in tandem.
STATE: NEVADA
COUNTIES: Nevada Test Site including Tonopah Test Range in Clark, Lincoln and Nye Counties, Nevada

DECISION NUMBER: NV79-5107
DATE: March 10, 1978

DESCRIPTION OF WORK: Building Projects (does not include single family homes and garden type apartments up to and including 4 stories), heavy and highway construction

<table>
<thead>
<tr>
<th>BASIC HOURS</th>
<th>FRINGE BENEFITS PAYMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>H &amp; W</td>
<td>Pensions</td>
</tr>
<tr>
<td></td>
<td>Education</td>
</tr>
<tr>
<td></td>
<td>and/or Appr</td>
</tr>
</tbody>
</table>

| ASBESTOS WORKERS | $ 14.52 | $ 1.10 | $ 1.30 | 06 |
| BRICKLAYERS      |         |        |        |    |
| Brick Layers     | 12.97   | 90     | 60     | 06 |
| CARPENTERS       | 12.16   | 85     | 1.10   | 80 |
| FLOOR LAYERS     | 12.165  | 85     | 1.10   | 80 |
| MILLWRIGHTS      | 12.96   | 85     | 1.10   | 80 |
| CEMENT MASON     | 9.90    | 1.00   | 1.00   | 2.00 |
| FLOOR Finishing Machine | 10.25 | 1.00   | 1.00   | 2.00 |

| ELECTRICIANS     |         |        |        |    |
| Operators; Lineman | 14.22 | 90     | 34.155 | 05 |
| Cable Splicers   | 14.55   | 90     | 34.155 | 05 |
| Groundman        |         | 95     | 34.155 | 05 |
| AIR CONDITIONERS | 14.63   | 85     | 34.155 | 05 |
| Elevator Constructors | 14.53 | 85     | 34.155 | 05 |
| Elevator Constructors' Helpers | 14.56 | 85     | 34.155 | 05 |
| Elevator Constructors' Helpers (Prob.) | 14.57 | 85     | 34.155 | 05 |
| IRONWORKERS      |         |        |        |    |
| Reinforcing; Ornamental; Structural | 12.01 | 1.29 | 2.57 | 1.65 | 0.07 |
| MASON TENDERS    | 10.82   | 66     | 1.35   |    |
| PAINTERS         | 10.76   | .75    | .65    | 1.50 | 0.06 |
| Brusher Roller   |         |        |        |    |
| Paperhangers; Spray; Steel; Sandblasters; Sizing; Tapers; Buffing; Sandblasters; Steel | 11.11 | 75 | 65 | 1.50 | 0.06 |
| PLUMBERS; Steamfitters | 12.63 | 1.25 | 2.32 | 2.00 | 0.08 |
| ROOFERS          | 14.75   | 80     |        |    |
| SHEET METAL WORKS| 12.46   | 1.14   | 1.61   | 1.50 |
| SPARKLER FITTERS | 15.50   | 75     | 1.05   |    |

FOOTNOTE
A. Employer contributes 4% basic hourly rate for over 5 years' service and 8% basic hourly rate for 6 months to 5 years' service as Vacation pay
B. Credit Six Paid Holidays: A through F

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
### DECISION NO. NV79-5107

**LABORERS** (Cont'd)

Group 7: Chucktender (except tunnels); Scaler; Tank scaler and cleaner

Group 8: Caspool digger and installer

Group 9: Concrete curer - impervious membrane and oiler of all materials and form oiler; Riprap stonepaver; Sandblaster (pot tender); Making and caulking of all non-metallic pipe joints

Group 10: Operators and tenders of pneumatic and electric tools, vibrating machines, and similar mechanical tools not separately classified herein, including hand guided ditch witch and hand type roller; Asphalt raker, ironer, spreader; Duggymobile man; Cement dumper (on 1 yard or larger mixers and handling bulk cement); Concrete saw man excluding tractor type; Concrete core cutter; Gas and oil pipeline wrapper - pot tender and form man; Operator of cement grinding machines; Roto-scraper; Tree climber, faller, chain saw operator; Pittsburgh chipper and similar type brush shredders

Group 11: Rock digger; Scaler (using bos'ns chair or safety belt or power tools)

Group 12: Driller and/or pavement breaker

Group 13: Laying of all nonmetallic pipe, including sewer pipe, drain pipe and underground tile

Group 14: Gas and oil pipeline wrappers - 6 inch pipe and over

Group 15: Criber or shorer; Powderman

Group 16: Steel headerboard man

Group 17: Driller (Cone, Diamond or Wagon), Joy Driller Model 2K-2A, Gardner-Denver Model DH 143 and similar type drills; Sandblaster (norslemann)

Group 18: Head Rock Slinger

### DECISION NO. NV79-5107

**POWER EQUIPMENT OPERATORS** (Except Piledriving and Steel Erection)

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vocation</th>
<th>Education and/or App Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>$10.78</td>
<td>$1.10</td>
<td>$2.00</td>
<td>35</td>
</tr>
<tr>
<td>Group 2</td>
<td>11.02</td>
<td>1.10</td>
<td>2.00</td>
<td>35</td>
</tr>
<tr>
<td>Group 3</td>
<td>11.26</td>
<td>1.10</td>
<td>2.00</td>
<td>35</td>
</tr>
<tr>
<td>Group 4</td>
<td>11.37</td>
<td>1.10</td>
<td>2.00</td>
<td>35</td>
</tr>
<tr>
<td>Group 5</td>
<td>11.56</td>
<td>1.10</td>
<td>2.00</td>
<td>35</td>
</tr>
<tr>
<td>Group 6</td>
<td>11.66</td>
<td>1.10</td>
<td>2.00</td>
<td>35</td>
</tr>
<tr>
<td>Group 7</td>
<td>12.36</td>
<td>1.10</td>
<td>2.00</td>
<td>35</td>
</tr>
<tr>
<td>Group 7-A</td>
<td>10.07</td>
<td>1.10</td>
<td>2.00</td>
<td>35</td>
</tr>
<tr>
<td>Group 7-B</td>
<td>9.95</td>
<td>1.10</td>
<td>2.00</td>
<td>35</td>
</tr>
<tr>
<td>Group 7-C</td>
<td>9.72</td>
<td>1.10</td>
<td>2.00</td>
<td>35</td>
</tr>
</tbody>
</table>

---

**NOTICES**

Group 1: Air Compressor, pump or generator; Engineer oiler and Signal Man; Heavy duty repairman's helper; Switchman or Brakeman

Group 2: Concrete Mixer, Skip type; Conveyor and Beltman; Fireman; Generator, Pump or Compressor (2-5 units inclusive, over 5 units, $10.10 per hour for each additional unit up to 10 units, portable units); Generator, Pump or Compressor Plant; Rotary drill Helper (oilfield type); Skiploder, wheeltype, Ford, Ferguson, Jeep or similar type, 3/4 yard or less (w/o drag-type attachments); Temporary heating Plant; Truck Crane Oilers; Hydrostatic Pump

Group 3: A-Frame or Winch Truck; Dinky Locomotive or Tunnel Motor; Elevator Hoist; Equipment Greaser; Ford, Ferguson or similar type (with drag-type attachments); Hydra-hamdr or similar type equipment; Power Concrete Curing Machine; Power Concrete Saw; Power-driven Jumbo Form Setter; Ross Carrier; Self-propelled Tar Piping Machine; Stationary Pipe Wrapping and Cleaning Machine; Towblade Operator
NOTICES

Group 4: Asphalt Plant Fireman; Boring Machine; Dozerman or Mixer Box (concrete or asphalt plant); Derrickman (oilfield type); Drilling Machine (including water wells); Highline Cableway Signalmans; Locomotive Engineer; Power Sweeper; Roller, compacting; Screed; Trenching Machine (up to 6 feet depth)

Group 5: Asphalt or Concrete Spreading; Mechanical Tamping or Finishing Machine - Roller (all types and sizes); Soil, Cement, Asphalt - finisher; Asphalt Plant Engineer; Deck Engine; Grade Checker; Heavy Duty Holder; Machine Tool; Pavement Breaker; Pneumatic Tamping Shield - tunnel; Road Oil Mixing Machine; Forklift, under five tons; Rubber-tired, heavy duty equipment (Oshkosh, DM, Euclid, Letourneau, LePlant-Chatte, or similar type equipment with any type attachments); Sliploader, wheeled type, over 3/4 yards, up to and including 1/4 yards; Slip Form Pump (power-driven hydraulic lifting device for concrete forms); Tractor Operator - Drag-type Shovel, Bulldozer, Tamper, Scraper and Push Tractor

Group 6: Combination Heavy Duty Repairman and Welder; Concrete Mixer - paving; Concrete Mobile Mixers; Concrete Pump or Pumpcrete Gun; Crushing Plant Engineer; Elvating Grader; Heavy Duty Repairman; Highline Cableway; Hoist (Chicago Boom and Mine); Holman Belt Loader and similar type; Lift Slab Machine; Loader Operator - Athey, Euclid, Hancock, Sierra or similar type; Motor Patrol (any type or sizes); Multiple-engine earth-moving machinery; Pneumatic Concrete Placing Machine - Mackey-Precision or similar type; Rotary Drill, excluding paslinor type; Skiploader, wheeled type, over 1/2 yards; Surface Heater and Planer; Tractor Loader - crawler type - all types and sizes; Tractor, with boom attachments; Traveling Pipe Wrapping, Cleaning and Bonding Machine; Trenching Machine (over 6 ft. depth); Universal equipment (Shovel, Backhoe, Derr- line, Cleamshell, Derrick, Derrick Barge, Crane, Piledriver and Hucking Machines); Forklift, over 5 tons

Group 7: Driller Operator; Fishing Tool Engineer

Group 7-A: Derrickman

Group 7-B: Motorman

Group 7-C: Drill Helper

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asbestos Workers</td>
<td>12.89</td>
<td>55</td>
<td>1.00</td>
<td>0.02</td>
</tr>
<tr>
<td>Boilermakers</td>
<td>11.78</td>
<td>5</td>
<td>7%</td>
<td>0.01</td>
</tr>
<tr>
<td>Bricklayers &amp; Stonemasons</td>
<td>11.25</td>
<td>75</td>
<td>60</td>
<td>0.02</td>
</tr>
<tr>
<td>Mercer County</td>
<td>10.98</td>
<td>75</td>
<td>87</td>
<td>0.02</td>
</tr>
<tr>
<td>Carpenters:</td>
<td>11.15</td>
<td>62%</td>
<td>8%</td>
<td>6%</td>
</tr>
<tr>
<td>Lawrence County</td>
<td>10.74</td>
<td>65</td>
<td>1.10</td>
<td>0.05</td>
</tr>
<tr>
<td>Cement Masons:</td>
<td>11.86</td>
<td>68</td>
<td>1.61</td>
<td></td>
</tr>
<tr>
<td>Electricians:</td>
<td>11.32</td>
<td>68</td>
<td>1.61</td>
<td></td>
</tr>
<tr>
<td>Lawence County</td>
<td>12.08</td>
<td>62%</td>
<td>3%</td>
<td>1.00</td>
</tr>
<tr>
<td>Mercer County</td>
<td>11.45</td>
<td>33</td>
<td>1% + 45</td>
<td>0.01</td>
</tr>
<tr>
<td>Elevator Constructors:</td>
<td>11.99</td>
<td>745</td>
<td>56</td>
<td>b+c</td>
</tr>
<tr>
<td>Elevator Constructors' Helpers:</td>
<td>70G2R</td>
<td>845</td>
<td>56</td>
<td>b+c</td>
</tr>
<tr>
<td>Glaziers</td>
<td>50X1R</td>
<td>10.00</td>
<td>40</td>
<td>20</td>
</tr>
<tr>
<td>Ironworkers, structural, ornamental &amp; reinforcing laborors:</td>
<td>12.03</td>
<td>40</td>
<td>1.30</td>
<td>0.07</td>
</tr>
<tr>
<td>Laborers:</td>
<td>12.03</td>
<td>40</td>
<td>1.30</td>
<td>0.07</td>
</tr>
<tr>
<td>Laborers, carryable pumps, west brick bugy or similar, vibrator operators, walk behind fork lift or similar (non self-propelled) strippe &amp; mover or forms, combat masons, footers, window cleaner, tool room man, all material conveyor regardless of power used, including starting &amp; stopping:</td>
<td>9.49</td>
<td>85</td>
<td>71</td>
<td></td>
</tr>
</tbody>
</table>
| Laborers, west brick bugy or similar (self-propelled), power wheelbarrows and buggies, walk behind fork lift or similar, (self-propelled) wagon drill runners' helper, (including drill mounted on truck, track.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
<table>
<thead>
<tr>
<th>Pilothousemen:</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Lawrence</td>
<td>11.85</td>
<td>5.5%</td>
<td>10%</td>
</tr>
<tr>
<td>Mercer County</td>
<td>11.55</td>
<td>1.17</td>
<td>1.10</td>
</tr>
<tr>
<td>Plasterers:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lawrence County</td>
<td>11.70</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mercer County: Shenango, Sandy</td>
<td>11.70</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lake &amp; Redington Towns, Rem.</td>
<td>10.98</td>
<td>75</td>
<td>87</td>
</tr>
<tr>
<td>Plumbers &amp; Steamfiters:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lawrence</td>
<td>12.39</td>
<td>71</td>
<td>71</td>
</tr>
<tr>
<td>Mercer County</td>
<td>11.75</td>
<td>50</td>
<td>80</td>
</tr>
<tr>
<td>Roofers:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lawrence</td>
<td>11.70</td>
<td>75</td>
<td>80</td>
</tr>
<tr>
<td>Sheet Metal Workers:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lawrence</td>
<td>11.60</td>
<td>95</td>
<td>133</td>
</tr>
<tr>
<td>Mercer County</td>
<td>11.84</td>
<td>75</td>
<td>79</td>
</tr>
<tr>
<td>Sprinkler Fitters</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lawrence County</td>
<td>10.66</td>
<td>66</td>
<td>66</td>
</tr>
<tr>
<td>Mercer County</td>
<td>10.20</td>
<td>1.17</td>
<td>1.10</td>
</tr>
<tr>
<td>Terrazzo Workers &amp; Tile Setters:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lawrence County</td>
<td>10.98</td>
<td>75</td>
<td>87</td>
</tr>
<tr>
<td>Mercer County</td>
<td>12.30</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Paid Holidays (When Applicable):**

- A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day;
- E-Thanksgiving Day; F-Christmas Day

**Footnotes:**

a. 8 paid holidays, A through F and Washington's Birthday, Good Friday, and Christmas Day, provided the employee has worked 45 days for the employer during the 120 days prior to the holiday, and is available for work the days preceding and following the holiday.

b. Employer contributes 8% basic hourly rate for 5 years or more of service or 6% basic hourly rate for 6 months to 5 years of service as vacation pay credit.

c. Paid holiday: A through F, plus the Friday after Thanksgiving Day.

---

**NOTICES**

13229

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
CLASS 1-A - Austin-Western or similar type under 25 tons with jib, austin-western or similar type 25 tons or over with jib, cranes (boom or mast 100 ft, or over up & including 150 ft + $ 25); (truck or crawler type), cranes mobile (any type 15 tons or over placed on any bldg. structure + $ 25), hoist-hod (2 cages over 10 floors) Class I rate + $ 25, hoist single cage with

CLASS 1-B - Cranes (boom or mast over 150 ft up to & including 200 ft + $ 50) (truck or crawler type), engineer lead

CLASS 1-C - Cranes (boom or mast over 200 ft + $ 75)

CLASS 2 - Asphalt plant operator, athey loader, auger - truck or tractor, mounted, back filling machine, boat material or personnel carrying (powered) boat - job work (inboard or outboard), bulldozer, cable layer, compactor with blade, compressor (1) and air tugger (1) (combination), concrete bowl placer, crane - overhead, crushing & screening plants, drill - davey or similar type drill - core (truck or skid mounted), drill - wall & core (truck mounted), elevator (new buildings), euclid loader, excavating equipment (all other), forklift-lull or similar, grader; grader-elevating, grader-equipment (head), hi-lift - less than 4 yrs., hoist - one drum (4 floors or over), hoist - 60 (buildings 4 floors or more), hoist - (2 drums or more in one units), jumbo operator, locomotive, lift slab machine (hydraulic) mixer - paving, machine, pipe cleaning machine, refrigeration plant (used for construction jobs that is, cooling concrete & holding tanks), road carrier (or similar type), scoop (single bowl) (self-powered & tractor drawn), spreader - concrete, asphalt and stone, tower mobile (hoisting or lowering material), trencher, well point systems, (the following machines shall be considered minor), compressors (0 within a reasonable distance), generators electric (3) (over 5 KW up to 20 KW), pumps (4 1/2 discharge or less) (4 to 5 within reasonable distance), pumps (3) (over 1 1/2 discharge) (within reasonable distance), welding machines (4 to 6 within reasonable distance) (other than electrically driven), grout pump (10 H P or over), elevator (when used for alterations & remodeling all buildings), power operator - asphalt (spreader), pumper or similar type (not self-propelled), pumpercrete machine operator (stationary), tire repairman (when assigned job), welder (repairman)

CLASS 3 - Boiler, compactor (ridden or self-propelled), compressor (over 125 CFM and air pump), compressor (1) and sand blast machine (1), (combination), crane (carry), curb builder (self-propelled), drills – well & horizontal truck mounted, forklifts (ridden or self-propelled), hoist one drum (regardless of power used), pavement breaker (self-propelled or ridden), pipe dream, roller, saw (concrete), soil stabilizer (pump type), stone crusher, stone spreader self-propelled, tractors (when used for snaking and hauling), tubo finisher (CH or similar type), tugger, truck, (which) truck or hydraulic boom (when hoisting & placing), (the following machines shall be considered minor) compressors (2), generators (2), mortar machine over 10 cu ft, and single unit conveyor, pumps (1 1/2 discharge or less (2 to 3), pumps (over 1 1/2 discharge (2) in bank) (within reasonable distance), welding machine (2 to 3), (other than electrically driven)

CLASS 3-A - Conveyors 4 units or more

CLASS 4 - Ballast regulator, boring machine, broom, power (except push type), compressor - single (over 65 CFM), conveyor over 1 and up to 3 units (regardless of power used) form line machine, generator (over 5 KW), hoist (monorail) (regardless of power used) hoist roof (regardless of power used), hunk machine or similar type, mixer concrete (regardless of power used) mixer mortar - over 10 cu ft (regardless of power used) pump (over 1 1/2 discharge regardless of power used) spray cure machine (power driven) steam jenny (or similar type) syphon (steam or air) welding machine single (200 amp or over) (other than electrically driven) plant, private or industrial air of steam valve

CLASS 5 - Compressor - 65 cubic ft or under (regardless of power used) conveyor one (1) unit (regardless of power used) heaters - up to and including 6 jack motor hydraulic (single type) power driven ladravator, mixer mortar, (10 cubic ft or under), mulching machine, pin puller (powered) pulverizer, pump - 1 1/2 discharge or less, seeding machine, spreader (side delivery), shoulder (attachment) tie tamper (multiple heads) tractor farm (when used for landscaping) water blaster, oiler-tractor crane 50 ton up to not incl 100 ton

CLASS 6 - Brake man, deck hand, helicopter signalman, oiler, mechanic helper

CLASS 6-A Crane truck oiler & fireman

CLASS 6-B Oilier - Truck crane 50 ton up to & incl 100 ton

CLASS 6-C Oilier - Truck crane 100 ton and over
### Notices

#### SUPERSEDES DECISION

**STATE:** South Carolina  
**COUNTY:** Sumter

DECISION NUMBER: SC79-1037  
DATE: Date of Publication: SC79-1008 dated January 9, 1976 in 41 FR 16999.

**DESCRIPTION OF WORK:** Building Construction Projects (excluding single family homes and garden type apartments up to and including 4 stories).

<table>
<thead>
<tr>
<th>CLASS</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Warehouseman, chauffeur and ambulance drive, service truck (pickup, jeep, buses, station wagon, panel truck, escort vehicle, including fuel and water trucks)</td>
</tr>
<tr>
<td>2</td>
<td>Dump and flat top (including fuel and water trucks, fork lift in warehouse or job site storage area and single axle trucks with power tailgate) distributor truck over 33,000 lbs. gross weight (oil, tar asphalt products two man operation, both men)</td>
</tr>
<tr>
<td>3</td>
<td>Transit mix, single axle</td>
</tr>
<tr>
<td>4</td>
<td>Transit mix, tandem</td>
</tr>
<tr>
<td>5</td>
<td>Heavy duty tractor and trailer with high bed, 4 wheels</td>
</tr>
<tr>
<td>6</td>
<td>Heavy duty tractor and trailer with low bed, 6 to 16 wheels and pole trailer and wide load</td>
</tr>
<tr>
<td>7</td>
<td>Distributor truck up to 33,000 lbs. gross weight (oil, tar asphalt products) one man operation; truck with dolly and scissor truck; truck with dump trailer or tandem, including fuel and water, tandem axle truck with power tailgate and scissor truck; sucula or equivalent, tri-axle including mixer, drivers towing equipment</td>
</tr>
<tr>
<td>8</td>
<td>Winch truck and form truck</td>
</tr>
</tbody>
</table>

### Footnote:

- Paid Holidays: New Year's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, Christmas Day and Veteran's Day and Good Friday, provided the employee is available for work the day before and the day after the holiday and has been employed by the employer a minimum of 40 hours each calendar month for two consecutive months.

---

### Basic Hourly Rates and Fringe Benefits Payments

<table>
<thead>
<tr>
<th>CLASS</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>9.10</td>
<td>6.5%</td>
<td>5.6%</td>
<td>a</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>9.15</td>
<td>6.5%</td>
<td>5.6%</td>
<td>a</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>9.17</td>
<td>6.5%</td>
<td>5.6%</td>
<td>a</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>9.18</td>
<td>6.5%</td>
<td>5.6%</td>
<td>a</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>9.19</td>
<td>6.5%</td>
<td>5.6%</td>
<td>a</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>9.46</td>
<td>6.5%</td>
<td>5.6%</td>
<td>a</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>9.48</td>
<td>6.5%</td>
<td>5.6%</td>
<td>a</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>9.44</td>
<td>6.5%</td>
<td>5.6%</td>
<td>a</td>
<td></td>
</tr>
</tbody>
</table>

---

### PAYROLLS

<table>
<thead>
<tr>
<th>CLASS</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CLASS</th>
<th>Basic Hourly Rates</th>
<th>H &amp; W</th>
<th>Pensions</th>
<th>Vacation</th>
<th>Education and/or Appr Tr</th>
</tr>
</thead>
<tbody>
<tr>
<td>BRICKLAYERS</td>
<td>$5.75</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CARPENTERS</td>
<td>5.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CEMENT MASONS</td>
<td>4.75</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ELECTRICIANS</td>
<td>4.50</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRONWORKERS</td>
<td>4.30</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LABORERS</td>
<td>3.90</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PAINTER</td>
<td>7.25</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PUMBERS &amp; Pipelayers</td>
<td>5.03</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ROOFERS</td>
<td>5.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SHEET METAL WORKERS</td>
<td>3.50</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SPRINKLER FITTERS</td>
<td>3.25</td>
<td>0.75</td>
<td>1.05</td>
<td>0.08</td>
<td></td>
</tr>
<tr>
<td>TRUCK DRIVERS</td>
<td>2.90</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WELDERS - Rate for craft.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>POWER EQUIPMENT OPERATORS:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Backhoes</td>
<td>3.75</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bulldozers</td>
<td>5.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Granes, derricks, draglines</td>
<td>5.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### SUPERSEDAS DECISION

**STATE:** South Carolina  
**COUNTIES:** See below*  
**DECISION NUMBER:** SC79-1045  
**DATE:** Date of Publication  
**Superseded Decision No:** SC79-1040 dated April 14, 1978 in 43 FR 16110  
**DESCRIPTION OF WORK:** Building Construction Projects (does not include single family homes and garden type apartments up to and including 4 stories).

*Abbeville, Edgefield, Greenwood, Laurens, McCormick, Newberry, and Saluda

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H &amp; W</td>
</tr>
<tr>
<td>Air Conditioning Mechanic</td>
<td>850</td>
</tr>
<tr>
<td>Bricklayers</td>
<td>650</td>
</tr>
<tr>
<td>Carpenters</td>
<td>475</td>
</tr>
<tr>
<td>Cement Masons</td>
<td>600</td>
</tr>
<tr>
<td>Electricians</td>
<td>674</td>
</tr>
<tr>
<td>Elevator Constructors</td>
<td>602</td>
</tr>
<tr>
<td>Glaziers</td>
<td>585</td>
</tr>
<tr>
<td>Ironworkers</td>
<td>451</td>
</tr>
</tbody>
</table>
| Laborers:  
| Laborers, unskilled | 300 | 50 | 70 | 10 |
| Mortar mixers | 325 | 50 | 70 | 10 |
| Pipelayers | 325 | 50 | 70 | 10 |
| Lathers | 450 | 50 | 70 | 10 |
| Metal building erector | 400 | 50 | 70 | 10 |
| Painters | 489 | 50 | 70 | 10 |
| Plasterers | 510 | 50 | 70 | 10 |
| Plumbers & Pipefitters | 550 | 50 | 70 | 10 |
| Roofers | 392 | 50 | 70 | 10 |
| Sheet Metal Workers | 518 | 50 | 70 | 10 |
| Sprinkler Fitters | 750 | 50 | 70 | 10 |
| Tile Setters | 575 | 50 | 70 | 10 |
| Truck Drivers | 351 | 50 | 70 | 10 |

**Welders - rate for craft**

**POWER EQUIPMENT OPERATORS:**

<table>
<thead>
<tr>
<th>Basic Hourly Rates</th>
<th>Fringe Benefits Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Backhoe</td>
<td>450</td>
</tr>
<tr>
<td>Bulldozer</td>
<td>400</td>
</tr>
<tr>
<td>Crane, derricks, draglines</td>
<td>450</td>
</tr>
<tr>
<td>Front End Loader</td>
<td>450</td>
</tr>
<tr>
<td>Motor Grader</td>
<td>350</td>
</tr>
<tr>
<td>Scraper - pans</td>
<td>350</td>
</tr>
<tr>
<td>Tractors</td>
<td>450</td>
</tr>
</tbody>
</table>

(FR Doc 79-8839 Filed 3-8-79; 8:45 am)
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

MEDICAL DEVICES

Administrative Detention Procedures
RULES AND REGULATIONS

APPLICABILITY

1. A question has arisen about the applicability of the regulation to veterinary devices.

The Commissioner has decided that the regulation should, for now, apply only to devices intended for human use. In contrast to the provisions of the act that authorize classification, performance standards, and premarket approval only for devices intended for human use, the administrative detention authority in section 304(g) of the act is not expressly limited to devices intended for human use. The legislative history shows, however, that risks to humans were the moving force behind the Medical Device Amendments of 1976 (H. Comm. on Interstate and Foreign Commerce, Medical Amendments of 1976, H.R. Rep. No. 94-853, 94th Cong. 2d Sess. 14 (1976)). Similarly, the agency's principal concern in the medical devices area is risks to human health. If the Commissioner decides that FDA needs to have authority to detain adulterated or misbranded veterinary devices, the agency will propose an amendment to the regulation.

CRITERIA FOR ORDERING DETENTION

2. One comment on proposed § 800.55(b) stated that the detention procedure should be used only if the manufacturer, importer, owner, or distributor refuses to suspend voluntarily shipments of the device.

The Commissioner disagrees with the comment. There is no statutory requirement that persons having possession of devices must have refused an FDA request to suspend or discontinue shipments before FDA can order detention. When demands to voluntarily suspend shipments are broken, the public may be exposed to violative products, and enforcement efforts may be hampered. The Commissioner recognizes, however, that in certain circumstances, voluntary suspension of shipments may be an appropriate alternative to administrative detention. The Commissioner believes that each FDA District Director has the authority to permit a voluntary suspension of distribution rather than to order detention if the district director believes, based on the facts in a given situation, that the person having possession of the device will voluntarily suspend shipment and adhere to any agreement with FDA to correct any possible violations before distribution of the device. There is no need for the regulation to include a description of this authority. FDA always has the option to accept voluntary compliance with a regulation instead of taking legal or administrative action to compel compliance.

3. Three comments on proposed § 800.55(b) suggested that the person having possession of a device should be given notice and an opportunity to discuss the detention, with an FDA representative, before issuance of the detention order.

The Commissioner does not believe that the regulation should include provision for notice and opportunity for discussion before issuance of a detention order. A requirement of prior notice and opportunity for discussion would unduly burden the administrative detention procedure, lessening its effectiveness. Such a requirement may also result in shipment of violative products before issuance of a detention order. The FDA inspection during which the detention occurs does provide an opportunity to discuss the situation with FDA representatives. It is FDA policy for investigators, upon completion of inspections, to meet with management of regulated firms to discuss findings and observations. Those discussions may address the circumstances that led to the detention, but ordinarily would not occur until after issuance of the detention order.

4. Three comments on proposed § 800.55(b) suggested that "technically" misbranded or adulterated devices not be detained unless the devices present a public health hazard.

The Commissioner disagrees with the comment. There is no reason to include in the regulation a provision that the statute imposes neither on detentions nor on FDA-initiated legal actions. One purpose of administrative detention authority is to make FDA-initiated legal actions more effective in preventing shipment of violative devices. For this reason, FDA's authority to detain violative devices is as broad as its authority to initiate a seizure or an injunction suit to prevent shipment of these devices. Moreover, in many cases adulterated or misbranded devices do present a health hazard. At the time of detention, however, FDA may not know whether a hazard exists and, if so, the degree of hazard.

5. Other comments on proposed § 800.55(b) suggested that guidelines or criteria for ordering detention are needed.

The Commissioner disagrees with the comments. There is no reason to include in the regulation a provision that the statute imposes neither on detentions nor on FDA-initiated legal actions. One purpose of administrative detention authority is to make FDA-initiated legal actions more effective in preventing shipment of violative devices. For this reason, FDA's authority to detain violative devices is as broad as its authority to initiate a seizure or an injunction suit to prevent shipment of these devices. Moreover, in many cases adulterated or misbranded devices do present a health hazard. At the time of detention, however, FDA may not know whether a hazard exists and, if so, the degree of hazard.

6. Other comments on proposed § 800.55(b) suggested that guidelines or criteria for ordering detention are needed.

The Commissioner disagrees with the comments. There is no reason to include in the regulation a provision that the statute imposes neither on detentions nor on FDA-initiated legal actions. One purpose of administrative detention authority is to make FDA-initiated legal actions more effective in preventing shipment of violative devices. For this reason, FDA's authority to detain violative devices is as broad as its authority to initiate a seizure or an injunction suit to prevent shipment of these devices. Moreover, in many cases adulterated or misbranded devices do present a health hazard. At the time of detention, however, FDA may not know whether a hazard exists and, if so, the degree of hazard.
RULES AND REGULATIONS

ing or adulteration violations. Moreover, the procedures in the regulation, especially the requirement of FDA District Director approval of detentions, will ensure that the administrative detention remedy is applied only in appropriate cases. If additional guidelines or criteria are needed, they will be specified in internal FDA manuals that are available to the public.

PERIOD OF DETENTION

6. One comment suggested that proposed § 800.55(c) could be interpreted to mean that the Commissioner may authorize a detention period of 30 days beyond the original 20 days initially ordered.

The Commissioner agrees with the comment and emphasizes that the total detention period cannot exceed 30 calendar days (i.e., 20 calendar days initially plus 10 additional calendar days if an extension of the period is warranted) except as provided in § 800.55(d)(6). Section § 800.55(c) of the final regulation, therefore, has been clarified.

7. Several comments on proposed § 800.55(c) argued that the original 20-day order should be extended only by order of an FDA Regional Director. Related comments suggested that only the FDA Bureau of Medical Devices should be empowered to extend the order.

The Commissioner believes that FDA Regional Directors, who are in direct contact with the investigators and the circumstances involved in each case, are in the best position to make these decisions. In most instances, the FDA Regional Director and the Director of the Bureau of Medical Devices will be too remote in the chain of supervision from the investigators and circumstances involved to discharge this function effectively. Any FDA Regional Director who would preside over any regulatory hearing on a detention order may not participate in a decision to extend the detention period, under FDA's regulations to ensure fairness in regulatory hearings. (See 21 CFR 16.40.) Therefore, no change is made in the final regulation.

ISSUANCE OF DETENTION ORDER

8. Three comments on proposed § 800.55(d) suggested that detention procedures apply to devices in the hands of users, including consumers, during inspections. In the past, FDA has initiated seizures of violative articles in the hands of consumers and other users. (See, e.g., United States v. Olsen, 161 F.2d 699 (9th Cir. 1947); cert. denied, 332 U.S. 768; United States v. U.S. London Line, 218 F.2d 578 (2d Cir. 1955).) Although FDA does not believe that it is necessary to include the term "user" in the regulation, the agency has, for clarification, amended the final regulation in § 800.55(d) to include this term. FDA advises that devices in the possession of consumers will be detained in such situations as when the devices present a potential danger to health.

9. Several comments on proposed § 800.55(d) argued that the detention order be more specific. Nine comments argued that the detention order should state specifically the reason for the detention.

In response to the comments, the Commissioner is amending the final regulation to require the detention order, which is issued in the form of a detention notice, to include a brief, general statement of the reasons for the detention. The text of the detention notice is available in the Hearing Clerk's office (HPA-305), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. However, in the final regulation, adopting the comments and other suggestions that the detention order be made more specific. For example, the detention order need not contain a description of the exact nature of the suspected violation. Additional comments underscore the usefulness of administrative detention as a swift, informal means of stopping shipment of devices that FDA representatives reasonably believe are violative. Brevity in the detention order is justified because detention is of limited duration and because FDA's regulatory hearing procedures already require FDA to prepare a comprehensive statement of the basis for the detention prior to any regulatory hearing on an appeal of a detention (21 CFR 16.24(d)). In addition, the FDA representative who issued the detention order will, whenever possible, state the reasons for suspecting the device to be adulterated or misbranded, often in the Notice of Inspectional Observations (Form FD-483) presented after the inspection.

10. Two related comments on proposed § 800.55(d) questioned whether common carriers used to transport the devices would be subject to detention orders.

The Commissioner advises that common carriers in possession of devices are subject to detention orders. Proposed § 800.55(d)(2) provided for the notice of detention of devices in a vehicle or other carrier of the devices. Vehicles in which devices are detained may not be moved until the devices are removed from the vehicles. Because proposed § 800.55(d)(2) did not contain a provision covering such removal, the agency has amended § 800.55(d)(3) in the final regulation to allow the removal from vehicles of detained devices upon written approval of the Commissioner. If suitable storage is available, the authorized FDA representative may permit the removal from the vehicle of detained devices at the carrier's, consignor's, or consignee's request, or if storage and handling of the devices may not be at government expense.
and the devices may only be removed from storage in accordance with §800.55(h). The Commissioner objects to the comment. Although the proposed regulation did not directly prohibit use of detained devices, proposed §800.55(f)(2) stated that official FDA labels or tags affixed to the detained devices shall contain a statement that the devices shall not be used, moved, altered, or tampered with in any manner by any person. The Commissioner has amended §800.55(a) of the final regulation to clarify that “use” of detained devices during the detention period is prohibited.

APPEAL OF THE DETENTION ORDER

The Commissioner agrees with the comment. In many instances it is unlikely that both parties will be prepared for the hearing within 5 calendar days, and special provisions would be necessary if the hearing date fell on a weekend. Accordingly, FDA has provided that the time frame shall be 5 working days.

Another comment on proposed §800.55(g) suggested that a manufacturer should, as a matter of right, be able to obtain an expedited appeal hearing where the detention will cause a contract violation with a consignee. The Commissioner rejects the suggestion as unnecessary. An appellant must file a request for hearing within 5 working days after receiving the detention order and may request that the hearing be held within 5 working days after the appeal is filed. It is unlikely that a faster procedure could be devised. There is nothing in the regulation to prevent presiding officers from granting requests to hold a hearing less than 5 working days after an appeal is filed, if the parties are prepared for a hearing that soon.

Because FDA believes that any hearing should be conducted within a specified time period to swiftly resolve an appeal, the agency has changed §800.55(f)(1) and (f)(6) of the final regulations to require that an requested hearing be scheduled no later than 20

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
The agency has redesignated proposed § 800.55(g)(8) as (g)(9) and has added a new § 800.55(g)(8) to the final regulation to specify that when the presiding officer affirms an order, the devices detainted after FDA terminates the detention or the detention period expires, whichever occurs first.

The Commissioner has amended § 800.55(g)(3) to identify those requirements of 21 CFR Part 16—Regulatory Hearing Before the Food and Drug Administration, that do not apply to hearings on appeals of detention orders. First, the detention order under paragraph (d) of this section, rather than the notice under § 16.24(a), provides notice of opportunity for a hearing under § 800.55. In this way, FDA can provide for a standardized, personally delivered form to serve both as the detention order and as the notice of opportunity for a hearing. In addition, the detention order, rather than the notice under § 16.24(a), is part of the administrative record of a regulatory hearing under § 800.55. Second, a request for a hearing under § 800.55 should be addressed to the FDA district director, not to the presiding officer as provided in the second sentence of § 16.24(b). Third, the last sentence of § 16.24, stating that a hearing may not be required to be held at a time less than 2 working days after receipt of the request for a hearing, does not apply to a hearing under § 800.55 because of the time constraints imposed by section 30(g) of the act. Fourth, the specific provisions of § 800.55(g)(4), rather than the general provisions of § 16.40(a), describe the FDA employees, i.e., regional food and drug directors, who preside at hearings under § 800.55.

In the Federal Register of November 7, 1978 (43 FR 51966), FDA published proposed revisions of the procedures in Part 16 that govern FDA's regulatory hearings. When FDA publishes these proposed revisions in final form, the agency will make any necessary conforming changes in § 800.55.

**Movement of Detained Devices**

27. Two comments on proposed § 800.55(h) argued that permission to complete in-process devices should not be at the discretion of the Commissioner. The Commissioner agrees with the comment and is amending § 800.55(h)(2) of the final regulation to allow a manufacturer to move detainted devices “within” the place where they have been detainted to complete the work needed to put them in final form for shipment. However, to ensure that the agency does not lose track of any detainted devices, the manufacturer is required to notify the agency immediately of any such movement and of the location of the detainted devices after they have been put in final form. The agency has provided that this notification be oral so that FDA will learn of any movement of detainted devices without a minimal burden on the manufacturer.

However, permitting movement of detainted devices “from” the establishment, with only after-the-fact notification to FDA, could interfere with the agency’s ability to take legal action and would increase the likelihood that the devices may be lost, unlawfully moved or used, or mixed with other lots. Therefore, FDA has limited movements of detainted devices at the discretion of the manufacturer to movements “within” the establishment where the devices are detainted. Proposed paragraph (h)(2) (now paragraph (h)(3)) provides for the FDA to approve in writing, in advance, other movement of detainted devices from the establishment for certain specified purposes which FDA believes are appropriate for the given situation.

The Commissioner has modified paragraph (h)(3) in the final regulation to allow FDA representatives other than the district directors to approve movements of devices.

28. Proposed § 800.55(h)(4) references actions, such as initiating legal action, reconditioning of violative devices, and destruction or dismantling in all cases, if the detention order is terminated because § 800.55(h)(4) (now § 800.55(k)) must begin at the time the device is ordered detainted to facilitate a determination of whether and how the device may have become adulterated or misbranded. This requirement is also necessary to permit FDA to trace articles for which the detention period expired before a seizure is accomplished or injunctive relief is obtained. FDA experience with articles for which seizure or injunctive relief has been recommended has revealed numerous instances in which by the time legal action is filed, the articles have been shipped and no records are available to enable the articles to be located.

31. Other comments on proposed § 800.55(i)(1) (now § 800.55(k)) suggested that recordkeeping be discontinued if the detention order is terminated.

The agency believes that recordkeeping is necessary in many cases, if the detention order is terminated because FDA has determined that the devices are not in violation of the act, or that the violation is such that recordkeeping is not necessary to protect the public health, further recordkeeping may be unnecessary, or necessary only for a limited time. The agency has revised the regulation so that, in these cases, FDA will advise persons required to keep records under § 800.55(k) whether further recordkeeping is required. In addition, the required maintenance period for required records shall be 2 years after the detention order or for such shorter period as FDA directs.

**Recordkeeping Requirements**

30. A number of comments were received on proposed § 800.55(1) (now § 800.55(k)) of the final regulation. One comment questioned whether FDA should require recordkeeping by the manufacturer or other person in whose possession the device was detainted before the detention order is confirmed on appeal. The Commissioner believes that recordkeeping requirements under § 800.55(k) must begin at the time the device is ordered detainted to facilitate a determination of whether and how the device may have become adulterated or misbranded. This requirement is also necessary to permit FDA to trace articles for which the detention period expired before a seizure is accomplished or injunctive relief is obtained. FDA experience with articles for which seizure or injunctive relief has been recommended has revealed numerous instances in which by the time legal action is filed, the articles have been shipped and no records are available to enable the articles to be located.

The Commissioner believes that most establishments maintain records required under § 800.55(k) as normal business practice or as required by good manufacturing practices regulations under 21 CFR, part 820. Accordingly, the recordkeeping requirements will not be an unreasonable burden on industry.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
grounds that initiating new records would be burdensome and that these records might be used in product liability claims against the manufacturer. A related comment objected that an investigative file on a detained product is equivalent to an "internal audit.

The Commissioner disagrees with the comments. If the manufacturer or other responsible person would not voluntarily, or as required by the GMP regulation, undertake an investigation to prevent adulterated or misbranded devices from entering commerce, that person should at least be required to gather that information needed to prepare records relating to the facts connected to the detention.

The agency declines to consider the impact that the proposed recordkeeping may have on product liability for injuries from allegedly defective products. This consideration is not properly involved in a general set of procedures to protect the public from adulterated or misbranded devices in commerce. FDA believes that, in the long run, recordkeeping may help prevent future acts of adulteration or misbranding of the device and may thus reduce product liability claims.

33. Additional comments on proposed § 800.55(c) (now § 800.55(k)) questioned whether the recordkeeping provisions relating to detained products are authorized by the statute and whether the provisions violate the constitutional privilege against compelled self-incrimination.

The Commissioner rejects the comments. The recordkeeping required in this regulation is authorized under sections 304(g), 519, and 701(a) of the act.

With respect to the concern about compelled self-incrimination, it is settled that the privilege against compelled self-incrimination is an individual privilege relating to personal matters; the privilege is not available to a collective entity, such as a business enterprise, or to an individual acting in a representative capacity on behalf of a collective entity (California Bankers Ass’n v. Shultz, 416 U.S. 21, 55 (1974); Aetna Life Ins. Co. v. Duff, 297 U.S. 385 (1936); United States v. Kordel, 328 U.S. 535 (1946); United States v. Byers, 380 U.S. 39 (1965)); the privilege does not need to be applied to a recordkeeping requirement when the information is not being used for the purpose of prosecution. The Commissioner advises that term

34. A comment on proposed § 800.55(k) argued that section 704 of the act (21 U.S.C. 374) (which deals with inspections) applies to consulting laboratories only with respect to prescription or other restricted devices. The Commissioner disagrees with the comments. The recordkeeping requirements to records about restricted devices is not applied to "a highly selective group inherently suspect of criminal activities" in "an area permeated with criminal statutes" (California Bankers Ass’n v. Shultz, 416 U.S. 21, 55 (1974); United States v. Kordel, 328 U.S. 535 (1946); United States v. Byers, 380 U.S. 39 (1965)); even in the rare instance that the recordkeeping requirement were to be applied to a recordkeeping requirement when the information is not being used for the purpose of prosecution. The Commissioner advises that term

35. Several comments suggested that the term may be a need for a special means of notifying the parties when a detention order is revoked, if the detained devices are held by several parties at different locations.

The Commissioner agrees with the comments. The notice of detention termination will be sent to each person who received the detention notice. The Commissioner is not persuaded that any additional procedures are needed. To clarify the procedures to be followed upon termination of detention, the Commissioner has added new § 800.55(j) and has referred to this paragraph in § 800.55(c) and (g)(8).

New § 800.55(j) specifies that if FDA decides to terminate the detention, the agency will issue a detention termination notice releasing the devices and remove, or authorize removal of, all detention tags from the devices. The Commissioner advises that termination of the detention order is not to be construed as an agency determination that the device is not adulterated or misbranded, or that further shipments of the device are in compliance with the act.

36. Related comments suggested that the FDA representative detaining the devices be required to release them within 1 day of determining the detention is not warranted or when the detention order is revoked.

The Commissioner advises that devices will be released from detention as soon as possible after determining
that detention should be revoked. In most instances, release will occur within 1 day, but because early release may not always be feasible, the Commission declines to include in the regulation a requirement that devices be released within 1 day after determining that detention should be revoked.

CONFIDENTIALITY OF THE DETENTION ORDER

37. Several comments stated that the detention order should be held confidential until after the time for appeal has expired or until the appeal has been denied.

The agency advises that the detention order will not routinely be publicly announced in FDA's weekly listing of recalls and enforcement actions or otherwise. A detention order may, however, be announced if necessary to inform the public of a potential or direct danger to health, e.g., from shipments of similar devices, or for other appropriate reasons. In addition, information concerning any detention order is releasable under the Freedom of Information Act upon request.

Related comments suggested that if FDA publicly disclosed a detention order, then revoked the order, FDA should make public the revocation. Although a detention order will not routinely be announced or otherwise extensively publicized, the agency agrees that if it does announce a detention order, it should also announce any subsequent revocation of the order.

PENDING COURT ACTIONS

38. One comment suggested that any court action pending at the time a detention order is revoked be dismissed.

It would be inappropriate for the regulation to require dismissal of any pending court action when a detention order is revoked. In appropriate cases FDA will file motions to dismiss a pending court action after revoking an order detaining devices that are the subject of this action. FDA believes that appropriate internal procedures for coordinating seizure and detention actions will adequately address these situations. Moreover, the claimant or respondent in the pending court action can always file a motion to dismiss the action.


1. In Subchapter A, Part 6 is amended in §16.1 by adding new paragraph (b)(32) to read as follows:

§16.1 Scope.

• • • • • • • • •

(b) • • •

(32) Section 800.55(g) relating to an appeal of a detention order under section 304(g) of the act.

2. In Subchapter H by adding a new Part 800, Subpart C, consisting at this time of §800.55 to read as follows:

PART 800—GENERAL

Subparts A-B [Reserved]

Subpart C—Administrative Practices and Procedures

Sec.

800.55 Administrative detention.


Subparts A-B [Reserved]

Subpart C—Administrative Practices and Procedures

§800.55 Administrative detention.

(a) General. This section sets forth the procedures for detention of medical devices intended for human use believed to be adulterated or misbranded. Administrative detention is intended to protect the public by preventing distribution or use of devices encountered during inspections that may be adulterated or misbranded, until the Food and Drug Administration (FDA) has had time to consider what action it should take concerning the devices, and to initiate legal action, if appropriate. Devices that FDA orders detained may not be used, moved, altered, or tampered with in any manner by any person during the detention period, except as authorized under paragraph (h) of this section, until FDA terminates the detention order under paragraph (j) of this section, or the detention period expires, whichever occurs first.

(b) Criteria for ordering detention. Administrative detention of devices may be ordered in accordance with this section when an authorized FDA representative, during an inspection under section 704 of the Federal Food, Drug, and Cosmetic Act (the act), has reason to believe that a device, as defined in section 201(h) of the act, is adulterated or misbranded.

(c) Detention period. The detention is to be for a reasonable period that may not exceed 20 calendar days after the detention order is issued, unless extended under paragraph (g) of this section, and is to be held regardless of the district the devices are located in.

(d) Issuance of detention order. (1) The detention order shall be issued in writing. In the form of a detention notice, signed by the authorized FDA representative who has reason to believe that the devices are adulterated or misbranded, and issued to the owner of the devices at the place where the devices are located. If the owner of the devices is different from the operator, agent in charge of the place where the devices are detained, a copy of the detention order shall be provided to the owner or user of the devices if the owner's or user's identity can be readily determined.

(2) If detention of devices in a vehicle or other carrier is ordered, a copy of the detention order shall be provided to the shipper of record and the owner of the vehicle or other carrier, if their identities can be readily determined.

(3) The detention order shall include the following information: (i) A statement that the devices identified in the order are detained for the period shown; (ii) a brief, general statement of the reasons for the detention; (iii) the location of the devices; (iv) a statement that these devices are not to be used, moved, altered, or tampered with in any manner during that period, except as permitted under paragraph (h) of this section, without the written permission of an authorized FDA representative; (v) identification of the detained devices; (vi) the detention order number; (vii) the date and hour of the detention order; (viii) the period of the detention; (ix) the text of section 304(g) of the act and paragraphs (g) (1) and (2) of this section; (x) a statement that any informal hearing on an appeal of a detention order shall be conducted as a regulatory hearing under Part 16 of this chapter, with certain exceptions described in paragraph (g)(3) of this section; and (xi) the location and telephone number of the FDA district office and the name of the FDA district director.

(f) Appeal of detention order. A detention order, before issuance, shall be approved by the FDA district director in whose district the devices are...
located. If prior written approval is not feasible, prior oral approval shall be obtained and confirmed by written memorandum within FDA as soon as possible.

(i) Labeling or marking a detained device. An FDA representative issuing a detention order under paragraph (d) of this section shall label or mark the device with official FDA tags that include the following information:

(1) A statement that the devices are detained by the United States Government in accordance with section 304(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334(g)).

(2) A statement that the devices shall not be used, moved, altered, or tampered with in any manner for the period shown, without the written permission of an authorized FDA representative, except as authorized in paragraph (h) of this section.

(3) A statement that the violation of a detention order or the removal or alteration of a tag is punishable by fine or imprisonment or both (section 333 of this act, 21 U.S.C. 333).

(4) The detention order number, the date and hour of the detention order, the detention period, and the name of the FDA representative who issued the detention order.

(g) Appeal of a detention order. (1) A person who would be entitled to claim the devices, if seized, may appeal a detention order. Any appeal shall be submitted in writing to the FDA District Director in whose district the devices are located within 5 working days of receipt of a detention order. If the appeal includes a request for an informal hearing, as defined in section 301(y) of the act, the appellant shall request either that a hearing be held within 5 working days after the appeal is filed or that the hearing be held at a later date, which shall not be later than 20 calendar days after receipt of a detention order.

(2) The appellant of a detention order shall state the ownership or proprietary interest the appellant has in the detained devices. If the detained devices are located at a place other than an establishment owned or operated by the appellant, the appellant shall include documents showing that the appellant has legitimate authority to claim the devices if seized.

(3) Any informal hearing on an appeal of a detention order shall be conducted as a regulatory hearing pursuant to regulation in accordance with Part 16 of this chapter, except that:

(i) The order under paragraph (d) of this section, rather than the notice under §16.80(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under §16.80(a) of this chapter.

(ii) A request for a hearing under this section shall be addressed to the FDA District Director, not to the presiding officer who affirms, revokes, or imposes a detention order.

(iii) The last sentence of §16.24(c) of this chapter, stating that a hearing may not be required to be held at a time less than 2 working days after receipt of the request for a hearing, does not apply to a hearing under this section.

(iv) Paragraph (g)(4) of this section, rather than §16.40(a) of this chapter, describes the FDA employees, i.e., a director of an FDA regional office listed in §5.115 of this chapter, who is permitted by §16.40(b) of this chapter to preside over the hearing.

(5) If the appellant requests a regulatory hearing and requests that the hearing be held within 5 working days after the appeal is filed, the presiding officer shall, within 5 working days, hold the hearing and render a decision, affirming, revoking, or imposing the detention.

(6) If the appellant requests a regulatory hearing and requests that the hearing be held at a date later than within 5 working days after the appeal is filed, but not later than 20 calendar days after receipt of a detention order, the presiding officer shall hold the hearing at a date agreed upon by FDA and the appellant. The presiding officer shall decide whether to affirm or revoke the detention within 5 working days after the conclusion of the hearing. The detention period extends to the date of the decision even if the 5-working-day period for making the decision extends beyond the otherwise applicable calendar-day or 30-calendar-day detention period.

(7) If the appellant appeals a detention order but does not request a regulatory hearing, the presiding officer shall render a decision on the appeal affirming or revoking the detention within 5 working days after the filing of the appeal.

(8) If the presiding officer affirms a detention order, the devices continue to be detained under §16.24(c) of this chapter. If the appeal is not filed within 5 working days of the conclusion of the appeal, the order is affirmed.

(9) If the presiding officer revokes a detention order, FDA shall terminate the detention under paragraph (j) of this section.

(h)(1) Movement of detained devices. Except as provided in this paragraph, no person shall move detained devices within or from the place where they have been ordered detained until FDA terminates the detention under paragraph (l) of this section or the detention period expires, whichever occurs first.

(2) If detained devices are not in final form for shipment, the manufacturer may move them within the establishment where they are detained to complete the work needed to put them in final form. As soon as the devices are moved for this purpose, the individual responsible for their movement shall orally notify the FDA representative who issued the detention order, or another responsible district office official, of the movement of the devices. As soon as the devices are put in final form, they shall be segregated from other devices, and the individual responsible for their movement shall orally notify the FDA representative who issued the detention order, or another responsible district office official, of their new location. The devices put in final form shall not be moved further without FDA approval.

(3) The FDA representative who issued the detention order, or another responsible district office official, may approve, in writing, the movement of detained devices for any of the following purposes:

(i) To prevent interference with an establishment's operations or harm to the devices.

(ii) To destroy the devices.

(iii) To bring the devices into compliance.

(iv) For any other purpose that the FDA representative who issued the detention order, or other responsible district office official, believes is appropriate in the case.

(4) If an FDA representative approves the movement of detained devices under paragraph (h)(3) of this section, the detained devices shall remain segregated from other devices and the person responsible for their movement shall immediately orally notify the official who approved the movement of the devices, or another responsible FDA district office official, of the new location of the detained devices.

(5) Unless otherwise permitted by the FDA representative who is notified of, or who approves, the movement of devices, the devices shall remain segregated from other devices or in final form for shipment, and shall remain with the devices until FDA terminates the detention or the detention period expires, whichever occurs first.

(i) Actions involving adulterated or misbranded devices. If FDA determines that the detained devices, including any that have been put in final form, are adulterated or misbranded, or both, it may initiate legal
action against the devices or the responsible individuals, or both, or request that the devices be destroyed or otherwise brought into compliance with the act under FDA's supervision.

(j) Detention termination. If FDA decides to terminate a detention or when the detention period expires, whichever occurs first, an FDA representative authorized to terminate a detention will issue a detention termination notice releasing the devices to any person who received the original detention order or that person's representative and will remove, or authorize in writing the removal of, the required labels or tags.

(k) Recordkeeping requirements. (1) After issuance of a detention order under paragraph (d) of this section, the owner, operator, or agent is charge of any factory, warehouse, other establishment, or consulting laboratory where detained devices are manufactured, processed, packed, or held shall have, or establish, and maintain adequate records relating to how the detained devices may have become adulterated or misbranded, records on any distribution of the devices before and after the detention period, records on the correlation of any in-process detained devices that are put in final form under paragraph (h) of this section to the completed devices, records of any changes in, or processing of, the devices permitted under the detention order, and records of any other movement under paragraph (h) of this section. Records required under this paragraph shall be put in final form under paragraph (h) of this section to the completed devices, records of any changes in, or processing of, the devices permitted under the detention order, and records of any other movement under paragraph (h) of this section. Records required under this paragraph shall be provided to the FDA on request for review and copying. Any FDA request for access to records required under this paragraph shall be made at a reasonable time, shall state the reason or purpose for the request, and shall identify to the fullest extent practicable the information or type of information sought in the records to which access is requested.

(2) Records required under this paragraph shall be maintained for a maximum period of 2 years after the issuance of the detention order or for such other shorter period as FDA directs. When FDA terminates the detention or when the detention period expires, whichever occurs first, FDA will advise all persons required under this paragraph to keep records concerning that detention whether further recordkeeping is required for the remainder of the 2-year, or shorter, period. FDA ordinarily will not require further recordkeeping if the agency determines that the devices are not adulterated or misbranded or that recordkeeping is not necessary to protect the public health, unless the records are required under other regulations in this chapter (e.g., the good manufacturing practice regulation in Part 820 of this chapter).

Effective date. This regulation becomes effective April 9, 1979.

(Dated: March 1, 1979.

JOSEPH P. HILL
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-7030 Filed 3-8-79; 8:45 am]
FRIDAY, MARCH 9, 1979
PART V

DEPARTMENT OF LABOR
Employment and Training Administration

FY 1979 VETERANS PREFERENCE INDICATORS OF COMPLIANCE LEVELS
Title 20—Employees’ Benefits

CHAPTER V—EMPLOYMENT AND TRAINING ADMINISTRATION, DEPARTMENT OF LABOR

PART 653—SERVICES OF THE EMPLOYMENT SERVICE SYSTEM

Subpart C—Services for Veterans

FISCAL YEAR 1979 VETERANS PREFERENCE INDICATORS OF COMPLIANCE LEVELS

AGENCY: Employment and Training Administration, Labor.

ACTION: Final Rule.

SUMMARY: These regulations are published to establish the FY 1979 levels for the veterans preference indicators of compliance, used by the Department of Labor to monitor State employment service agencies to ensure that veteran applicants receive priority service.

EFFECTIVE DATE: April 9, 1979.

FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION: The Department published proposed regulations for the FY 1979 compliance levels on October 27, 1978, at 43 FR 56379. Interested persons were advised to submit comments on the proposed levels until November 27, 1978. The Department received approximately thirty comments from components of the public employment service system, veterans organizations and general public. The most significant comments and the Department's responses thereto are listed below:

1. Some commentors suggested uniform job development and inactivated with some reportable service floor levels be established for all States to eliminate the inequity among States and, at the same time, more effectively promote service to veterans. The Department, in accordance with 20 CFR 653.230(c), based its computations of individual State job development and inactivated with some reportable service floor levels on State agency past-year accomplishments and the influence of external factors such as State, employment conditions and occupational differences among the applicant population. The regression analysis used to set the proposed floor levels, however, did not reflect the direct and substantial control that State agencies have over delivery of these services to veterans. Thus, the Department acknowledges that various State agencies have successfully undertaken specific management actions to increase job development and overall reportable services to veterans.

In light of these experiences, the Department has determined that management control over the provision of these services is an appropriate factor under 20 CFR 653.230(c) to be used in computing State agency floor levels. State performance and influence of management control, the Department has changed the proposed FY 1979 individual State floor levels as published in the Federal Register on October 27, 1978 to a job development level of 7.3 percent for job development and 60.0 percent for inactivated with some reportable service to be applied to all States.

Several State employment service agencies objected to the variation in individual State floor levels established for placement of veterans. Commentors indicated individual State floor levels for this service area were too high for high performing States and too low for the low performing States. A national floor level requirement that would not vary among States was suggested as a substitute for the proposed FY 1979 individual State placement levels. The Department, however, has found that the proposed individualized placement floor levels are necessary to allow for differing economic and other external conditions among States.

Unlike job development and inactivated with some reportable service (discussed above), placement is an area over which management does not have substantial control. External factors such as employer hiring decisions, level of unionization in nonfarm employment, level of unemployment and distribution of occupational skills among applicants affect the ability of the State agency to achieve placement success. The Department anticipated that high performing States will have little difficulty in meeting their assigned floor level for this indicator. It should also be remembered that failure to meet the placement floor level or preference indicators does not automatically place a State agency into noncompliance with the standards of performance in the regulations. Changed economic conditions may be taken into account when the Department determines whether or not a State agency is in compliance. Accordingly, the proposed floor levels for each State have been adopted without change.

Several State employment service agencies commented that the proposed referred to training indicators and corresponding floor and preference levels were based on insufficient data and did not take into account the limited training opportunities which will be available to ES veteran applicants given the emphasis of the 1978 CETA Reauthorization on serving the economically disadvantaged. Some commentors stressed the need to clarify the definition of “referred to training” in view of the different interpretation by State agencies as to what can appropriately be reported for these indicators. One commenter believed the preference level for disabled veterans referred to training was too high and did not reflect the exposure to counseling and rehabilitation services disabled veterans receive from the Veterans Administration prior to filing job applications with ES. Several commentors suggested that the Department conduct further review of the proposed referred to training indicators before including them in the veteran indicators of compliance package.

The Department proposed the establishment of referred to training indicators to measure services provided in accordance with the requirements of 38 U.S.C. Chapter 41 and the performance standards described in Federal regulations at 20 CFR 653.221(a)(17). However, the Department considers the comments received pertaining to these indicators. One commenter believed the proposed indicator for the referred to training indicator for FY 1978 CETA Reauthorization and on serving the disadvantaged could limit training opportunities for ES veteran applicants since less than one-fourth of ES's veteran applicants are economically disadvantaged during any given year. In addition, the Department agrees that inadequate historical data is currently available to set meaningful levels for the referred to training indicators. Since the decision to include referred to training as a reporting item on the Department's Employment Security Automated Reporting System (ESARS) was not reflected on the FY 1978 ESARS reporting forms, some confusion arose concerning how to record these referred to training counts. The result was inconsistent implementation of the referred to training reporting standards during FY 1978. In view of these concerns the Department believes the inclusion of referred to training indicators of compliance for FY 1979 would not be appropriate at this time. Accordingly, the Department will reconsider the establishment of referred to training indicators for FY 1980.

As a result of the Department's decision to delay implementation of the referred to training indicators, State agencies will be required to meet the placement and any two of the remain-
ing floor levels of accomplishment and meet nine of the sixteen veterans preference indicators described at 20 CFR 653.230.

4. One commentator complained that the proposed FY 1979 preference level for placement of disabled veterans was too high, since some disabled veterans are very selective in their job choices due to the uncertainty of work prospects if a job can have on their receipt of disability payments. The Department was informed by the Veterans Administration (VA) that compensation received by disabled veterans is affected by job acceptance. Therefore, the Department most likely would have the proposed placement preference level for disabled veterans necessary to ensure that the special needs of these veterans are addressed by all State agencies. Therefore, the proposed FY 1979 preference level for placement of disabled veterans will remain unchanged.

5. Several commentators felt that the proposed indicators were too low in view of the statutory requirement in 38 U.S.C. 2007(a)(1) that the Secretary of Labor establish a comprehensive standards of performance governing services to veterans and eligible persons which must be met by State agencies. ETA Regional Administrators have responsibility for the quarterly review and assessment of State agency compliance with these standards of performance pursuant to 20 CFR 653.230(c).

The veterans preference indicators provide an additional monitoring and assessment instrument for determining compliance in accordance with the mandate of 38 U.S.C. 2007(b). The indicators set numerical values for measuring some key areas of service to veterans and eligible persons utilizing data available through the Department’s ESARMS reporting system. The Department drafted the proposed indicators for FY 1979 after analyzing performance data from FY 1977 and FY 1978. The Department adapts the indicators to a level which could be realistically achieved but which would encourage improvement by low performing State agencies. The value of this approach has been demonstrated by the continuing decline, over the past two years, in the number of State agencies not meeting the indicators. Furthermore, the Department intends to analyze this year’s results carefully so that any appropriate adjustments may be made for FY 1980.

6. Three commentators discussed the problems involved with the placement of disabled Vietnam-era veterans in the so-called mandatory job listing openings which government contractors are required to list with the employment service under 38 U.S.C. 2012(a). The comments pointed out that the number of recently separated Vietnam-era veterans would be minimal after May 1979 because of the definitional limitation to veterans submitting job applications within four years of their discharge from the military. This definitional restriction would in turn make it difficult for State employment service agencies to meet the preference indicator for mandatory job listings. One commentator also expressed concern that veterans who faced combat in Vietnam and who were discharged from the military more than four years ago would not be eligible for the preference.

The Department notes that Congress was explicit in its determination that recently separated Vietnam-era veterans be provided preference in job openings which government contractors are required to list with the employment service under 38 U.S.C. 2012(a). Any change with regard to this statutory preference would therefore have to be made by Congress. The Department does not anticipate that the definitional limitation for recently separated Vietnam-era veterans will be a significant barrier to State agency compliance with the mandatory job listing preference indicator in FY 1979 and, therefore, the preference level has not been changed. However, to the extent that the definitional limitation may be shown to substantially prevent a State agency from complying with this preference indicator, the Department may consider such a showing as good cause evidence for noncompliance under 20 CFR 653.230(c)(2). Since the impact of the definitional limitation will be felt most heavily in FY 1980, the Department will reconsider its position on this issue at that time.

7. One commentator suggested that the number of veterans inactivated with some reportable service be measured against the total number of veterans who were inactivated. Current practice is to measure the number of veterans inactivated with some reportable service against the total number of veteran applicants, in both active and inactive status. Although this suggested change would provide a more technically accurate measure of service rates for veterans inactivated with some reportable service, the Department has determined that it would not be in the best interest of the veterans served to change the method of computation at this time. The current method of computation affords a reasonably accurate measure of overall services provided to veterans. Moreover, such a substantial change in methodology following only one year of experience with the current formulas may create unnecessary confusion and reduce the potential effectiveness of the compliance indicators in promoting increased services to veterans. However, the Department will further consider the suggested computational change in the future.

The final regulations also make several clarifying and technical changes to reflect recent organizational changes within ETA. For the convenience of its readers, the Department is republishing the entire 20 CFR Part 653, Subpart C, as amended.

Accordingly, 20 CFR Chapter V, part 653, Subpart C, is revised to read as follows:

Subpart C—Services for Veterans

PURPOSE AND DEFINITIONS

Sec. 653.200 Purpose and scope of subpart.

653.201 Definitions of terms used in subpart.

FEDERAL ADMINISTRATION

653.210 Role of the Administrator.

653.211 Role of the Veterans Employment Service (VES).

653.212 Role of Regional Administrator (RA).

653.213 Assignment and role of Regional Veterans Employment Representatives (RVERs).

653.214 Assignment and role of State Veterans Employment Representatives (SVERs).

STANDARDS OF PERFORMANCE GOVERNING STATE AGENCY SERVICES TO VETERANS AND ELIGIBLE PERSONS

653.220 Standards of performance.

653.221 Standards of performance governing State agency services.

653.222 Performance standard on facilities for VES staff.

653.223 Performance standards on reporting.

653.224 Performance standards governing the assignment and role of Local Veterans' Employment Representatives (LVERs).

653.225 Standards of performance governing State agency cooperation and coordination with other agencies and organizations interested in the employment development of veterans and eligible persons.

653.226 Standards of performance governing complaints of veterans and eligible persons.
RULES AND REGULATIONS

FEDERAL MONITORING OF STATE AGENCY COMPLIANCE.

653.200 Veterans preference indicators of compliance.

653.211 Secretary's annual report to Congress.


Subpart C—Services for Veterans

PURPOSE AND DEFINITIONS

§ 653.200 Purpose and scope of subpart.

(a) This subpart contains the Department of Labor's regulations for implementing 38 U.S.C. 2001-2059 (Chapter 41) which requires the Secretary of Labor to refer eligible veterans and eligible persons to employment and training opportunities through the public employment service system established pursuant to the Wagner-Peyser Act, as amended, 49 U.S.C. et seq.

(b) This subpart reiterates the requirement contained in the Department of Labor's Office of Federal Contract Compliance Programs' regulations under 38 U.S.C. 2007(c) that requires the Secretary of Labor to refer eligible veterans to job openings listed with them by certain Federal contractors pursuant to 38 U.S.C. 2007(c). Section 653.221(a)(7)(i), moreover, goes beyond the requirement of 41 CFR 60-250.33, paragraphs (a) and (b), require State employment service agencies to refer qualified disabled veterans and veterans of the Vietnam era on a priority basis to job openings listed with them by certain Federal contractors pursuant to 38 U.S.C. 2007(c). That regulation provides that disabled veterans and veterans of the Vietnam era may file with Local Veterans' Employment Representatives complaints alleging violations of 38 U.S.C. 2007(c) or of the Department's regulations at 41 CFR Part 60-250.40. 41 CFR 60-250.26 also sets forth the procedures for handling such complaints.

(d)(1) This subpart partially implements section 104 of the Emergency Jobs and Unemployment Assistance Act of 1974, Pub. L. 93-567, 88 Stat. 1945, Sec. 104 of that Act requires the Secretary of Labor, in consultation and cooperation with the Administrator of Veterans' Affairs and the Secretary of Health, Education, and Welfare, to provide a comprehensive employment and public information program to produce jobs and training opportunities for all persons who were discharged from the Armed Forces within four years of the date they apply for such jobs or job training.

(2) The Department has also implemented section 104 of the Emergency Jobs and Unemployment Assistance Act of 1974 in the regulations under Comprehensive Employment and Training Act (CETA) at 29 CFR Parts 94-99.

(3) The Secretary has also implemented section 104 of the Emergency Jobs and Unemployment Assistance Act of 1976 by Secretary's Order 17-76, which established within the Department of Labor a Secretary's Committee on Veterans' Affairs, and which assigns to the Committee the following functions:

- Serving as the principal advisory and coordinating group to the Secretary of Labor on matters affecting veterans;
- Consulting with and providing guidance to the appropriate DOL Agencies and the DOL Program and Review Coordinating Board (PRCB) (reconstituted as the Management Review Committee by Secretary's Order 3-77) on the formulation, implementation and redirection of departmental policies and programs as they affect veterans, especially in the areas of unemployment, job training, employment and reemployment;
- Reviewing the operational effectiveness of departmental plans and programs affecting veterans;
- Facilitating DOL executive-level communications on veterans' affairs within the Department and with other governmental agencies, veterans' organizations, labor, management, and the Congress;
- Reviewing and suggesting research essential to the implementation of effective departmental programs on behalf of veterans; and
- Coordinating the preparation of any reports to the Congress concerning veterans' programs and activities of more than one DOL agency.

(e)(1) This subpart also implements 38 U.S.C. Chapter 42 in that: (i) Title IV of the Vietnam Era Veterans' Readjustment Assistance Act of 1974 amended 38 U.S.C. Chapter 41, section 2007 by adding a new subsection (b) which states:

The Secretary of Labor shall establish definite performance standards for determining compliance by State public employment agencies with the provisions of this chapter and chapter 42 of this title. A full report as to the extent and reasons for any noncompliance by any such State agency during any fiscal year, together with the agency's plan for corrective action during the succeeding year, shall be included in the annual report of the Secretary of Labor required by subsection (c) of this section.

(2) The Secretary shall include as part of the annual report required by section 2007(c) of this title the number of complaints filed pursuant to subsection (b) of this section (2012), the actions taken thereon, and the resolutions thereof. Such report shall also include the number of contractors listing suitable employment openings, the nature, type, and number of positions listed and the number of veterans receiving priority pursuant to subsection (a)(2) of this section.

(3) Since section 2012 of 38 U.S.C. Chapter 42 places responsibilities on State employment service agencies, this subpart prescribes performance standards for such agencies. The Department has also prescribed regulatory standards under 38 U.S.C. 2007 for such agencies at 41 CFR Part 60-260 and 60-270.

(f) This subpart references section 205(c)(5) of the Comprehensive Employment and Training Act of 1973 (CETA), as amended, 29 U.S.C. 801 et seq. Section 205(c)(5) requires that applicants for public service employment under Title II of CETA must provide the Department of Labor with assurances that they will give special consideration to certain unemployed veterans who served in the Armed Forces in Indochina or Korea on or after August 5, 1964. (See 29 CFR 94.4(2).)

§ 653.201 Definitions of terms used in subpart.

"Administrator, United States Employment Service (Administrator)" shall mean the chief official of the United States Employment Service (USES).

"Assistant Veterans' Director for Employment (ASDVE)" shall mean a Federal employee who is designated as an assistant to the State Director for Veterans' Employment (SDVE).

"Deputy Assistant Secretary for Veterans Employment (DASVE)" shall mean the Department of Labor official who is the chief official of the Veterans Employment Service.

"Disabled Veteran" shall mean either: (1) A person entitled to disability compensation under laws administered by the Veterans Administration for a disability rated at less than 30 per centum, or (2) a person who is a "special disabled veteran" as defined in this section. (Note: Special disabled veterans are a subcategory of disabled veterans. Persons who are special disabled veterans, therefore, are one kind of disabled veterans, but they shall be pursuant to subsection (b) of this section for application and referral purposes.) "Eligible person" shall mean:
(1) The spouse of any person who died of a service-connected disability; or

(2) The spouse of any member of the armed forces serving on active duty who, at the time of application for assistance under this subpart, is listed pursuant to 37 U.S.C. 556 and the regulations issued thereunder, by the Secretary concerned, in one or more of the following categories and has been so listed for a total of more than 90 days: (i) Missing in action, (ii) captured in line of duty by a hostile force, or (iii) forcibly detained or interned in line of duty by a foreign government or power; or

(3) The spouse of any person who has a total disability permanent in nature resulting from a service-connected disability or the spouse of a veteran who died while a disability so evaluated was in existence.

"Eligible veteran" means a person who served in the active military, naval, or air service and who was discharged or released therefrom with other than a dishonorable discharge.

"Local Veterans' Employment Representative (LVER)" means an official in a local office of a State employment service agency, designated by the State Director to serve veterans and eligible persons pursuant to this subpart.

"Recently separated veteran of the Vietnam era" means a "veteran of the Vietnam era" who was discharged or released from active duty within 48 months of his/her application for employment.

"Regional Administrator (RA)" shall mean the chief official of the Employment and Training Administration in each Department of Labor region.

"Regional Director for Veterans' Employment (RDVE)" shall mean the Federal official designated by the DASVE, who, under the RDVE, serves the employment needs of veterans and eligible persons in a particular State pursuant to this subpart.

"United States Employment Service (USES)" shall mean the component of the Employment and Training Administration of the Department of Labor, established under the Wagner-Peyser Act of 1933 to coordinate a national system of public employment service agencies.

"Veteran" shall mean "eligible veteran", "disabled veteran", "special disabled veteran", and "Vetern of the Vietnam era".

"Veteran of the Vietnam era" shall mean a person who: (1) Served on active duty for a period of more than 180 days, any part of which occurred during the Vietnam era as defined in section 107(26) of the Vocational Rehabilitation Act of 1964 through May 7, 1975 and was discharged or released therefrom with other than a dishonorable discharge; or (2) was discharged or released from active duty for a service-connected disability if any part of such active duty was performed during the Vietnam era.

"Veterans Employment Service (VES)" shall mean the organizational component within the Employment and Training Administration which is concerned with policies and services relating to employment development on behalf of veterans and eligible persons.

FEDERAL ADMINISTRATION

§653.210 Role of the Administrator.

The Administrator, USES, shall have overall responsibility for administering this subpart and for monitoring, in coordination with other ETA components, State agency compliance with the regulations under this subpart.

§653.211 Role of the Veterans Employment Service (VES).

(a) The Deputy Assistant Secretary for Veterans Employment (DASVE) shall monitor and evaluate the performance of the State agencies under this subpart. The DASVE shall make every effort, in coordination with the Veterans Administration, Department of Health, Education, and Welfare, other Federal and State agencies, educational institutions, unions, veterans organizations, and community groups to produce job and training opportunities for veterans and eligible persons through Department of Labor administered programs relating to unemployment, job training, and employment.

(b) The DASVE shall have a VES field staff comprised of Regional Directors for Veterans' Employment (RDVES), State Directors for Veterans' Employment Representatives (SDVES), and assistants to the SDVES (ASDVES) and their staffs. RDVES, SDVES and ASDVES shall provide functional supervision, guidance and assistance to the State agencies pursuant to this subpart.


§653.212 Role of the Regional Administrator (RA).

Each RA shall have overall responsibility in the region for administering this subpart and for monitoring State agency compliance with the regulations under this subpart.

§653.213 Assignment and role of Regional Veterans' Employment Representatives (RVERs)

(a) The DASVE shall assign an RDVE to each Employment and Training Administration office. Every RDVE shall be an eligible veteran, who shall be appointed pursuant to the provisions of 5 U.S.C. which govern appointments in the Federal competitive service, and who shall be paid pursuant to the provisions of 5 U.S.C which govern appointments in the Federal competitive service, and who shall be paid pursuant to the provisions of 5 U.S.C. Chapter 51, and Chapter 53 of subchapter III.

(b) An RDVE shall be stationed in each ETA regional office. The RDVE shall be a member of the ETA regional executive staff.

(c) The RDVE shall provide advice and expertise to the RA on matters relating to ETA services to veterans and eligible persons. The RDVE shall also:

(1) Supervise the activities of all VES field staff within the region;

(2) Provide support in the coordination of, all ETA policies and programs as they affect veterans, especially policies and programs relating to unemployment, job training, and employment by:

(i) Providing direction and support to SDVES and ASDVES;

(ii) Reviewing SDVEs and ASDVEs and other findings and recommendations of State agency compliance with the regulations under this subpart and recommending appropriate corrective action to the RA;

(iii) Assist the overall ETA regional office staff in the coordination of ETA employment and training programs as they affect veterans;

(iv) Coordinating within the region ETA activities relating to veterans' services with other agencies and organizations, such as the Department of Defense, the Veterans Administration, the U.S. Civil Service Commission, the President's Committee on Employment of the Handicapped, the Office of Vocational Rehabilitation and other Department of Health, Education, and Welfare agencies, labor.
unions, veterans organizations, employers and community organizations; 
(v) Cooperating with the Employment Standards Administration of the Department of Labor in the resolution of complaints by veterans under the Department's regulations at 41 CFR Part 653, Subpart D; and 
(vi) Monitoring and assessing unemployment, job training, employment and other services to veterans under ETA regulations.

(3) Monitor and evaluate State agency performance under this subpart by:

(i) Reviewing and analyzing monthly, quarterly and annual reports required by ETA data systems. SDVEs shall be assigned to each State agency by comparing the statistics generated by the veteran preference indicators of compliance set forth in § 653.230 against the performance standards set forth at § 653.221–26; and

(ii) With input from SDVEs as appropriate, assisting the RA in conducting that portion of periodic and special reviews of State agency performance pertaining to the provision of services to veterans.

§ 653.214 Assignment and role of State Veterans' Employment Representatives (SDVEs)

(a) A representative of the VES shall be assigned to each State agency to serve as the State (Director for Veterans’ Employment (SDVE)). One Assistant (Director for Veterans’ Employment Representative (ASDVE)) shall be assigned to each State agency to serve as the Veterans' Employment Representative (VES) for each 250,000 eligible veterans and eligible persons in the State population and additional (ASDVEs) shall be assigned whenever the data collected under this subpart indicates that additional ASDVEs are necessary.

(b) Each SDVE and ASDVE shall be an eligible veteran, who, at the time of appointment, shall have been a bona fide resident of the State for at least 2 years, and shall be appointed pursuant to the provisions of 5 U.S.C. which govern appointments to the Federal competitive service, and who shall be paid pursuant to the provisions of 5 U.S.C. Chapters 51 and 55. Chapter 53, Subchapter III.

(c) The SDVE, ASDVEs, and their VES Federal support staff shall be attached to the State office staff of the State agency to which they are assigned.

(d) Under the direction and supervision of the RDVE, and in cooperation with the State agency staff and the staffs of other ETA funded employment and training programs in the State, the ASDVEs and SDVE shall:

1. Provide support and assist in coordinating all ETA policies and all ETA funded programs in the State as they affect veterans and eligible persons, especially policies and programs relating to unemployment, job training, and employment;

2. Functionally supervise services to veterans by the State agency. Functional supervision shall consist of assigning a Supervisor of Employment and Training Programs to carry out services to veterans and eligible persons and evaluating their performance. Functional supervision shall entail providing technical assistance, making suggestions for improvement of programs, helping to locate programs and projects, checking for compliance with ETA regulations affecting veterans helping to correct errors by working with local and State staffs, analyzing work under the Federal Employment and Training Act and other acts including the Veterans Employment Opportunities Act, and matching veterans and eligible persons, training new State agency employees and providing refreshers for State agency staff, bringing matters which require corrective action to the attention of those agency personnel who have authority over policy, procedures and staff. Functional supervision does not authorize an SDVE or ASDVE to hire, fire, discipline or issue directives to State agency employees. It does authorize and SDVE to make regulations, change procedures or establish policies, for the State agency without specific authority from the State agency.

3. Engage in job development and job advancement activities on behalf of veterans and eligible persons, including coordination with the Veterans Administration in its carrying out of the Veterans Outreach Services Program under subchapter IV of chapter 3 of 38 U.S.C., and including the conduct of job fairs, job shops and special programs to match veterans and eligible persons with appropriate and job-training opportunities; and

4. Assist in collecting and maintaining current information on available employment and training opportunities, using, when feasible, electronic data processing and telecommunications systems, and in matching veterans and eligible persons applicants' qualifications with available jobs, training and apprenticeship opportunities;

5. Promote the interest of employers and labor unions in employing and in conducting on-the-job training and apprenticeship programs for veterans and eligible persons;

6. Maintain regular contact with employers, labor unions, training program sponsors and veterans organizations to keep them advised of veterans and eligible persons who are available for employment and training;

7. Keep veterans and eligible persons advised of opportunities for employment and training.

8. Coordinate, in conjunction with the RDVE as appropriate, ETA activities relating to veterans services within the State with the activities of other agencies and organizations such as the Veterans Administration, the Department of Defense, the U.S. Civil Service Commission, the Department of Health, Education, and Welfare, State agencies such as Vocational Rehabilitation agencies, Governors Committees on Employment of the Handicapped, and unions, veterans organizations, employer associations and other community groups.

9. Monitor and evaluate State agency performance under this subpart by:

(i) Monthly, quarterly and annual reports of actual activity levels generated by required data systems;

(ii) Reports generated by the State agency Self-Appraisal System; and

(iii) Internal reports prepared by State agency staffs such as field supervisory, technical assistance and research staffs.


(11) Conduct periodic on-site visits of local offices to assess their performance under this subpart. Such reviews shall include detailed, comprehensive analyses of all local office activities related to serving veterans and eligible persons, and spot-checks of particular local offices to validate information the SDVE has obtained through the State agency Self-Appraisal System, regular data systems, field supervisors, technical staff or otherwise. The SDVE shall review the performance of large local offices at least once each fiscal year on a formal, comprehensive, in-depth basis, and shall periodically review smaller local offices which evidence problems in providing services to veterans and eligible persons pursuant to this subpart until the problems are resolved.

STANDARDS OF PERFORMANCE GOVERNING STATE AGENCY SERVICES TO VETERANS AND ELIGIBLE PERSONS

§ 563.220 Standards of performance.

Sections 563.221–226 set forth the standards of performance governing services to veterans and eligible persons which must be met by the State employment service agencies.

§ 563.221 Standards of performance governing State agency services.

(a) Each State agency shall assure that all of its local offices, using VESRs and other staff, offer the following services to all veterans and eligible persons:

1. Registration. Local offices shall encourage all veterans and eligible persons, veterans organizations, employers and community organizations;
persons to file complete applications for appropriate job or training opportunities by explaining the services they may expect to receive on the filing of a full application. Local offices, however, may take partial applications from disabled veterans and eligible persons if they are job attached, or if they are on strike or layoff and expecting to return to work unless such applicants request the opportunity to file full applications. Local offices may also take partial applications on veteran and eligible person applicants who say they do not wish to file full applications after the benefits of filing a full application have been explained to them.

(2) Interviewing. As appropriate, local offices shall interview veterans and eligible persons on a priority basis to review and analyze the information on their application cards, to assure that all of the applicant's qualifications for employment are adequately presented, to determine any need for employment counseling, to evaluate the occupationally significant facts about the applicants, and to select suitable job choices and job-finding techniques.

(3) Counseling. As appropriate, qualified local office staff shall discuss with veteran and eligible person applicants on a priority basis their present and possible job and training opportunities, to develop alternative vocational choices, and to develop occupational aptitude and proficiency tests to determine any need for employment counseling, to evaluate the occupationally significant facts about the applicants, and to select suitable job choices and job-finding techniques.

(4) Testing. As appropriate, qualified local office staff shall administer objective and subjective tests to veteran and eligible person applicants on a priority basis.

(5) Referral to supportive services. As appropriate, local offices shall refer veteran and eligible person applicants on a priority basis to supportive services available in the community such as medical, legal aid, child care and transportation assistance, which are likely to assist them to obtain employment and/or training.

(6) Job development. As appropriate, local offices shall attempt to develop job openings for veteran and eligible person applicants on a priority basis through employer contacts and otherwise whenever suitable job openings are not available in local office files. Such efforts shall include attempts to foster the elimination of hiring requirements not related to job performance.

Job and training referral. (1) Whenever there is more than one applicant qualified for a job opening, or for a training opportunity, local offices, except as provided in paragraphs (a)(7)(i) and (iii) of this section, shall observe the following order of priority in making referrals to the job openings or training opportunities:

(A) Qualified special disabled veterans;

(B) Qualified veterans of the Vietnam era;

(C) Qualified disabled veterans other than special disabled veterans;

(D) All other qualified veterans and eligible persons;

(E) Qualified nonveterans.

(ii) Whenever there is more than one applicant qualified for a job opening listed under the mandatory listing requirement of 29 U.S.C. 2012, local offices shall observe the order of priority in making referrals set forth in paragraph (a)(7)(i) of this section, except that qualified recently separated veterans of the Vietnam era shall be referred ahead of other qualified veterans of the Vietnam era.

(iii) Whenever a State agency or a local official is a subcontractor or contractor under the Comprehensive Employment and Training Act (CETA) or the Work Incentive (WIN) Program, the local office shall refer veterans to job and training opportunities under those programs in accordance with the CETA regulations at 29 CFR Parts 94-99 or the WIN regulations at 29 CFR Part 56.

(b) State agencies shall:

(1) Establish outreach programs designed to make veterans and eligible persons aware of the ES services available, to include contact with veterans organizations, Veterans Administration facilities, military bases, military hospitals and other appropriate organizations. The State agency public information program shall include disseminating labor market information to assist veterans and eligible persons in job search activities, using public service announcements in the media as appropriate.

(2) Provide special designation, filing and retrieval procedures in each local office to readily identify veteran and eligible person applicants and to monitor the provision of services to veteran and eligible person applicants on a priority basis. Separate special designation shall also be given to applicants for disabled veterans.

(c) Local offices shall review veterans and eligible person applications each 30 calendar days and, if no reportable service has been recorded during the previous 30 calendar days, shall, if possible, determine each applicant's current status and desire for further ES assistance by telephone, visit, or mail. If further assistance is desired by the applicant, the local office shall initiate reportable services as appropriate. All reportable services given shall be noted on the applicant's application card.

(d) Local offices shall assure that the applications of veterans and eligible persons are not automatically inactivated, but shall review them in accordance with normal procedures without the following special review:

(1) Identification of the applications of veterans and eligible persons scheduled for inactivation.

(2) A file search for their records; and evidence that warrants inactivation such as placement in a job or training opportunity, an explicit request from an applicant to inactivate an application, notice that applicant has moved out of the local office jurisdiction, etc. If inactivation is scheduled but not warranted, appropriate reinstatement actions should be taken.

(e) Whenever feasible, local offices shall refer qualified veterans and eligible applicants within two working days after they file their applications to job opportunities developed under the mandatory listing requirement of the Department's regulations at 41 CFR Parts 60-250, under the Comprehensive Employment and Training Act (CETA), or contained in Job Bank listings. If necessary, local office hours and staff working schedules shall be adjusted so that this requirement can be met.

§ 653.222 Performance standard on facilities for VES staff.

Each State agency shall provide adequate and appropriate facilities including office space, furniture, telephone, etc. to the SDVE, ASDVE and VES support staff attached to the State agency.

§ 653.223 Performance standards on reporting.

(a) State agencies shall provide RDVEs, SDVEs, and ASDVEs with access to regular and special internal State agency reports which relate in whole or in part with services to veterans and/or eligible persons.

(b) No special reporting requirements are established by this subpart. Existing reporting systems include information on services to veterans and eligible persons and shall be used by ETA and the State agencies to administer the provisions of this subpart. ETA, however, may require special reports from State agencies from time to time.

§ 653.224 Performance standards governing the assignment and role of Local Veterans' Employment Representatives (LVERs).

(a) At least one member of each State agency staff, preferably an eligible veteran, shall be assigned by the State Director as a full-time Local Vet-
veterans' Employment Representative (LVER) to every local office which:

(1) Has had 1,000 new and renewal applications from veterans and eligible persons during the last Federal fiscal year; or

(2) Has a total of 6,000 veterans and eligible persons in the local office administrative area population.

(b) The State Director may:

(1) Assign additional full-time LVERs to local offices described in paragraph (a) of this section based on the State Director's determination of need; and

(2) Assign less than full-time LVERs to local offices described in paragraph (a) of this section if a lack of need for a full-time LVER is documented to the satisfaction of the DASVE as evidenced by the written approval of the DASVE.

(c) The State Director shall assign LVERs on a part-time basis to local offices other than those described in paragraph (a) of this section. State Directors shall assure that periodic evaluations are made to determine the adequacy of services provided to veterans and eligible persons, and if necessary, they shall reallocate the time devoted to serving veterans and eligible persons by, for example, assigning additional full-time LVERs.

(d) Each LVER shall discharge, at the local office level, the duties prescribed for the SDVE in paragraph (d) of § 653.214. The LVER may also be delegated line supervision over veterans' units assistant LVERs and veteran aides and may be assigned direct duties with respect to services to veterans and eligible persons by the local office manager.

(e) Each LVER shall be administratively responsible to the local office manager and shall provide functional supervision over all local office services to veterans and eligible persons. The term "functional supervision" as used in this paragraph shall mean evaluative supervision of local office personnel in their performance of services to veterans and eligible persons and assisting them to carry out these services more effectively.

1. Functional supervision entails providing technical assistance, making suggestions for the improvement of services, helping to plan programs, initiating projects, checking for compliance with regulations, helping to correct errors by working with local office staff; analyzing work as it affects veterans and eligible persons, training new local office employees, providing refresher courses for other staff, and assisting all local office personnel to improve services to veterans and eligible persons. It also involves the bringing of matters which the LVER believes require corrective action to the attention of the local office manager and other officials who have line authority to set or change policy and procedure and to supervise staff.

2. Functional supervision does not entail the right to hire, fire, or discipline any local office employee. Nor does it authorize an LVER to make regulations, change procedures or establish policies for the local office without specific authority from the local office manager.

§ 653.225 Standards of performance governing State agency cooperation and coordination with other agencies and organizations interested in the employment development of veterans and eligible persons.

(a) Each State agency shall establish cooperative working relationships with the Veterans Administration (VA) office serving the State to maximize the use of VA training programs for veterans and eligible persons; particularly on-the-job and other skill training. Such working relationships should provide for the exchange of information on available training opportunities and on veterans and eligible persons, particularly on-the-job and other skill training. Such working relationships should provide for the exchange of information available training opportunities and on veterans and eligible persons.

(b) Each State agency shall develop a written agreement with its VA counterparts covering areas of mutual concern and delineating each agency's areas of responsibility.

(c) The State Director shall assign LVERs on a part-time basis to local offices other than those described in paragraph (a) of this section based on the State Director's determination of need; and

(d) Assign less than full-time LVERs to local offices described in paragraph (a) of this section if a lack of need for a full-time LVER is documented to the satisfaction of the DASVE as evidenced by the written approval of the DASVE.

§ 653.226 Standards of performance governing complaints of veterans and eligible persons.

(a) Any veteran or eligible person may file a complaint with the LVER. The LVER shall handle the complaint in accordance with the provisions of Subpart E of Part 656 of this chapter except that, if the complaint relates to the responsibilities of an employer under 38 U.S.C. 202, the LVER shall follow the Department's complaint procedures set forth at 41 CFR Parts 60-250.

(b) Each local office shall have information on the complaint system available to veterans and eligible persons at all times, and shall display a poster which advises applicants about the system.

Federal Monitoring or State Agency Compliance

§ 653.230 Veterans preference indicators of compliance.

(a) To help in determining whether the standards of performance set forth in §§ 653.226 and 653.227 have been met, the ETA shall use the floor levels and the veterans preference indicators of compliance set forth in this section.

(b) The terms "applicants" as used in this section shall mean individuals who filed or renewed job applications during the prior fiscal year. To improve statistical comparability, the term "veteran" as used in this section shall include women and persons 10 years of age or younger. The term "veteran" as used in this section shall be the "veteran" as used in this section shall include women and persons 10 years of age or younger. The term "disabled veteran" as used in this section shall include "special disabled veteran".

(c) To prevent State agencies, which are actually performing at low levels of accomplishment, from being rated unfairly, the ETA shall establish a floor (minimum) level of expected accomplishment for each State for each reportable service for each Federal fiscal year. Each year ETA shall consider each State agency's past accomplishments as a major factor in establishing the floor level of accomplishment for the next Federal fiscal year. Computation of the floor levels shall also be based on external and other appropriate factors.

1. The floor levels shall be stated as the ratio of veteran individuals served to the number of veterans applying for service, rather than the number of veterans served, to avoid the difficulties associated with establishing absolute numbers under varying conditions, time periods, and locations. The floor levels of accomplishment for FY 1979 shall be as follows:

(i) A minimum of 6 percent of those veterans applying for service shall be counseled.

Veterans Counseled/Veteran Applicants=6 percent.

(ii) A minimum of (NA FY 1979) percent of all veteran applicants shall be referred to in training.
Veterans Referred to Training/Veteran Applicants—(FY 1979) percent.

(iii) A minimum of 7.5 percent of all veteran applicants shall be provided job development.

Veteran Job Development Contacts/Veteran Applicants—7.5 percent.

(iv) A minimum of 60 percent of all veteran applicants shall be placed in jobs.

Veteran Applicants Placed/Veteran Applicants—(see list below for State values).

(v) A minimum of (individual State values) percent of all veteran applicants shall be inactivated with some reportable service.

Veteran Applicants Inactivated With Some Service/Veteran Applicants—60 percent.

(vi)

<table>
<thead>
<tr>
<th>Region I (Boston):</th>
<th>Connecticut</th>
<th>14</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Maine</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>Massachusetts</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>New Hampshire</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>Rhode Island</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>Vermont</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>Region II (New York):</td>
<td>New York</td>
</tr>
<tr>
<td></td>
<td></td>
<td>New York</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Puerto Rico</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Virgin Islands</td>
</tr>
<tr>
<td></td>
<td>Region III (Philadelphia):</td>
<td>Delaware</td>
</tr>
<tr>
<td></td>
<td></td>
<td>District of Columbia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Maryland</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pennsylvania</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Virginia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>West Virginia</td>
</tr>
<tr>
<td></td>
<td>Region IV (Atlanta):</td>
<td>Alabama</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Florida</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Georgia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Kentucky</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mississippi</td>
</tr>
<tr>
<td></td>
<td></td>
<td>North Carolina</td>
</tr>
<tr>
<td></td>
<td></td>
<td>South Carolina</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tennessee</td>
</tr>
<tr>
<td></td>
<td>Region V (Chicago):</td>
<td>Illinois</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Indiana</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Michigan</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Minnesota</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ohio</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wisconsin</td>
</tr>
<tr>
<td></td>
<td>Region VI (Dallas):</td>
<td>Arkansas</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Louisiana</td>
</tr>
<tr>
<td></td>
<td></td>
<td>New Mexico</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Oklahoma</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Texas</td>
</tr>
<tr>
<td></td>
<td>Region VII (Kansas City):</td>
<td>Iowa</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Kansas</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Missouri</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nebraska</td>
</tr>
<tr>
<td></td>
<td>Region VIII (Denver):</td>
<td>Colorado</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Montana</td>
</tr>
<tr>
<td></td>
<td></td>
<td>North Dakota</td>
</tr>
<tr>
<td></td>
<td></td>
<td>South Dakota</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Utah</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wyoming</td>
</tr>
<tr>
<td></td>
<td>Region IX (San Francisco):</td>
<td>Arizona</td>
</tr>
<tr>
<td></td>
<td></td>
<td>California</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Guam</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hawaii</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nevada</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Region X (Seattle):</td>
</tr>
</tbody>
</table>

**RULES AND REGULATIONS**

(i) Veteran applicants shall be placed in jobs to the total number of veteran applicants by at least 10 percent.

Veterans placed/Veteran applicants = Nonveterans placed/Nonveteran applicants — 1.00 = 10 percent.

(ii) The ratio of veteran applicants placed in jobs to the total number of veteran applicants shall exceed the ratio of nonveteran applicants placed in jobs to the total number of nonveteran applicants by at least 10 percent.

Veterans placed/Veteran applicants = Nonveterans placed/Nonveteran applicants — 1.00 = 10 percent.

The ratio of veteran applicants inactivated with some reportable service to the total number of veteran applicants shall be more than the ratio of nonveteran applicants inactivated with some reportable service to the total number of nonveteran applicants by at least 15 percent.

Veterans inactivated with some reportable service/Veteran applicant = Nonveterans inactivated with some reportable service/Nonveteran applicants — 1.00 = 15 percent.

(g) Veterans preference indicators of compliance for service to all veterans of the Vietnam era are as follows:

(1) The ratio of Vietnam-era veteran applicants counseled to the total number of Vietnam-era applicants shall exceed the ratio of nonveteran applicants counseled to the total number of nonveteran applicants by at least 35 percent.

Vietnam-era veteran applicants counseled/Vietnam-era veteran applicants + Nonveterans counseled/Nonveteran applicants — 1.00 = 35 percent.

(2) The ratio of Vietnam-era veteran applicants referred to training to the total number of Vietnam-era veteran applicants shall exceed the ratio of nonveteran applicants referred to training to the total number of nonveteran applicants by at least (NA FY 1979) percent.

Vietnam-era veterans referred to training/Vietnam-era veteran applicants + Nonveterans referred to training/Nonveteran applicants — 1.00 = (NA FY 1979) percent.

(3) The ratio of job development contacts made for Vietnam-era veterans to the total number of Vietnam-era veteran applicants shall exceed the ratio of job development contacts made for nonveterans to the total number of nonveteran applicants by at least 60 percent.

Job development contacts for Vietnam-era veterans/Vietnam-era veteran applicants + Job development contacts for nonveterans/Nonveteran applicants — 1.00 = 60 percent.

(4) The ratio of Vietnam-era veterans placed in jobs to the total number of Vietnam-era veteran applicants shall exceed the ratio of nonveterans placed in jobs to the total number of nonveteran applicants by at least 15 percent.

Veterans placed/Veteran applicants = Nonveterans placed/Nonveteran applicants — 1.00 = 15 percent.

The ratio of veteran applicants inactivated with some reportable service to the total number of veteran applicants shall be more than the ratio of nonveteran applicants inactivated with some reportable service to the total number of nonveteran applicants by at least 15 percent.

Veterans inactivated with some reportable service/Veteran applicant = Nonveterans inactivated with some reportable service/Nonveteran applicants — 1.00 = 15 percent.

(g) Veterans preference indicators of compliance for service to all veterans of the Vietnam era are as follows:

(1) The ratio of Vietnam-era veteran applicants counseled to the total number of Vietnam-era applicants shall exceed the ratio of nonveteran applicants counseled to the total number of nonveteran applicants by at least 35 percent.

Vietnam-era veteran applicants counseled/Vietnam-era veteran applicants + Nonveterans counseled/Nonveteran applicants — 1.00 = 35 percent.

(2) The ratio of Vietnam-era veteran applicants referred to training to the total number of Vietnam-era veteran applicants shall exceed the ratio of nonveteran applicants referred to training to the total number of nonveteran applicants by at least (NA FY 1979) percent.

Vietnam-era veterans referred to training/Vietnam-era veteran applicants + Nonveterans referred to training/Nonveteran applicants — 1.00 = (NA FY 1979) percent.

(3) The ratio of job development contacts made for Vietnam-era veterans to the total number of Vietnam-era veteran applicants shall exceed the ratio of job development contacts made for nonveterans to the total number of nonveteran applicants by at least 60 percent.

Job development contacts for Vietnam-era veterans/Vietnam-era veteran applicants + Job development contacts for nonveterans/Nonveteran applicants — 1.00 = 60 percent.

(4) The ratio of Vietnam-era veteran applicants placed in jobs to the total number of Vietnam-era veteran applicants shall exceed the ratio of nonveterans placed in jobs to the total number of nonveteran applicants by at least 15 percent.

Veterans placed/Veteran applicants = Nonveterans placed/Nonveteran applicants — 1.00 = 15 percent.
Vietnam-era veterans placed/Vietnam-era veterans applicants \( \times 0.65 \) = 15 percent

(5) The ratio of Vietnam-era veteran applicants inactivated with some reportable service to the total number of Vietnam-era veteran applicants shall be more than the ratio of nonveteran applicants inactivated with some reportable service to the total number of nonveteran applicants by at least 20 percent.

Vietnam-era veterans inactivated with some reportable service/Vietnam-era veterans candidates \( \times 0.65 \) = 20 percent

(6) Veterans preference indicators of compliance for service to disabled veterans are as follows:

(1) The ratio of disabled veteran applicants referred to the total number of disabled veteran applicants shall exceed the ratio of nonveteran applicants referred to the total number of nonveteran applicants by at least 100 percent.

Disabled veterans referred/Nonveterans referred \( \times 0.65 \) = 100 percent

(2) The ratio of disabled veteran applicants referred to training to the total number of disabled veteran applicants shall exceed the ratio of nonveteran applicants referred to training to the total number of nonveteran applicants by at least 100 percent.

Disabled veterans referred/Nonveterans referred \( \times 0.65 \) = 100 percent

(3) The ratio of job development contacts made for disabled veterans to the total number of disabled veteran applicants shall exceed the ratio of job development contacts made for nonveterans to the total number of nonveteran applicants by at least 75 percent.

Job development contacts for disabled veterans/Job development contacts for nonveterans \( \times 0.65 \) = 75 percent

(4) The ratio of disabled veteran applicants placed in jobs to the total number of disabled veteran applicants shall exceed the ratio of nonveteran applicants placed in jobs to the total number of nonveteran applicants by at least 20 percent.

Disabled veterans placed/Nonveterans placed \( \times 0.65 \) = 20 percent

(5) The ratio of disabled veteran applicants inactivated with some reportable service to the total number of disabled veteran applicants shall exceed the ratio of nonveterans inactivated with some reportable service to the total number of nonveteran applicants by at least 25 percent.

Disabled veterans inactivated with some reportable service/Nonveterans inactivated \( \times 0.65 \) = 25 percent

(i) The veterans preference indicator of compliance for State agency action shall be calculated by the formula

\[ \frac{\text{Nonveterans placed}}{\text{Disabled veterans placed}} \times 0.65 = \] 1.00

(ii) The veterans preference indicator of compliance for State agency action shall be calculated by the formula

\[ \frac{\text{Nonveterans referred to training}}{\text{Disabled veterans referred to training}} \times 0.65 = \] 1.00

(6) The ratio of the total number of veterans of the Vietnam era and special disabled veterans placed in mandatory listing job openings to the total number of individuals placed in mandatory listing job openings shall exceed 7 percent.

(7) Following analysis of the past fiscal year's accomplishments, the numerical value for each of the veteran's preference compliance indicators for the next fiscal year will be published in the FEDERAL REGISTER as amendments to paragraphs (f) through (i) of this section.

(k)(1) State agency performance under this subpart shall be reviewed on a quarterly basis by the ETA regional offices during the conduct of regular Operational Planning and Review System (OPRS) reviews. In addition, State agency performance under this subpart shall be formally reviewed by the ETA national office on an annual basis using the floor levels of accomplishment and the veterans preference indicators of compliance. The full results of these reviews shall be incorporated into the Secretary's annual report to the Congress. In order to meet the indicators of compliance, a State agency must:

(i) Meet the placement and any two of the remaining three floor levels of accomplishment at paragraph (c) of this section; and

(ii) Meet 9 of the 16 veterans preference indicators of compliance at paragraphs (f) through (i) of this section, giving each of the three placement indicators double weight.

(2) ETA shall consider failure to meet either of these conditions as evidence that the State agency is not complying with the performance standards at § 653.221–226. Such State agencies shall be required to provide documentary evidence to the ETA that their failure is based on good cause. If good cause is not shown, the ETA, pursuant to Subpart H of Part 658 of this chapter, shall formally designate the State agency as out of compliance, shall require it to submit a corrective action plan for the following Federal fiscal year, and may take other action against the State agency pursuant to Subpart H of Part 658 of this chapter.

(d) Even though a State agency veterans' services statistics, including the floor levels of accomplishment and the veterans preference indicators of compliance, indicate adequate services to veterans, the ETA may take corrective action against a State agency pursuant to Subpart H of Part 658 of this chapter if other information comes to the attention of the ETA which indicates that a State agency is not complying with the requirements of this subpart.

§ 653.231 Secretary's annual report to Congress.

(a) The Secretary shall report, after the end of each Federal fiscal year, on the success of the Department and the State agencies in carrying out the provisions of this subpart. The report shall include, by State:

(1) The number of recently discharged or released eligible veterans, disabled veterans, other eligible veterans, and eligible persons who requested assistance through the State agency; and

(2) Of the categories set forth in paragraph (a)(1) of this section, the number placed in employment, placed in job-training opportunities, or otherwise assisted.

(b) The report shall include any determinations that:

(1) A State agency demonstrated a lack of need for assigning a full-time person in accordance with § 653.224.

(2) Funds made available under the prior year's appropriations Act were not needed for carrying out the purposes of this subpart.

(c) The report shall include a designation of State agencies which ETA formally designated as out of compliance pursuant to § 653.230(k) with the standards of performance set forth in this subpart along with those agencies' plans for corrective action during the succeeding Federal fiscal year.

Signed at Washington, D.C., this 27th day of February 1979.

ERNST G. GREEN, Assistant Secretary for Employment and Training.

[FR Doc. 79-7137 Filed 3-8-79; 8:45 am]
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of Human Development Services

Administration for Children, Youth and Families

CHILD ABUSE AND NEGLECT GRANT PROGRAM PRIORITIES—FISCAL YEARS 1979 AND 1980

Research, Demonstration and Service Improvement Grants
NOTICES

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of Human Development Services, Administration for Children, Youth and Families

CHILD ABUSE AND NEGLECT GRANT PROGRAM PRIORITIES—FISCAL YEAR 1979 AND 1980

Research, Demonstration and Service Improvement Grants

AGENCY: Office of Human Development Services, Department of Health, Education, and Welfare.

ACTION: Notice of proposed Fiscal Year(s) 1979 and/or 1980 Child Abuse and Neglect Research, Demonstration and Service Improvement priorities.

SUMMARY: This notice states the research, demonstration and service improvement (R, D, & S) priorities that the Children's Bureau's National Center on Child Abuse and Neglect proposes to initiate in Fiscal Year 1979 and/or 1980, depending on the availability of funds, under the Child Abuse Prevention and Treatment Act (Pub. L. 93-247, as amended). This notice is being published in order that the final R, D, & S priorities may incorporate and reflect the expertise of individuals knowledgeable in the field.

DATE: In order to be considered, comments must be received no later than May 8, 1979. Comments on these proposed priorities or suggestions for other priorities are invited. No proposals, concept papers or other forms of application should be submitted at this time.

ADDRESS: Comments should be sent to: Associate Chief, Children's Bureau, P.O. Box 1182, Washington, D.C. 20013.

FOR FURTHER INFORMATION CONTACT:

National Center on Child Abuse and Neglect, Children's Bureau/ACYF, P.O. Box 1182, Washington, D.C. (202) 755-0593.

SUPPLEMENTARY INFORMATION: This statement announces the proposed R, D, & S priorities to be funded in Fiscal Year 1979 and/or 1980, depending on the availability of funds, under the Federal Child Abuse Prevention and Treatment Act. Public review of these proposed priorities is being sought, as required by Pub. L. 93-247, as amended, in order to draw upon the experience, expertise and most advanced thinking of persons in the field and to maximize the potential benefits of the child abuse and neglect research, demonstration and service program.

The Children's Bureau's National Center on Child Abuse (CB/NCCAN) conducts activities designed to assist and enhance national, state, community and institutional prevention, identification, and control of child abuse and neglect. The activities include: conducting research and demonstrations; supporting service improvement projects; providing technical assistance; gathering, analyzing and disseminating information and data on research and programs through a clearinghouse, providing grants to eligible States for strengthening and improving their child abuse and neglect programs; and coordinating Federal activities in child abuse and neglect with those of other Federal agencies, through the Federal Advisory Board on Child Abuse and Neglect. Thus, there are many activities other than research, demonstration and service which require staff and financial support by CB/NCCAN.

Previous and current CB/NCCAN research, demonstration and service activities have focused primarily on identifying and treating the effects of childhood sexual abuse and neglect by parental caretakers and increasing the involvement of community-based human service agencies in child protection. The proposed priorities indicate a specific program emphasis in FY 1979 and FY 1980 on protection for children in residential institutions, primary and secondary prevention of child abuse and neglect, and the treatment of child sexual abuse. Residential institutions are here defined to include residential treatment centers, temporary and long-term shelters, detention centers and homes, centers for the mentally retarded and developmentally disabled, and foster care institutions and homes. Primary prevention is here defined to include efforts to provide the necessary educational and social services needed by families in order to make it possible for them to manage their child-rearing responsibilities adequately and to reduce the likelihood of child abuse and neglect. Secondary prevention is here defined to include programs for families that are "at risk" of child abuse or child neglect, but have not yet been actually abusive or neglectful to their children, to take self-initiated action to get help to solve their child rearing problems. Child sexual abuse is here defined to include contacts or interactions between a child and an adult in which the child is being used for the sexual stimulation or gratification of the perpetrator or an other person.

The proposed priority to support research on the needs and resources for child protection in residential institutions is based on the premise that specific analysis is needed to effectively translate the proposed priorities into Federal and State law and regulation regarding the prevention, identification, reporting, independent investigation and correction of child maltreatment in residential institutions into practical procedures.

The proposed priority to support primary prevention is based on the premise that State and community organizations can mobilize existing agency resources to bring about specific changes in health, social service, educational or mental health services that will more adequately equip parents for their child-nurturing roles.

The proposed priority to support secondary prevention is based on the premise that public Child Protective Services (CPS) at the local level can incorporate innovations already successfully demonstrated by nonpublic agencies which will encourage and support parents to seek help in "at risk" situations and will implement ways of providing such help on a voluntary basis.

The proposed priority on training in the treatment of child sexual abuse reflects an increase in identified and reported cases of intrafamily child sexual abuse in this country, the small number of professionals trained to provide appropriate treatment for victims, perpetrators and families in child sexual abuse cases, and the legislative mandate contained in Pub. L. 93-247, as amended (Section 5).

The priority projects described below are planned for funding in Fiscal Year 1979 and/or Fiscal Year 1980, depending on the availability of funds, for an initial budgetary period of fifteen months including a three-month start-up period. Continuation funding for these projects is planned either through Fiscal Year 1981 or 1982. Total project periods will be either two and one-quarter or three and one-quarter years.

Specific comments and suggestions are solicited concerning each of the priorities described below. In addition, reviewers are invited to suggest any additional research, demonstration or service priorities. Suggested additional priorities must be in the form of a concept paper or other forms of application. All submissions will be discarded. In order to maintain a procedure fair to everyone, applications will be accepted only in response to the final Program Announcement to be published at a later date in the Federal Register.

No acknowledgement will be made of the comments received, but all of them will be considered in finalizing the child abuse and neglect research, demonstration and service improvement priorities. In addition, all per-
sons commenting on the proposed priorities will be placed on the Child Abuse and Neglect mailing list and will be sent the final research, demonstration and service improvement Program Announcements which will serve as the invitation for grant applications. It is anticipated that the Program announcements will be published in the Spring of 1979 and grants awarded in Fall, 1979 subject to Departmental approvals and the availability of funds.

PROPOSED PROJECT DESCRIPTIONS

(1) PROJECT TITLE: RESEARCH ON THE NEEDS AND RESOURCES FOR CHILD PROTECTION IN RESIDENTIAL INSTITUTIONS

Number, Cost and Duration

Approximately three grants will be awarded for total project periods of two and one-fourth years each. The initial award and subsequent noncompeting continuation award will be funded at a level of $75,000 each.

Importance and Purpose

Very little is known about the actual extent or the exact nature of institutional abuse and neglect in the United States. To a large degree, this is so because the administrative, regulatory and proprietorial systems which have charge of such institutions do not lend themselves to public monitoring. There is only meager data on the extent or the exact nature of institutional child maltreatment. Yet, there is compelling public responsibility for the adequate safety and protection of children in institutions.

As part of the eligibility for State grants, required by Pub. L. 93-247, as amended, each State must provide for the reporting of known or suspected incidents of child abuse and neglect in such a way that the legally authorized investigative agency may not be made responsible for investigating itself if it also happens to be responsible for running residential programs for children.

In Fiscal Year 1978, a total of 47 States had attained full or conditional eligibility for State grants. It is expected that these States will reach 50 during Fiscal Year 1979. To meet the eligibility requirements as they affect institutional child maltreatment, States have vested Investigative authority in various agencies.

In September, 1978, the National Center on Child Abuse and Neglect awarded four demonstration grants on the “Investigation and Correction of Child Abuse and Neglect in Residential Institutions.” Eligibility for these grants was limited to State agencies with legal authority to make investigations and take corrective action. The grantees are the Utah Division of Family Services, the Massachusetts Office for Children, The District of Columbia School Health and Education Administration, and the New Jersey Division of Youth and Family Services.

The Utah project has contracted with the Department of Special Education of Utah State University to serve as the organizer and sponsor of a team to develop and evaluate a system for reporting known and suspected cases of institutional abuse or neglect, to act as the State’s independent investigative authority and to recommend corrective action. The Massachusetts project will create substate regional visitation-review committees and a statewide task force to address primary prevention issues, refine licensing and standard setting functions for residential placements of children, and refine the mechanisms worked out with the State Department of Welfare for receiving reports and investigating and correcting individual cases.

The District of Columbia project will: (1) create a system for allowing residents to report maltreatment by signing their names to a form and depositing it directly into locked boxes which will be checked daily. These reports, together with staff-initiated “unusual incident reports,” will begin an investigative and corrective process that will involve independent investigators, a review panel which will include residents and outside advocates and will make recommendations to the Administrator of the Social Rehabilitation Administration. In addition, the project will provide Advance Counseling Groups for staff on alternative means of dealing with staff-child confrontations and discipline.

New Jersey’s project will examine and test three different approaches to advocacy and procedures using internal, State administered and private citizen advocacy systems of investigation. It will also happen to be responsible for running residential programs for children.

Expected Findings

These projects are designed to generate knowledge about the nature, scope, and severity of residential child maltreatment and to analyze and define appropriate alternative approaches for protecting children in residential institutions against abuse or neglect. The hypothesis underlying these projects is that, with better definition and analysis of the dimensions of the problem, the inferred need for institutional child protective measures can be directly addressed. The results of these projects will be definitions of protective service requirements, model approaches and recommended policies, programs, procedures and materials that can be used by the States in implementing on-going systems to provide child protection in residential institutions.

Methodology

Approximately three grants will be awarded to agencies or organizations with field research capability and with the appropriate administrative capacity as the source of research information. Among the approaches that these projects may choose are: (1) Collaboration with the four demonstration projects described in the Background section above in order to analyze, synthesize and develop guidelines from their experiences; (2) investigative studies in institutional settings of factors contributing to incidence of child maltreatment; (3) state
of the art" studies to identify existing or planned residential protective services; (4) analysis of policy and procedural requirements for providing residential protective services; and (5) feasibility studies for collecting and analyzing data on the incidence of child maltreatment in residential institutions.

Utilization

The findings of these projects will be directly disseminated to State Child Protective Service agencies, other relevant State and Federal agencies and decisionmakers, and private and quasi-public advocacy organizations (such as State Committees for Children and Youth). Findings will also be reviewed by the Federal Advisory Board on Child Abuse and Neglect and be used there to inform future research, demonstration and service-improvement planning.

(2) PROJECT TITLE: DEMONSTRATIONS OF STATE AND COMMUNITY ACTION TO PREVENT CHILD ABUSE AND NEGLECT

Number, Cost and Duration

Approximately 12 grants will be awarded for total project periods of three and one-fourth years each. The initial award and subsequent noncompeting continuation awards will be funded at a level of $50,000 each.

Importance and Purpose

Through these grants, CB/NCCAN will test the assumption that existing service systems can be mobilized, to provide family supportive services to prevent child abuse and neglect and that organized, ongoing and efficient approaches can be developed and thus transform primary prevention efforts from rhetoric to action. The larger and encompassing policy question which will be examined is whether or not, and by whom and in what manner, can small amounts of money be used to effect and augment needed planning and utilization of primary prevention activities. Eligible recipients of such financial support to undertake prevention efforts will be State and local public and private nonprofit agencies or organizations and minority private nonprofit organizations (including Black, Native American, Hispanic and other cultural minority populations and migrant farmworkers.

Background

In the recent past, there has been a heavy emphasis on programs and projects which focus on the treatment of child abuse and neglect (i.e., services to decrease or eliminate the possibility of recurrence of child abuse and neglect). A variety of techniques for supporting and treating abusive and neglectful parents, ranging from psychosocial consultation to lay therapy, and surrogate parenting to participation in self-help groups (such as Parents Anonymous) have been tested and often proven successful.

By definition, primary prevention can be considered to encompass the bulk of supportive, stress-reducing community services and can include many existing primary prevention activities. Services such as those offered by school systems with breakfast and lunch programs, community-based family planning services and prenatal care through health clinics, to name a few, are well known.

Primary prevention efforts have been lauded by professionals and paraprofessionals in those fields which most often are involved in child abuse and neglect concerns (such as child protective service workers, medical and health personnel, law enforcement officials and educators). Yet, many of these groups of involved professionals and paraprofessionals working within traditional state and local human service programs explain that their mandated work tasks are too often crisis-oriented and allow no time for involvement in needed prevention services.

Moreover, many of the traditional primary prevention services are insufficient and are rarely part of a well thought out system to prevent the most severe forms of parent-child dysfunctioning—child abuse and neglect. Many of the newly tested primary prevention services, such as parent education and coping classes, are not utilized extensively. In addition, there are new primary prevention plans which are being conceptualized but have not yet been tested.

To date, there has been no widespread, structured commitment and funding for primary prevention activities by agencies and organizations at the state and local level. There exists within planning and advocacy units for children and families and within a number of other agencies, a great potential to set in place a structure through which planning, organizing and overseeing state or local primary prevention efforts can be accomplished. The structure could be, for example, a comprehensive plan to assure the availability of a number of needed primary prevention services in a state or locality; or a design to alter those state procedures most amendable to change, which will allow for and facilitate primary prevention activities.

Minority organizations, as well, should have a major role in the development and testing of primary prevention structures. Indeed, minority organizations, representing large economically disadvantaged populations, are acutely aware of the difficulties of raising children and maintaining
family organization when unsafe and otherwise unfit housing, a scarcity of food and money are pervasive problems.

**Expected Findings**

CB/NCCAN expects to identify approaches to child abuse and neglect prevention that appear to be particularly promising for further development and widespread implementation.

**Methodology**

Approximately twelve projects will be funded to demonstrate how social and institutional forces can be enlisted to prevent child maltreatment before it occurs. Through grants to approximately six State agencies or organizations, three metropolitan area public or private agencies or organizations and three minority organizations, this primary prevention effort will seek to: (1) strengthen those societal forces which can prevent child abuse and neglect, and (2) lessen or counteract those societal forces which can lead families to abuse or neglect their children. These projects are expected to demonstrate practical approaches to prevention such as: encouraging requiring hospitals to provide pre- and post-natal counseling for parents; instituting family education and supportive social services in public schools; providing parent/family education and courses on child rearing skills for adults through public schools and community education; strengthening informal helping networks through the improvement of Information and Referral services; and mounting public education on family support resources through the public media.

**Utilization**

Information on how to devise systems for assuring primary prevention services is clearly needed at the state and local level. The exploration of this question can provide, on the one hand, models of how such systems can be best developed and, on the other hand, insight into specific areas and processes for further development.

(4) **PROJECT TITLE: COLLABORATIVE RESEARCH STUDY OF STATE AND COMMUNITY ACTION TO PREVENT CHILD ABUSE AND NEGLECT**

**Number, Cost and Duration of Project**

One grant will be awarded for a total project period of three and one-fourth years. The initial award and subsequent noncompeting continuation awards will be funded at a level of $100,000.

**Importance and Purpose of the Project**

Through this grant, CB/NCCAN will support a collaborative analysis of the approaches and implementation of the Demonstration of State and Community Action to Prevent Child Abuse and Neglect. The project will serve as the focal point for a collaborative effort undertaken with the demonstration projects to collect and analyze information on how primary prevention can be made part of the programs of existing service systems and what are the most promising programmatic avenues for effecting preventive results. Thus, the project will be the principal vehicle for utilization and dissemination of the demonstration findings to other State and community organizations and agencies capable of replicating their successful programs.

**Background**

[See same section under (2) above]

**Expected Findings**

[See same section under (2) above]

**Methodology**

The project will establish a collaborative relationship with the (approximately) 12 Demonstration projects of State and Community Action to Prevent Child Abuse and Neglect. It will serve as a central coordinator to: (1) Analyze each project's plans; (2) design a research framework for analyzing the processes of projects' implementation; (3) develop data collection instruments for addressing process issues; (4) analyze the data; and (5) prepare a descriptive and analytical report on cross-project findings. The project will meet with the demonstration project directors on a semianual basis, receive project progress reports on a quarterly basis as a means of gathering data and insuring effective collaboration with the demonstration projects.

**Utilization**

[See same section under (2) above]
systems for the receipt, assessment, case management, and treatment of self-referrals which are responsive to the needs and special concerns of voluntary clients. In addition, procedures for establishing accountability for voluntary, private treatment of identified abuse and neglect cases and referral of high-risk cases to sources outside the formal child protection system will be developed. Efforts will be aimed at the development of a comprehensive service network from intake to follow-up which will provide compassionate, fair, and voluntary services to self-referred families.

**Background**

Increased public awareness concerning the availability of treatment for child abusing and neglecting families has increased the rate of self-referrals in recent years. According to American Humane Association 1976 statistics of reported cases from 51 States, approximately 7% (or 6,700) of the cases reported to public child protection agencies fall into the category of self-referral. An even greater number of self-referrals from families whose problems include actual or potential child maltreatment are received by private family service agencies each year.

Based on the experience of the joint demonstration projects, the CS/ NCCAN Treatment and Innovative projects, and Parents Anonymous, we know that programs can maximize the number of families voluntarily requesting assistance, increase early intervention efforts and improve treatment programs by tailoring the type and management of services to fit the needs of self-referred clients. For example, self-referrals constituted 60% of the caseload of the Family Stress Center in San Diego, which emphasized the voluntary aspects of prevention and treatment in a nontreatment atmosphere. The community-based prevention and treatment projects funded in FY 1978 have carried this concern further by instituting a variety of self-referral programs in non-Child Protective Service settings.

**Methodology**

The grants will be awarded to State, multicity county, or local public child protection agencies. An effort will be made to fund projects in demographically and culturally diverse settings. Each project will be required to document the cooperation of the appropriate community prevention and treatment referral resources. (Projects may enter into contractual relationships with private agencies to provide intake and treatment services.)

Each project will also be required to develop a system for: (1) Improved and supportive handling of self-referrals which will be responsive to the needs of self-referred clients, and (2) coordination and joint management of self-referrals which are received by other agencies or professionals in the community. Methods for improving the external management of self-referrals could involve: specialized intake and investigation procedures, policies which minimize intrusion on family life and support individual rights of self-determination, increased availability of prevention and outreach services, provision of supportive services (such as group treatment and parent aides) which maximize clients' willingness to share their problems, and improved community referral systems to resources which are most appropriate for voluntary clients. Methods for improving coordination of self-referrals received by community agencies could include: guidelines for appropriate handling of reports to child protection agencies of self-referred cases, provisions for waiving formal child protection agency investigations in selected cases, contracts of cooperation between child protection agencies and community service agencies, and monitoring systems for maintaining treatment accountability for voluntary clients.

**Utilization**

The information gained and the program components developed will be communicated to the more than 3,000 public child protection agencies across the country. It is expected that reporting and referral guidelines, model contracts of interagency cooperation, and specialized procedures for the management and treatment of voluntary clients, will be utilized by CPS agencies to restructure improved community coordination and handling of self-referrals.

(5) PROJECT TITLE: CHILD SEXUAL ABUSE TREATMENT TRAINING INSTITUTE

**Number, Cost and Duration**

Approximately one grant will be awarded for a total project period of three and one-fourth years. The initial award will be approximately $100,000. Noncompeting continuation awards will be funded at a level of $300,000.

**Importance and Purpose**

The proposed project addresses the problem of providing quality professional training on the treatment of incest and child sexual abuse in settings where therapeutic interventions can be effectively demonstrated.

**Background**

While it is generally agreed that ordinary instructional programs or workshops are not sufficient to provide the kind of treatment skills or level of understanding necessary to work with incestuous families, existing specialized treatment programs do not have ade-
Primary questions to be addressed by the proposed training/treatment projects are:

* What are the best means of transferring clinical skills and knowledge within a treatment setting?
* What are the most effective, replicable training techniques for dealing with a sensitive and difficult subject such as incest?
* What is the maximum number of professionals that can be trained at one time, and what is the minimum length of time necessary for an effective training program?
* What combination of staff/client/trainee ratios are conducive to the success of an in-service training program?
* What types of replicable training/treatment models are most cost-effective in terms of numbers served and quality of training experience?

As a secondary benefit, we expect these projects to continue refining clinical treatment methods.

**Methodology**

One pilot project will be established for the purpose of planning, developing, and implementing the groundwork for comprehensive institutes on the training and treatment of child sexual abuse. The proposed demonstration project will develop and refine the specific approaches and methodologies that are most applicable and cost-effective for future training/treatment efforts. Activities will include, but are not to be limited to: in-service programs for the training of personnel involved in the treatment of child sexual abuse; refinement of specific therapeutic treatment techniques; technical assistance in the area of case consultation; and the development of resource and training materials for use by other child protection and family treatment programs.

Because the proposed project will be focused primarily on in-service training (requiring actual therapeutic involvement with client families), potential grantees must be ongoing, child sexual abuse treatment programs of demonstrated effectiveness in order to be eligible for funding. In addition, their services must be related to public child protection agencies in order to insure that necessary linkages and institutionalization of the programs are maintained. The methodology for in-service training programs will include the provision for training community teams of professionals who function as treatment supervisors or lead therapists in their own service settings. Written support of their agencies to implement training programs will be required. Training will consist of intensive, in-service clinical experiences at the grantee agency, supplemented by course work, training seminars, and structured supervision of assigned caseloads. Initial in-service training programs could be followed up by advanced programs several months later.

While the proposed project will act as a forerunner or small scale model of the larger, comprehensive training/treatment centers described in Pub. L. 93-247, as amended, its primary purpose will be to refine the strategies and methodology of undertaking a major in-service training/treatment approach to staff development and skill building on a national basis.

**Utilization**

The proposed project is intended to develop the framework, demonstrate feasible methodologies, and serve as a model for a comprehensive approach to in-service training which is, thus far, relatively untested in the field of child protection. The findings and techniques developed by this short-term demonstration will be used in preparing the guidelines for future staff development efforts in the area of sexual abuse and professional training in the treatment of other forms of child abuse and neglect. In addition, it will develop a cadre of training/treatment centers with the experience, expertise, and potential ability to implement training programs on a national/regional basis without the need for lengthy start-up periods.

(Catalog of Federal Domestic Assistance Program Number: 13.628—Child Development—Child Abuse)

Dated: February 27, 1979.

Blandina Cardenas Ramirez,
Commissioner for Children,
Youth and Families.

Approved: March 5, 1979.

Arabela Martinez,
Assistant Secretary for
Human Development Services.

[FR Doc. 79-7060 Filed 3-8-79; 8:45 am]
DEPARTMENT OF COMMERCE
National Telecommunications and Information Administration

PUBLIC TELECOMMUNICATIONS FACILITIES PROGRAM
Planning and Construction Grants
PROPOSED RULES

- Eligibility of Applicants
- Priority Among Applicants
- Processing and Evaluation of Applications
- Administration and Recovery of Grant Funds

The numerous comments received in response to that publication have been extremely valuable in the shaping of the proposed rules, which are printed below. The four categories of issues will be discussed in order.

ELIGIBILITY OF APPLICANTS

5. Eligibility of applicants was perhaps the most frequently addressed issue in the comments on the Advance Notice. The two major topics in these comments centered on the status of religious groups and the role of Internal Revenue Code Section 501(c)(3). Before presenting our proposals, in this area, it would be helpful to review the relevant portions of the Act which framed our conclusions.

6. The primary purpose of the Act is the extension of “public telecommunications services” (defined as noncommercial educational and cultural radio and television programming and related noncommercial instructional or informational materials) to as many citizens as possible. (Sections 390 and 392(14).) To accomplish this goal, Congress has authorized DOC to fund the planning and construction of facilities. Eligible applicants must be organized primarily for educational or cultural purposes and must agree to use their PTFP-funded facilities “only” for the provision of public telecommunications services. (Section 392(a)).

7. As long as the primary-purpose test of Section 392(a) is satisfied, there are no questions concerning the eligibility of a “noncommercial educational or public broadcast station,” a State or local government (or any agency thereof) or a “political or special purpose subdivision of a State.” (Section 392(a)(11).) The difficult questions arise when the applicant is a “Noncommercial telecommunications entity or a nonprofit foundation corporation institution or association * * *” (id.).

8. In paragraph 14 of the Advance Notice, we questioned whether churches and other religious groups, labor unions, fraternal groups and special interest groups, such as NOW and the NAACP, could qualify for funding. We propose to accept applications for qualified subsidiaries of these organizations but with several safeguards to assure that the services provided by these groups meet the definition of Section 397(14) of the Act.

9. As an initial measure of eligibility, we would require that non-governmental applicants hold a current Section 501(c)(3) exemption from the Internal Revenue Service. The guidelines and requirements for this exemption are

---

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
well known and use of the exemption as a preliminary qualifier of applicants would facilitate the review and acceptance of applications. However, the types of organizations that can qualify for Section 501(c)(3) states are much broader than the requirements of the Act and therefore, PTFP applicants must establish that they are organized primarily for educational or religious purposes and will produce and distribute only educational or cultural radio or television programming and related noncommercial materials. Submission of the applicant's organic charter and evidence in Section 501(c)(3) exemption would, in most instances, satisfy this requirement. Thus, a religious or special interest group could not apply for a PTFP grant in its own name but, rather, it must form a nonprofit entity meeting the Section 392(a) requirements of primary purpose and exclusive use. We would require applicants to give an assurance that PTFP funds and any monies generated through the use of PTFP funded facilities would be used exclusively for public telecommunications purposes as outlined in the application. Use of such facilities to advance the special point of view of an applicant or its parent organization would not constitute compliance with the letter and spirit of the Act. To this end, we have attempted to define educational and cultural programming in § 2301.3 of the proposed rules. We urge parties to comment on this definition and the issues raised above.

10. A further word is in order regarding whether the First Amendment bars religious groups from obtaining PTFP funds altogether. Many of the comments received in response to the Advance Notice took the position that the First Amendment precluded funding of church or religious groups. Others suggested that funding of non-profit subsidiaries of such groups would be permissible as long as non-sectarian applicants were non-sectarian and meet the Section 392(a) requirements. We are disposed to agree with the latter view and, indeed, believe that such a requirement is justified by the Supreme Court's decision in Tilton v. Richardson, 430 U.S. 672, reh. denied 404 U.S. 974 (1971). Tilton involved a First Amendment Establishment Clause challenge to the Higher Education Facilities Act of 1963 which authorized Federal grants and loans to colleges and universities for the construction of "academic facilities." Expressly excluded from the definition of that term was "any facility used or to be used for sectarian instruction or as a place for religious worship, or for any facility which * * * is used or to be used primarily in connection with any part of the program of a school or department of divinity * * *

Further, the law provided that the Federal Government retained a 20-year interest in any facility funded under that program. Thus, within the 20 years after completion of the project, the facility was utilized for a prohibited purpose, the government would be entitled to recover an amount equal to the proportion of the present value that the Federal grant bore to the original cost of the facility. This provision is essentially identical to Section 392(g) of the Act. However, the Higher Educational Facilities Act, provision 20 U.S.C. § 394(a), included a finding that after 20 years, "the "benefit accruing to the United States" from the use of the facility "will equal or exceed in value" the amount of the Federal grant.

11. While the Court upheld that Act as having a secular legislative purpose, it nevertheless struck down the 20-year restriction, 430 U.S. at 683. The Court reasoned that a substantial structure funded under the program could not be deemed to lack all value after only 20 years. Unrestricted (including sectarian) use of a valuable property would, in effect, be a contribution of value to the religious group. Therefore, use of the building for a chapel or for other religious purposes after the 20-year term would violate the Establishment Clause. In short, the Court held that the 20-year restrictive clause of the Act could not constitutionally "expire while the building has a substantial value." 430 U.S. at 684.

12. For obvious reasons, the rule in Tilton governs our construction of Section 392(g) of the Act. Thus, as long as PTFP-funded facilities have a substantial value, they cannot be utilized for sectarian purposes. The problem arises, however, that some equipment funded under the Act (i.e., towers) will have a valuable life of in excess of 30 years. For such equipment, the period of restrict- ed use must exceed the 10 years required by the Act. In response to Tilton, supra, the Higher Education Facilities Act was amended to provide that a building funded under that program could never be used for "religious worship or a sectarian activity or for a school or department of divinity." 20 U.S.C. § 392(c).

13. A third issue raised in the comments concerns the eligibility of pro-

*Message from the President transmitting proposals to amend the Act, House Doc. 95-239, 95th Cong., 2nd Sess. 24 (1978) (Conference Report).

**In response to Tilton, supra, the Higher Education Facilities Act was amended to provide that: a building funded under that program could never be used for "religious worship or a sectarian activity or for a school or department of divinity." 20 U.S.C. § 392(c).
PROPOSED RULES

origination capacity. This category includes the activation of new facilities without local origination capacity, but which can provide services originating elsewhere.

Priority II—Activation or Expansion of Telecommunications Facilities for Significantly Different Additional Services. This priority includes the planning and construction of facilities to provide additional complementary program services which for a clear and substantial community need can be demonstrated. Eligible projects include services to identifiable ethnic or linguistic minority audiences; services to the blind or deaf; ITFS; electronic text; or significantly different alternative service to a general audience.

Priority III—Improvement for Existing Broadcast Station Facilities. Two subcategories are listed under this priority:

A. Projects to provide first local origination capacity for existing broadcast stations. This category includes projects to bring basic local program service to repeater transmitters and other licensed broadcast facilities now bringing in distant signals. Origination equity may be fixed or mobile, but must be locally based.

B. Projects to upgrade existing origination or delivery capacity to current industry performance standards. This category includes conversions to color, stereo, SCA, etc.; improvements in signal quality; and significant improvements in equipment flexibility or reliability.

Priority IV—Augmentation of Existing Broadcast Station Facilities. Projects under this priority would equip an existing station beyond a basic capacity to broadcast programming from distant sources and to originate local programming.

A. Projects to equip auxiliary studios at remote locations, or to provide mobile origination facilities. An applicant must demonstrate that significant expansion in public participation in programming will result. This category includes neighborhood production studios or facilities in other locations within a station's service area which would make participation in local programming accessible to additional segments of the population.

B. Projects to augment production capacity beyond basic level in order to provide programming or related materials for other than local distribution. This category would provide equipment for the production of programming for regional or national use. Need beyond existing capacity must be justified.

If in any one fiscal year, all other approvable applications have been funded and appropriated funds remain, we believe that NTIA pos-


FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
tions. This duty is similar to the publi-

cations. In large part it tracks the
form and content of the former EBFP
regulations and therefore no detailed
requirements of the Act, while, at the
same time, assuring equal treatment
of all applicants.

Applications and Application
Procedures

23. Subpart B of the proposed rules
sets forth the eligibility requirements
for applicants and the procedures to
be followed in the processing of appli-
cations. In large part it tracks the
form and content of the former EBFP
regulations and therefore no detailed
requirements of the Act, while, at the
same time, assuring equal treatment
of all applicants.

Applications and Application
Procedures

23. Subpart B of the proposed rules
sets forth the eligibility requirements
for applicants and the procedures to
be followed in the processing of appli-
cations. In large part it tracks the
form and content of the former EBFP
regulations and therefore no detailed
requirements of the Act, while, at the
same time, assuring equal treatment
of all applicants.

Applications and Application
Procedures

23. Subpart B of the proposed rules
sets forth the eligibility requirements
for applicants and the procedures to
be followed in the processing of appli-
cations. In large part it tracks the
form and content of the former EBFP
regulations and therefore no detailed
requirements of the Act, while, at the
same time, assuring equal treatment
of all applicants.

Applications and Application
Procedures

23. Subpart B of the proposed rules
sets forth the eligibility requirements
for applicants and the procedures to
be followed in the processing of appli-
cations. In large part it tracks the
form and content of the former EBFP
regulations and therefore no detailed
requirements of the Act, while, at the
same time, assuring equal treatment
of all applicants.

Applications and Application
Procedures

23. Subpart B of the proposed rules
sets forth the eligibility requirements
for applicants and the procedures to
be followed in the processing of appli-
cations. In large part it tracks the
form and content of the former EBFP
regulations and therefore no detailed
requirements of the Act, while, at the
same time, assuring equal treatment
of all applicants.

Applications and Application
Procedures

23. Subpart B of the proposed rules
sets forth the eligibility requirements
for applicants and the procedures to
be followed in the processing of appli-
cations. In large part it tracks the
form and content of the former EBFP
regulations and therefore no detailed
requirements of the Act, while, at the
same time, assuring equal treatment
of all applicants.

Applications and Application
Procedures

23. Subpart B of the proposed rules
sets forth the eligibility requirements
for applicants and the procedures to
be followed in the processing of appli-
cations. In large part it tracks the
form and content of the former EBFP
regulations and therefore no detailed
requirements of the Act, while, at the
same time, assuring equal treatment
of all applicants.

Applications and Application
Procedures

23. Subpart B of the proposed rules
sets forth the eligibility requirements
for applicants and the procedures to
be followed in the processing of appli-
cations. In large part it tracks the
form and content of the former EBFP
regulations and therefore no detailed
requirements of the Act, while, at the
same time, assuring equal treatment
of all applicants.

Applications and Application
Procedures

23. Subpart B of the proposed rules
sets forth the eligibility requirements
for applicants and the procedures to
be followed in the processing of appli-
cations. In large part it tracks the
form and content of the former EBFP
regulations and therefore no detailed
requirements of the Act, while, at the
same time, assuring equal treatment
of all applicants.
29. We also propose to require grantees to advise prospective equipment suppliers and creditors of the Federal government's continuing 10 year interest in public telecommunications facilities funded under this program. (Section 392(g)). This step would minimize the potential drastic, adverse effect of the use of facilities purchased with Federal monies in the event of a change in status or bankruptcy of the grantee. (See the Advance Notice, 42 FR at 899.) Another possible safeguard, proposed in § 3301.27 of the Rules, would be to require a grantee to execute a priority lien and/or some form of a bond to indemnify the government in the event of a default, bankruptcy or change in status. Comments as to the necessity, mechanics and expense of this suggestion are requested.

30. As noted previously, grants under this program are to foster the most efficient and economical means for the delivery of radio and television services to the public. Because we anticipate funding requests in excess of limited funds, ways must be explored to develop means for stretching the limited Federal dollars to their fullest extent. It appears that many applicants will require much common equipment. The Senate Subcommittee on Commerce suggested that consolidated or bulk equipment purchases by applicants might assist in the achievement of the most efficient use of the funds. (Senate Report at 9.) One means of implementing such a procedure would be to permit grantees to pool their grants funds through an approved agency for the bulk purchase of equipment. Grantees would, of course, remain individually responsible for the expenditure of Federal funds and the control of PTFP equipment. A proposed rule implementing this suggestion has been included as § 3201.26. NTIA requests comments on the feasibility of such a procedure and encourages other suggestions for maximizing the purchasing power of the limited available funds.

31. Section 2301.22(c) of the proposed rules states that no portion of an applicant's matching funds may come from Federal sources unless the match is authorized by statute. As noted in both the issues paper and Advance Notice, HEW had determined that CPB grants could be utilized to meet the matching requirement. (See 42 FR 5726, November 1, 1976.) We propose to depart from that policy. Section 392(a)(3) of the Act requires an applicant to give assurances that it has or will have sufficient funds available to construct, operate and maintain its facility. We believe that Congress intended by that language to enhance the viability of public telecommunications entities by requiring substantial state, local, community and organizational financial commitments to support the operation of the facility. This goal would be frustrated if a large majority of funds were provided by the Federal Government, either directly or indirectly—as through CPB grants. Therefore, we propose to preclude use of CPB funds by an applicant to meet its share of the cost of eligible equipment.

32. The EBFP regulations listed the requirements and standards by which broadcast equipment and related costs were to be deemed eligible for funding. The rules incorporated an appendix which listed fundable and nonfundable broadcast equipment and related costs and indicated standards by which eligible equipment was to be judged. (See Appendix A of the EBFP regulations, 42 FR at 57294-285.) Transmitters, translators and antenna systems and certain other equipment had to comply with FCC specifications and performance requirements. In addition, the Electronic Industries Association (EIA) standards were incorporated by reference to “serve as benchmarks for determining minimum system capacities * * *.” (42 FR at 57295.)

33. Based on comments at the public meeting and our engineering judgment, a tentative decision has been made to dispense with reliance on the approach. The reasons for that determination are two. First, EIA standards have failed to meet requirements of the program. Second, since Congress has broadened eligibility to cover recording and nonbroadcast technologies, continued reliance on EIA standards for broadcast equipment proposals would make relative judgments of broadcast and nonbroadcast equipment difficult. Moreover, there are no industry-wide standards for nonbroadcast equipment; a problem complicated by the fact of rapidly changing telecommunications technology. Therefore, we believe that the better approach would be to require applicants to propose professional quality equipment. Additionally, nonbroadcast equipment should be compatible with broadcast equipment wherever feasible. In assessing equipment proposals, however, the staff may consult the various EIA standards. NTIA would, of course, have the authority to deny an application because the proposed equipment was not compatible or of sufficient quality.

34. Moreover, since we are dealing with rapidly evolcing broadcast and nonbroadcast equipment, it appears to be preferable to list categories of ineligible equipment and require repayment of a portion of the Federal share. This suggestion has been included as § 3201.36 of the proposed regulations. Within this framework, however, it would be permissible for a grantee to utilize its PTFP-funded facility to prepare educational and cultural programs for other noncommercial purposes. See § 3201.37. Our primary concern here is to assure that applicants use PTFP funds to purchase reliable equipment of a quality sufficient to serve the public. If, in a given instance, this cannot be accomplished by less than professional quality equipment, the funding request should justify the selection of that equipment.

USE OF EQUIPMENT

35. Section 392(a)(4) continues the EBFP requirement that an applicant assure that facilities purchased with PTFP funds “will be used only for the production and dissemination of public telecommunications services.” Failure to comply with that assurance during the ten-year period of Federal interest constitutes grounds for the government to recover the remaining portion of its contributions. (Section 392(g)(3).) Further, Section 392(a)(2) continues the policy of requiring that the “operation” of PTFP equipment must remain “under the control” of the grantee.

36. Under both the previous program and in response to the Advance Notice, questions have been raised concerning the extent, if any, that facilities purchased with PTFP funds can be used for other than noncommercial educational and cultural programming and related purposes. The EBFP policy in this area was stated in a July 5, 1973 memorandum to educational television licensees. In pertinent part, that memorandum stated under no circumstances could EBFP-funded facilities be “made available for use for commercial purposes.” Use of the equipment by “commercial interests for any commercial purpose” during the ten-year period of Federal interest would result in revocation of the grant and require repayment of a portion of the Federal share.

37. NTIA's interpretation of the law is nearly identical to HEW's. We read the law to allow only noncommercial educational and cultural or related instructional or informational programs and materials to be produced and disseminated with PTFP-funded equipment. (§§ 392(a)(4) and 397(14).) If followed, therefore, that programming must be produced and distributed by the grantee primarily for noncommercial purposes. See § 2301.36 of the proposed regulations. Within this framework, however, it would be permissible for a grantee to utilize its PTFP-funded facility to prepare educational and cultural programs for other noncommercial educational and cultural purposes.
of the procedures. Specifically, §2301.38 of the proposed regulations provides that reconsideration shall be based exclusively on written presentations. Applicants would not be afforded an oral hearing. Secondly, we propose that a Grant Appeals Board be established within NTIA to decide petitions for reconsideration. This Board, which would sit in rotating panels of three members, would be comprised of high ranking NTIA personnel, including the Deputy Administrator, the Chief Counsel, the Associate Administrator of the Office of Policy Analysis and Development and the Directors of the Office of International Affairs and of Planning and Policy Coordination. The decision of the Board would constitute NTIA's final action on the petition. Our purpose behind the creation of the Appeals Board is to afford aggrieved applicants and grantees an expeditious and impartial review of adverse decisions.

Management and Employment Practices

41. Section 399(b) of the Act directs, in part, that public telecommunications entities receiving funding from CPB shall afford equal employment opportunities and shall not discriminate in employment on the grounds of race, color, national origin or sex. NTIA believes that its grant recipients should also be required to comply with this policy. In the case of grantees requiring an FCC authorization and employing at least five full-time employees, the EEO obligation is imposed by the FCC's rules. To this end, §2301.28 of the proposed Rules requires all grant applicants proposing five or more full-time employees to file an EEO plan.


43. NTIA has had no prior occasion to develop procedural guidelines concerning ex parte situations. However, we have stated that the objective of such guidelines should be to "foster genuine and fair dialogue" between interested parties and the agency while simultaneously creating a full administrative record. (Comments of NTIA in response to FCC Notice of Inquiry in FCC General Docket No. 78-161, Policies and Procedures Regarding Ex Parte Communications During Informal Rulemaking Proceedings.) This objective provides interested parties with an opportunity to furnish information and arguments regarding a proposal while preserving both basic fairness and the agency's flexibility in informal rulemakings. To further this end, NTIA is adopting Federal Rule of Practice 46 as the rule governing the remainder of this proceeding. NTIA decision-making personnel will be permitted to engage in communications with the public regarding the PTFP rulemaking. However, the public will be advised that copies of written communications and summaries of conversations and meetings will be placed in the public file. Such a procedure will give us the benefit of the fullest possible public input into our decisions, will assure basic fairness, and will create a record of all discussions, thus facilitating any judicial review.

44. NTIA personnel governed by these ex parte standards are:
- Henry Geller, Administrator
- Paul Bortz, Deputy Administrator
- William Lucas, Associate Administrator for Telecommunications Applications
- John Cameron, Director, Public Telecommunications Facilities Division
- Gregg Skall, Chief Counsel
- Kenneth Salomon, Assistant Chief Counsel
- Robert Sachs, Legislative Counsel
- Brooks Leffler, Consultant, Office of Telecommunications Applications

45. Interested parties are encouraged to submit comments on the Notice. An original and seven copies of any comments should be filed by April 12, 1979 with: Office of Chief Counsel, FCC, 1919 H Street, N.W., Washington, D.C. 20554.
NOTICE

A certificate of service reflecting that a copy of the comments has been served on the parties listed in Appendix A must be attached to the comments. Comments will be available for inspection during regular business hours in Room 703 at the above address. Finally, the public is advised that NTIA has tentatively selected May 15, 1979 as the closing date for applications.

Dated: March 6, 1979.

HENRY CIELEZ,
Administrator, National Telecommunications and Information Administration.

APPENDIX A

Andrew, Paul, 3 Hancock Avenue, Cambridge, MA 02138.
Archdiocese of San Francisco, Educational Television Center, 324 Middlefield Road, Menlo Park, CA 94025.
Center for Excellence, Inc., P.O. Box 158, Williamsburg, VA 23165.
City University of New York, Center for Advanced Study in Education, 33 West 42nd Street, New York, N.Y. 10036. (Att. Dr. Lee Cohen).

Footnotes continued from last page

Administrative Procedure Act (5 U.S.C. Sec. 553(a)(2)). Nevertheless, NTIA has opted to provide the public with the opportunity to participate. Both Executive Order 12044 and DOEs response to that Order, supra, indicate that at least 60 days shall be afforded for public comment on proposed significant regulations unless compliance with that standard is not possible. The Administrator has determined that it is not possible to comply with the 60 day standard if NTIA is to process and fund applications in the current fiscal year. Section 391 of the Act provides that funds appropriated in any fiscal year shall remain available throughout succeeding fiscal years. If NTIA cannot issue any rules that result from the public comments, it is proposed that Title 15 of the Code of Federal Regulations be amended by establishing Subtitle D—Regulations Relating to Telecommunications and Information, Chapter XXIII—National Telecommunications and Information Administration, Department of Commerce and establishing a new Part 2301, as follows:

PART 2301—PUBLIC TELECOMMUNICATIONS FACILITIES PROGRAM

Subpart A—General

Sec. 2301.1 Purpose and scope.
2301.2 Other pertinent rules and regulations.
2301.3 Definitions.

Subpart B—Eligibility and Application Procedures

2301.4 Eligible applicants.
2301.5 Application for financial assistance.
2301.6 Acceptance of applications.
2301.7 Deferred applications.
2301.8 Federal Communications Commission authorization.
2301.9 Closing date.
2301.10 Where to file: number of copies.
2301.11 Publication.
2301.12 Service of applications.
2301.13 Acceptance of applications.
2301.14 Comments on applications.
2301.15 Distribution of funds.
2301.16 Coordination with interested agencies and organizations.
2301.17 Funding criteria for construction applications.
2301.18 Funding criteria for planning applications.
2301.19 Action on applications.

Subpart C—Priorities Among Applications and the Role of Minorities and Women

2301.20 Program priorities.
2301.21 Special consideration.

Subpart D—Federal Financial Participation and Conditions of Federal Grant

2301.22 Amount of Federal grant.
2301.23 Payment of Federal grant.
2301.24 Conditions of Federal grant.
2301.25 Procurement standards.
2301.26 Consolidated procurement.
2301.27 Securing the Federal interest.
2301.28 Non-discrimination.

Subpart E—Accountability for Federal Funds

2301.29 Retention of records.
2301.30 Final certification.
2301.31 Annual status reports.
2301.32 Termination and change in eligibility.
2301.33 Petition for reconsideration.
Section 2301.34 Equipment.

2301.35 Items and costs ineligible for Federal funding.

2301.36 Control and use of facilities.

2301.37 Waiver.


Subpart A—General

§2301.1 Purpose and scope.

These regulations prescribe policies and procedures to insure the fair, equitable and uniform treatment of applications for planning and construction grants for wave interconnection facilities and planning and preparatory steps incidental to any such acquisition, installation, or modernization.

§2301.2 Other pertinent rules and regulations.

(a) Other rules and regulations pertinent to applications for the operation of noncommercial educational broadcast stations and public broadcast stations are contained in the rules and regulations of the Federal Communications Commission, 47 CFR Part I (General Rules and Procedures); Part 2 (Frequency Allocations and Radio Treaty Matters; General Rules and Regulations); Part 17 (Construction, Marking, and Lighting of Antenna Structures); Part 3, Subpart E (Television Broadcasting); Part 73 (Radio Broadcast Services); and Part 74 (Experimental Auxiliary and Special Broadcast and Other Program Distribution and Services).

§2301.3 Definitions.

(a) The following terms shall have the following meanings when used in this part:


(2) The term “Administrator” means the Administrator of the National Telecommunications and Information Administration, U.S. Department of Commerce.

(3) The term “construction” (as applied to public telecommunications facilities) means acquisition (including acquisition by lease), installation, and modernization of public telecommunications facilities and planning and preparatory steps incidental to any such acquisition, installation, or modernization.

(4) The term “preoperational expenses” means all nonconstruction costs incurred by new telecommunications facilities before the date on which they began providing service to the public, and all nonconstruction costs associated with the expansion of existing entities before the date on which such expanded capacity is activated, except that such expenses shall not include any portion of the salaries of any person employed by an operating public telecommunications entity.

(b) The term “public broadcasting entity” means the Corporation for Public Broadcasting, any licensee or permittee of a public broadcasting station, or any nonprofit institution engaged primarily in the production, acquisition, distribution or dissemination of educational and cultural television or radio programs.

(10) The term “public telecommunications entity” means any enterprise which—

(i) Is a public broadcast station or a noncommercial telecommunications entity; and

(ii) Dissemnates public telecommunications services to the public.

(11) The term “public telecommunications facilities” means apparatus necessary for production, interconnection, captioning, broadcast or other distribution of programming, including but not limited to, studio equipment, cameras, microphones, audio and video storage of reproduction equipment, or both, signal processing equipment and switches, towers, antennas, transmitters, translators, microwave equipment, mobile equipment, satellite communications equipment, instructional television fixed service equipment (TTFS), subsidiary communications authorization (SCA) transmitting and receiving equipment, cable television equipment, video and audio cassettes and discs, optical fiber communications equipment and other means of transmitting, emitting, storing and receiving images and sounds or intelligence, except that such term does not include the buildings to house such apparatus (other than equipment shelters which are part of satellite earth stations, translators, microwave interconnection facilities and similar facilities).

(12) The term “public telecommunications services” means noncommercial educational and cultural radio and television programs, and related noncommercial instructional or informational material that may be transmitted by means of electronic communications.

(13) The term “Secretary” means the Secretary of Commerce.

(14) The term “State” includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

(15) The term “system of public telecommunications entities” means any combination of public telecommunications entities acting cooperatively to produce, acquire or distribute programs, or to undertake related activities.

Subpart B—Eligibility and Application Procedures

§2301.4 Eligible applicants.

(a) Applications for funding under the Act may only be filed by:

(1) A public or noncommercial educational broadcast station.

(2) A noncommercial telecommunications entity.

(3) A system of public telecommunications entities.

(4) A nonprofit foundation, corporation, institution, or association organized primarily for educational or cultural purposes.

(5) A State or local government or agency or a political or special purpose subdivision of a State.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
(b) Applicants whose proposals require Federal Communications Commission authorizations must be eligible to receive such authorization.

§ 2301.5 Application for financial assistance.

(a) All applications for funding under the Act shall be made on an approved National Telecommunications and Information Administration (NTIA) form and each application shall be signed by an officer of the applicant.

(1) Approved forms may be obtained from the Public Telecommunications Facilities Division, NTIA/DOC, Room 296A, 1325 G Street, N.W., Washington, D.C. 20005.

(b) An applicant may amend its application or submit additional information at any time up to 45 calender days after the closing date published pursuant to § 2301.9 of the Rules.

(c) Radio, television and non-broadcast applications must be submitted separately. Where sharing of a major component (e.g., a tower) is justified, the cost of the shared equipment must be pro-rated between applications.

(d) If an environmental impact or narrative statement is required to be filed in connection with the proposed project by any Federal, State or local law or regulation, a copy must be submitted with the application.

§ 2301.6 Assurances.

No project will be approved unless the applicant has provided in the application information to establish to the Administrator's satisfaction that:

(a) The applicant is an eligible entity under Section 392a (l) of the Act and has authority to plan, construct and operate the public telecommunications facility for which funds are requested;

(b) The public telecommunications facility will be controlled by the applicant;

(c) The public telecommunications facility will be used only for the provision of public telecommunications services;

(d) Necessary funds to construct, operate and maintain the public telecommunications facility will be available when needed;

(2) All non-Federal financial sources available for the project have been taken into account, and the non-Federal share stated by the applicant as being available for use in the project is the maximum contribution available from such sources;

(3) PTTF funds and any monies generated through the use of PTTF funded facilities shall be used solely for noncommercial public telecommunications purposes, as proposed in the application;

(e) The applicant has participated in comprehensive planning for its proposed facility in the area to be served, including an evaluation of alternative technologies and coordination with State educational television, radio and telecommunications agencies, if any;

(f) The applicant will make the most economical and efficient use of the grant;

(g) The applicant holds or will hold appropriate title or lease to the site or sites on which apparatus proposed in the application will be operated, including the right to construct, maintain, operate and remove such apparatus, sufficient to assure continuity of operation of the facility for a period of 10 years following completion of the project;

(h) No person shall, on the grounds of race, color or national origin, be excluded from participation in, be denied the benefits of or otherwise be subjected to discrimination under any program or activity for which the applicant receives funding under this Act. (Title VI of the Civil Rights Act of 1964 as implemented by DOC regulations, 15 CFR §§ 8.1-15.);

(i) No person shall, on the basis of sex, be excluded from participation in, be denied the benefits of or otherwise be subjected to discrimination under any educational program or activity for which the applicant receives funding under the Act. (Title IX of the Education Amendments of 1972, as amended.);

(j) No otherwise qualified individual shall, solely by reason of handicap, be excluded from participation in, be denied the benefits of or otherwise be subjected to discrimination under any program or activity for which the applicant receives funding under this Act (Section 504 of the Rehabilitation Act of 1973, as amended);

§ 2301.7 Deferred applications.

(a) An application which has been accepted for filing may be deferred for funding until a succeeding fiscal year. If in the event that the Administrator defers an application, prompt written notification of that action, together with an explanation for the deferral, will be given to the applicant.

(b) An applicant may reactivate a deferred application if the stated purpose of the application has not substantially changed.

(c) To reactivate a deferred application, the applicant must notify the Administrator in writing, that it wishes the application to be reconsidered. Notice must be given before the closing date specified by the Administrator pursuant to § 2301.8 of the Rules for the filing of current fiscal year applications. An original and one copy of the notice must be filed.

(d) Any notice given under Subsection (c) must be accompanied by the following information contained in the form of a signed amendment to the deferred application:

(1) Pages 1 and 2 and the brief narrative description of the proposal submitted on the current application form;

(2) An update of availability of operating funds and the necessary non-Federal share of the project;

(3) A revised listing of current eligible project costs, if necessary;

(4) A current inventory of all public telecommunications facilities owned by the applicant. Applicants having previously submitted an inventory need only submit updating information;

(5) A five-year plan outlining the applicant's project facilities requirements, and the projected costs of such facilities. Applicants having previously submitted a five-year plan may submit any approved amendments including updating the dates to include the current year;

(6) Current information relating to the applicant's evaluation of alternate technologies currently available in the area and the extent to which there is no duplication of services;

(7) If special consideration is requested under Section 392(i) of the Act, current information detailing the basis for the request and;

(8) Such other information as the Administrator considers necessary.

§ 2301.8 Federal Communications Commission authorization.

(a) Each applicant whose project requires Federal Communications Commission authorization must file an application for that authorization on or before the closing date for filing the funding application;

(b) Any Federal Communications Commission authorization required for the project must be in the name of the applicant.

(c) If the project is to be associated with an existing station, Federal Communications Commission operating authority for that station must be current and valid.

(d) For any project requiring a new authorization or authorizations from the Federal Communications Commission, the applicant must file with the Administrator a copy of each Federal Communications Commission application and any amendments thereto;

(e) If the applicant fails to file a required Federal Communications Commission application or applications by any closing date established pursuant to § 2301.9 of these Rules, or if the Federal Communications Commission returns, dismisses or denies an application required for the project or any part thereof, or for the operation of the station with which the project is associated, the Administrator may...
return the application for Federal financial assistance to the applicant.

(f) No grant will be awarded until confirmation has been received from the Federal Communications Commission that any necessary authorization will be issued.

§ 2301.9 Closing date.

The Administrator shall select and publish in the Federal Register a date by which applications for funding in a current fiscal year are to be filed.

§ 2301.10 Where to file; number of copies.

All applications for grants shall be filed with the Public Telecommunications Facilities Division, NTIA, Room 200A, 1325 G Street, N.W., Washington, D.C. 20204. An original and one copy of the application and supporting documents shall be filed; and any subsequent amendments shall be filed in duplicate.

§ 2301.11 Publication.

(a) Applicants shall cause to be published in a newspaper of general circulation in the community to be served, a notice that it has tendered an application for a Federal grant under the Act, that it has tendered a substantial amendment to a pending application or that it has requested renewed consideration of a deferred application.

(b) The notice shall be published once a week for two consecutive weeks within the three week period following the publication of the acceptance of the application by NTIA. Proof of publication shall be submitted to NTIA in duplicate.

(c) The notice shall contain substantially the same information as the Federal Register notice of acceptance for filing including the invitation to file comments with the Administrator.

§ 2301.12 Service of applications.

(a) Any State or local agencies having jurisdiction over the development of broadcast and/or nonbroadcast telecommunications in the State and the community to be served by the proposed facility, shall be served with one copy of the application and all subsequent amendments. This requirement applies to both planning and construction grant applications and service shall be made within two weeks of the tendering of an application to NTIA.

(b) In the case of a construction grant for which Federal Communications Commission authorization is required, a copy of the application and all subsequent amendments shall, within two weeks of tendering the application to NTIA, be filed with:

1. The Secretary, Federal Communications Commission, Washington, D.C. 20554; and

2. The State educational television, radio or telecommunications agency, if any, in the State in which the channel associated with the project is assigned by the Federal Communications Commission, or, if the channel is assigned jointly to communities in different States, upon the State agency, if any, in each of such States.

(c) Each applicant must also give written notice of the filing of the application to the State educational television, radio or telecommunications agency, if any, in any State, any part of which is within the service area of the proposed facility.

§ 2301.13 Acceptance of applications.

(a) Applications tendered for filing with the Administrator will be given a preliminary examination. Those found to be complete and in accordance with the provisions of this part, will be accepted for filing. Applications which are not complete or which are determined to be not in accordance with the provisions of this part will not be accepted for filing and will be returned to the applicant.

(b) The time periods referred to in Subsections (b) and (c) may be extended by the Administrator if good cause is shown.

§ 2301.15 Distribution of funds.

With respect to applications accepted for filing pursuant to § 2301.13, the Administrator may at any time establish limitations on the maximum amount of Federal grants which may be approved for projects situated in each of the several States in order to assure an equitable distribution of funds among the States for any fiscal year.

§ 2301.16 Coordination with interested agencies and organizations.

In acting on applications and carrying out other responsibilities under the Act, the Administrator may consult with:

(a) The Federal Communications Commission with respect to functions which are of interest to or affect functions of the Federal Communications Commission;

(b) The Corporation for Public Broadcasting with respect to functions which are of interest to or affect the functions of the Corporation; and

(c) Other agencies, organizations and institutions administering programs which may be coordinated effectively with Federal assistance provided under the Act.

§ 2301.17 Funding criteria for construction applications.

In order to achieve the objectives of Section 393 of the Act, the Administrator, in determining whether to approve a construction grant application, in whole or in part, and the amount of such grant, or whether to defer action on such an application, will consider, in addition to how well the applicant has satisfied the assurances of Section 2301.13 of the Act, the following factors (the order of listing implies no priority):

(a) The priorities set forth in the Act and § 2301.20 of the Rules;

(b) The adequacy and continuity of financial resources for long-term operational support, which assures the applicant's continual service to the communities within the service area; and the availability of necessary funds for capital expenditures;
(c) The extent to which non-Federal funds will be used to meet the total cost of the project;
(d) The extent to which the applicant has:
(1) Evaluated alternate technologies, the bases upon which decisions were made as to the technology to be utilized and the extent to which the proposed service will not duplicate service already available;
(2) Assessed plans to meet the specific educational, informational and cultural needs of the total community to be served by the proposed telecommunications service;
(3) Designed the proposed service to help meet the assessed needs;
(4) Provided for the total community served to participate in the planning for and implementation of the proposed service;
(5) Provided opportunities for the intended audiences to use the proposed service; and
(6) Provided meaningful documentation of community support for the service to be provided (such as letters from agencies for whom the applicant produces or will produce programs or other materials and from key elected/appointed policy-making officials).
(e) The extent to which the evidence supplied in the project reasonably assures an increase in minority and women’s control, of operation of and participation in public telecommunications entities; and the extent to which similar concerns of handicapped individuals have been taken into consideration;
(f) The extent to which the various items of eligible apparatus proposed are necessary to, and capable of, achieving the objectives of the project and will permit the most efficient use of the grant funds in serving the proposed total community;
(g) The extent to which the eligible equipment requested meets current telecommunications industry performance standards;
(h) The extent to which the applicant will have available sufficient qualified staff, and will provide services of professional quality;
(i) The extent to which the applicant has planned and coordinated the proposed services with other telecommunications entities in the service area;
(j) The extent to which the project implements local, Statewide or regional public telecommunications systems plans, if any;
(k) The extent to which the applicant’s proposed five-year facilities plan required by Section 392(a) of the Act is practical, financially affordable and consistent with the intent of the Act and Regulations; and
(l) The approval by the Federal Communications Commission of any necessary authorization.

§ 3201.18 Funding criteria for planning applications.

In order to achieve the objectives of Section 392(a) of the Act, the Administrator, in determining whether to approve a planning grant application, in whole or in part, and the amount of such grant, or whether to defer action on such an application, will consider, in addition to how well the applicant has satisfied the assurances of Section 392(a) of the Act, the following factors (the order of listing implies no priority):
(a) The extent to which the applicant’s interests and purposes are relevant to the proposed planning;
(b) The qualifications of the proposed planner to provide a public telecommunications facilities plan;
(c) The extent to which the planning project’s procedural design will assure adequate:
(1) Knowledge of the needs of the area to be served;
(2) Financial, human and support resources necessary to conduct the plan;
(3) Public awareness of and participation in the proposed planning;
(4) Coordination with other telecommunications entities at the local, state, regional and national levels;
(5) Evaluation of alternate technologies and duplication of services; and
(6) Participation by minorities and women;
(d) The extent to which the completed plan incorporates provision for implementing the proposed telecommunications service and addresses the funding objectives of the Act (i.e., engineering, legal, site preparation, leases, land acquisition, etc.), construction, five-year plan of proposed services, appropriate facilities and operation (fiscal resources, staff, etc.).
(e) The extent to which the proposed procedure and timetable are feasible and can achieve the expected results.

§ 3201.19 Action on applications.

(a) After consideration of an application that has been accepted for filing, any comments and replies filed by interested parties and any other relevant information, the Administrator will take one of the following actions: select the application for funding, in whole or in part; defer the application for subsequent consideration pursuant to § 3201.7 of the Rules; or return the application to the applicant; Provided, That when the Administrator returns an application, the Administrator will notify the applicant of the grounds and reasons therefor.
(b) Upon the Administrator’s approval or deferral, in whole or in part, of an application, the Administrator will inform:
(1) The applicant;
(2) Each State educational television, radio or telecommunications agency, if any, in any State, any part of which lies within the service area of the applicant’s facility;
(3) The Federal Communications Commission; and
(4) The Corporation for Public Broadcasting.

§ 3201.20 Program priorities.

(a) The following objectives, listed in order of priority, shall govern the Administrator’s determination to fund an application and the amount of the grant awarded:
(1) Whether the application will provide new public telecommunications facilities to extend service to areas not currently receiving such services.
(2) Whether the application will result in the expansion of service areas of existing public telecommunications entities.
(3) Whether the application will result in the improvement of the capabilities of existing public broadcast stations to provide public telecommunications services.
(b) Notwithstanding the priorities among applications listed in Subsection (a), the Administrator may utilize any remaining appropriated funds to award grants to applicants who are otherwise eligible for funding but do not fall within any of the statutory priorities. Grants made pursuant to this subsection, must fulfill the overall objectives of the Act.

§ 3201.21 Special consideration.

In assessing applications, the Administrator will give special consideration to applications which foster control of, operation of and participation in public telecommunications entities by minorities and women.

Subpart D—Federal Financial Participation and Conditions of Federal Grant

§ 3201.22 Amount of federal grant.

(a) Planning grants. A Federal grant award for the planning of a public telecommunications facility shall be in an amount determined by the Administrator and set forth in the grant award document.
§ 2301.24 Conditions of Federal Grant.

(a) Each Federal grant under this part shall be subject to the conditions that the grantee shall:

(1) Continue to meet the requirements set forth in §§ 2301.4 and 2301.5;

(2) Use the Federal grant funds for the purposes for which the grant was made and for the items of apparatus and other expenditure items specified in the application for inclusion in the project, except that the grantee may substitute other items where necessary or desirable to carry out the purpose of the project as approved in advance by the Administrator;

(3) Promptly complete the project and place the public telecommunications facility into operation;

(4) Maintain, during construction of the project and for 10 years after completion of the project, protection against common hazards through adequate insurance coverage or other equivalent undertakings, except that, to the extent the applicant follows a different policy of protection with respect to its other property, the applicant may extend such policy to apparatus acquired and installed under the project;

(5) (i) Permit the Administrator and the Comptroller General of the United States or their duly authorized representatives access for the purpose of audit and examination to any books, documents, papers and records of any grantee that are pertinent to assistance received under this program.

(ii) Permit inspections by the Administrator, or the Administrator's duly authorized representatives, of the public telecommunications facilities acquired with Federal financial assistance at any reasonable time within 10 years after completion of the project.

(iii) In carrying out the authority conferred in this Section, the Administrator and the Administrator's duly authorized representatives, shall request admission for inspection, audits and examinations only during normal working hours of the grantee.

§ 2301.25 Procurement standards.

(a) Grantees that are States, political or special purpose subdivisions of States or public agencies shall adopt the current addition of Office of Management and Budget Circular No. A-102.

(b) Grantees that are nonprofit private foundations, corporations or associations shall adopt the current edition of Office of Management and Budget Circular A-110.

§ 2301.26 Consolidated procurement.

(a) In order to obtain quantity discounts, applicants are encouraged to explore with other applicants the consolidated procurement of public telecommunications facilities with program funds. Responsibility for the proper disbursement of program funds and the use and control of funds purchased pursuant to this Section must remain with the individual grantees. This Section does not supersede or modify the procurement standards, contained in Section 2301.25.

(b) Applicants may enter into consolidated purchase agreements at any time. Copies of agreements must be submitted with the application or as an amendment and may be used to establish that the applicants will make the most efficient and economical use of program funds.

(c) If a group of applicants agree to a consolidated procurement, a written copy of the agreement must be submitted to the Administrator before any order for facilities may be placed. The Administrator shall promptly notify the applicants of the approval or disapproval of the agreement.

§ 2301.27 Securing the Federal interest.

In order to assure that the Federal investment in public telecommunications facilities funded under the Act will continue to be used to provide public telecommunications services to the public during the 10 period of Federal interest in the event of a grantee's change of eligibility status, bankruptcy, failure, etc., grantees shall either:

(a) Obtain and keep current a bond to indemnify the Federal Government's investment in their public telecommunications facilities during the period of continuing Federal interest. The bond shall be in an amount at least equal to the Federal Government's contribution to the cost of the facility and the cost of the bond shall be borne by the grantee; or

(b) Execute and record a document establishing that the Federal Government has a priority lien on any facilities purchased with funds under the Act during the period of continuing Federal interest. The document shall be recorded where liens are normally recorded in the community where the facility is located and in the community where the grantee's headquarters are located.

(c) The bond and annual extensions or a certified copy of the recorded lien shall be filed with the Administrator.

(d) The continuing period of Federal interest shall be no less than 10 years from the date of completion of the project. In addition, for grantees that are subsidiaries of or affiliated with churches or other religious organizations, facilities purchased in whole or in part with program funds may not be utilized for any religious purpose.
§ 2301.28 Nondiscrimination.

(a) It is the purpose of this Section to reflect the fullest extent possible NTIA's commitment to the nondiscrimination policies of the Federal Government as expressed in the several statutes. Each applicant, and its employees and messengers of the President, dealing with civil rights and equality of opportunity, discrimination based on race, color, national origin, sex or physical handicap shall be prohibited by all grantees.

(b) NTIA shall enforce Title VI of the Civil Rights Act of 1964, as implemented by Department of Commerce regulations, 15 CFR Subtitle A, Part 8, which is hereby incorporated in this part by reference.

(c) NTIA shall enforce Title IX of the Education Amendments of 1972, as amended. Department of Commerce implementing regulations have not yet been adopted but will be incorporated by reference in this part upon their adoption.

(d) NTIA shall enforce Section 504 of the Rehabilitation Act of 1973, as amended. Department of Commerce implementing regulations have not been proposed, 43 FR 53765, published November 17, 1978. Final regulations will be incorporated by reference in this part.

(e) Equal Employment Opportunity Program. Each applicant shall establish, maintain and carry out a positive continuing program of specific practices designed to assure equal opportunity in every aspect of facilities employment policy and practice. Under the terms of its program, a grantee shall:

(1) Define the responsibility of each level of management to secure a positive application and vigorous enforcement of the policy of equal opportunity, and establish a procedure to review and control managerial and supervisory performance;

(2) Inform its employees and recognized employee organizations of the positive equal opportunity policy and program and enlist their cooperation;

(3) Communicate the equal opportunity opportunity policy and program and enlist their cooperation;

(4) Conduct a continuing campaign to exclude every form of prejudice or discrimination based upon race, color, national origin, sex or physical handicap and solicit their recruitment assistance on a continuing basis;

(5) Conduct a continuing review of job structure and employment practices and adopt positive recruitment, training, job design and other measures needed in order to insure genuine equality of opportunity to participate fully in all organizational units, occupations and levels of responsibility in the applicant.

(f) Each Applicant for a grant shall file with the Administrator, as part of the application, an action plan designed to provide equal employment opportunities to minorities, women and qualified physically handicapped individuals. A plan need not be filed by an applicant having less than five full-time employees or whose service area contains minorities in such insignificant numbers that an action plan would not be meaningful. In the latter situation, a statement of explanation must be filed.

(g) In the case of an applicant requiring an authorization from the Federal Communications Commission, a copy of the equal employment opportunity program filed with that agency shall be filed with the Administrator.

(5) Any person who believes that they have been the subject of discrimination prohibited by this part may file a written complaint with the Director, Public Telecommunications Facilities Division, NTIA, Room 285A, 1325 G Street, N.W., Washington, D.C. 20005. Any such complaint must be filed within 90 days of the date of the alleged discrimination, unless the time deadline is extended by the Director, Public Telecommunications Facilities Division.

(i) Intimidatory or retaliatory acts in response to complaints or potential complaints are prohibited.

(1) No other party shall intimidate, threaten, coerce or discriminate against, any person for the purpose of interfering with any right or privilege secured by this Subpart, or because the person has made a complaint, testified, assisted or participated in any manner in an investigation, proceeding or hearing under this Subpart.

(2) The identity of complainants shall be kept confidential except to the extent necessary to carry out the purposes of this Subpart, including the conduct of an investigation, hearing or judicial or other proceeding thereunder.

(j) The Director, Public Telecommunications Facilities Division shall make a prompt investigation whenever a compliance report, review, complaint or any other information indicates a possible failure to comply with this subpart.

(2) The investigation shall include, where appropriate, a review of the pertinent practices and policy of the grantee or other party subject to this Subpart, the circumstances under which the possible noncompliance occurred, and other factors relevant to a determination as to whether there has been a failure to comply with this subpart.

(3) If an investigation pursuant to Subsection (1) of this section indicates a failure to comply with this Section the Director, Public Telecommunications Facilities Division shall so inform the grantee and shall attempt to resolve the matter by informal means. If the investigation does not indicate a failure to comply with this Section, the grantee and the complainant, if any, shall be so advised in writing.

(k) If there is a failure to comply with this Section, and the matter cannot be resolved by informal means, the Administrator is authorized to:

(1) Terminate the grant; or

(2) Take such other action as may be authorized by law.

Subpart E—Accountability for Federal Funds

§ 2301.29 Retention of records.

(a) Each recipient of assistance under this program shall keep intact and accessible records to enable the Administrator to carry out the functions of the Administrator under the Act. Such records shall consist of:

(1) A complete and itemized inventory of all public telecommunications facilities under the control of the grantee, whether or not financed, in whole or in part, with Federal funds (this requirement is not applicable to planning grant applicants);

(2) Complete, current and accessible financial records which fully disclose the total amount of the project; the amount of the grant; the disposition of the grant proceeds; and the amount, nature and source of non-Federal funds associated with the project;

(b) The grantee shall mark project apparatus in a permanent manner in order to assure easy and accurate identification and reference to inventory records. (This requirement is not applicable to planning grant applicants.)

(c) The grantee, in advertising for bids for the purchase of apparatus, shall state that the Federal government has an interest in facilities purchased with Federal funds under this program. (This requirement is not applicable to planning grant applicants.)

§ 2301.30 Final certification.

Upon completion of the project, the grantee shall:

(a) Certify that the acquisition and installation of the project equipment has been completed in accordance with the project and is approved by the Administrator; and

(b) Certify that it has any necessary Federal Communications Commission authorizations to operate following acquisition and installation of project equipment.
§ 2301.31 Annual status reports.
(a) The grantee must file with the Administrator during the 10-year period commencing with the date of completion of a project, an annual status report on or before each April 1 following completion of the project, certifying that:

(1) The grantee continues to be an eligible agency, institution, foundation, corporation, association or municipality described in Section 2301.4;

(2) There has been no change in ownership of or use of project apparatus during the reporting period, or describing any change occurring during such period;

(3) Project apparatus owned by the grantee as of that date is being used only for the delivery of public telecommunications services; and

(4) The requirements of §§ 2301.20, 22 and 23 continue to be met.

§ 2301.32 Termination and change in eligibility status.
(a) The following circumstances shall constitute grounds for termination of a grant and for recovery from the applicant or other owner of the facilities of the amount bearing the same ratio to the value of the facilities as the federal grant bore to the project if they occur within 10 years after completion of the project:

(1) The applicant, grantee or other owner of the facilities ceases to be an agency, institution, foundation, corporation, association or other entity described in Section 392(a)(1) of the Act;

(2) The facilities, either permanently or for an indefinite period of time, cease to be used only for the provision of public telecommunications services (unless the Administrator determines, based on a petition for such relief with opportunity for filing oppositions by interested parties of the public, that good cause exists to release the applicant, grantee or other owner from this obligation);

(3) Final action by the Federal Communications Commission revoking a construction permit required for a project, denying an application for extension or a required modification of a construction permit, denying an application for construction permit, denying an application for a license to cover construction permit or revoking a license; or

(4) Forfeiture of a construction permit required for a project for which a grant has been approved.
(b) In the event that one or more of the circumstances listed in Subsection (a) occur, then the grantee shall, except as provided in Subsection (c), either relinquish title and control of the facilities purchased with Federal funds to the Administrator or shall pay to the United States the amount bearing the same ratio to the then fair market value of such apparatus, as the amount of the Federal participation bore to the cost of acquisition or installation of such apparatus.
(c) Where a grantee proposes to cease using any apparatus included in the project for public telecommunications services that grantee may file a petition with the Administrator requesting release from the obligation to make repayment to the United States, and setting forth with particularity the grounds and reasons for the request. These petitions will be granted by the Administrator only for good cause, and only if the proposed cessation of use for public telecommunications services has not already taken place, unless the petitioner demonstrates to the satisfaction of the Administrator, that the cessation was due to causes not under the control of the grantee or other owner of the facilities. The Administrator denies the petition, the grantee may, within 30 calendar days from the date of receipt of notice of the denial, file a petition for reconsideration pursuant to § 2301.33.
(d) In all cases where the Administrator has reason to believe that any change in eligibility or use of public telecommunications facilities (as described in Subsection (a)), has already taken place, the grantee will be notified promptly of the grounds and reasons and requested to relinquish control or to make repayment to the United States pursuant to Subsection (b). The Administrator will seek to reach agreement as to the amount and method of settlement.

If agreement cannot be reached, the Administrator will cause an action to be brought in the United States District Court for the district in which the facilities are situated to determine the amount of the repayment, and will take the necessary action to secure payment.

§ 2301.33 Petition for reconsideration.
(a) A petition for reconsideration as provided in §§ 2301.13 and 2301.32 and must be filed with the Administrator within 30 calendar days after the date of receipt of the notice of the adverse decision; must state specifically in what respect the Administrator’s action is claimed to be unjust, unwarranted or erroneous; must specifically indicate the relief sought; and must be accompanied by a written statement on the question presented.
(b) The Administrator shall delegate authority to review the petition for reconsideration to a five member Grant Appeals Board, comprised of the Deputy Administrator, the Chief Counsel, the Deputy Associate Administrator of the Office of Policy Analysis and Development, the Director of the Office of International Affairs, the Director of the Office of Planning and Policy Coordination or such other high-ranking NTIA employees as the Administrator may select; Provided, That no member of the Board shall be employed in the Office of Telecommunications Applications. The Board shall sit in panels of three members.
(c) The Board will notify each State telecommunications agency, if any, in any State, any part of which lies within the area served by petitioner’s programming, of the petition. Each such agency shall be given an opportunity to submit written comments on the petition.
(d) Interested persons other than a State educational television, radio or telecommunications agency referred to in Subsection (c) of this section may submit written comments on any petition for reconsideration filed under this section.
(e) The Board shall review the petition and any comments received pursuant to Subsections (c) and (d) and make a written report, detailing the basis of its decision. A copy of the report shall be mailed to the petitioner and any agency or party that filed comments. If the Board grants the petition, it shall concurrently direct the staff to take appropriate action on the application. The decision of the Board shall constitute final NTIA action.

Subpart F—Control and Use of Facilities
§ 2301.34 Equipment.
(a) All equipment proposed to be funded under this program shall be of professional quality. An applicant proposing to utilize non-broadcast technology shall propose and purchase equipment that is compatible with broadcast equipment wherever the two types of apparatus interface.
(b) Buildings to house eligible equipment are not themselves eligible for funding under this program; Provided, That small equipment shelters which are part of satellite earth stations, translators, microwave interconnection facilities and similar facilities are eligible for funding.

§ 2301.35 Items and costs ineligible for Federal funding.
The following items and costs are ineligible for funding under the Act:
(a) Equipment and Supplies:
(1) Vehicles, including those in which mobile equipment is mounted or carried;
(2) Receiving equipment (except as required for monitoring or transmission; vertical interval or subcarrier receivers and decoders; or satellite receivers);
(3) Equipment for motion picture or still photography or processing;
(4) Manual film or tape editing equipment, film, recording tape, reels, film or tape cleaning equipment;
(5) Scenery and props; art supplies and equipment;
(6) Sound installation devices, cyclorama, wall fixtures, studio clocks, furniture, and the like;
(7) Production devices such as prompting systems, background projection systems, sound effects, and the like;
(8) Office equipment, printing and duplication supplies;
(9) Maintenance equipment such as hand and power tools, storage cabinets and maintenance services;
(10) Air conditioning for control or equipment rooms, studios, transmitter buildings, mobile units and other operational rooms and offices (except that the cost to provide ventilation of project apparatus as is required by good engineering practice is an eligible installation cost);
(11) Primary power supply regulators and associated equipment;
(12) Expendable items, including spare recording heads, spare lenses, spare circuit components and other kits normally considered spares except for transmitters; and
(13) Such other equipment and supplies as the Administrator may select.

(b) Other Expenses:
(1) Land and land improvements;
(2) Any portion of the salaries of any personnel employed by an operating public telecommunications entity;
(3) Moving costs required by relocation; and
(4) Such other expenses as the Administrator may select.

§ 2301.36 Control and use of facilities.

Any public telecommunications facilities, funded in whole or in part under the Act, shall remain under the control of the grantee and shall be used only for the provision of public telecommunications services.

§ 2301.37 Waiver.

For good cause shown, the Administrator may waive the regulations adopted pursuant to Section 392(e) of the Act.

[FR Doc. 79-7298 Filed 3-8-79; 8:45 am]
EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

PREGNANCY DISCRIMINATION ACT

Adoption of Interim Interpretative Guidelines, Questions, and Answers
TITLE 29—LABOR
CHAPTER XIV—EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

PART 1604—GUIDELINES ON DISCRIMINATION BECAUSE OF SEX UNDER TITLE VII OF THE CIVIL RIGHTS ACT OF 1964, AS AMENDED

Adoption of Interim Interpretive Guidelines, Questions and Answers


SUMMARY: On October 31, 1978, President Carter signed into law the Pregnancy Discrimination Act, Pub. L. 95-555, 92 Stat. 2076, as an amendment to Title VII of the Civil Rights Act of 1964, as amended. The Act requires that persons affected by pregnancy, childbirth, or related medical conditions be treated the same as other persons not so affected but similar in their ability or inability to work, must be in compliance with the provisions of 1604.10(b) by April 30, 1979. The changes are made to reflect the fact that Congress did not require that health insurance be provided for abortions in all circumstances. Finally, the phrase “pregnancy, childbirth, or related medical conditions” is used when appropriate to track the language of the statute.

SUMMARY: Upon October 31, 1978, President Carter signed into law the Pregnancy Discrimination Act, Pub. L. 95-555, 92 Stat. 2076, as an amendment to Title VII of the Civil Rights Act of 1964, as amended. The Act requires that persons affected by pregnancy, childbirth, or related medical conditions be treated the same as other persons not so affected but similar in their ability or inability to work, must be in compliance with the provisions of 1604.10(b) by April 30, 1979. The changes are made to reflect the fact that Congress did not require that health insurance be provided for abortions in all circumstances. Finally, the phrase “pregnancy, childbirth, or related medical conditions” is used when appropriate to track the language of the statute.

RULES AND REGULATIONS

The Pregnancy Discrimination Act makes clear that Title VII of the Civil Rights Act of 1964, as amended, forbids discrimination on the basis of pregnancy, childbirth, and related medical conditions. As reflected in the Committee Reports (Senate Report 98-331, 95th Cong., 1st Session (1977) and House of Representatives Report 98-948, 95th Cong. 2d Session (1978)), Congress believed that the Equal Employment Opportunity Commission (EEOC or the Commission), in its Guidelines on Discrimination Because of Sex (29 CFR Part 1604, published at 39 FR 6836, April 5, 1974) had “sufficiently implemented the Title VII prohibition with respect to discrimination in the 1964 act.” H.R. 95-948 at p. 2. Contrary to the EEOC’s Guidelines and rulings by eightieth District Courts and all seven Courts of Appeal which faced the issue, in General Electric Co. v. Gilbert, 429 U.S. 125 (1976), the Supreme Court ruled that General Electric’s exclusion of pregnancy-related disabilities from its comprehensive disability plan did not violate Title VII. The Supreme Court further indicated that it believed that the EEOC Guidelines located at 29 CFR §1604.10(b) incorrectly interpreted the Congressional intent in the statute.

The Pregnancy Discrimination Act reaffirms EEOC’s Guidelines with but minor modifications. For that reason, the Commission believes that only slight modifications of its Guidelines are necessary, and is now reissuing them with changes.

The changes are the following:

§1604.10(a). After the word “pregnancy”, the phrase “childbirth and related medical conditions” is added to track the language of the Pregnancy Discrimination Act.

§1604.10(b). This section is changed as follows:

(b) Disabilities caused or contributed to by pregnancy, childbirth, or related medical conditions, for all-job-related purposes, shall be treated the same as disabilities caused or contributed to by other medical conditions, under any health or disability insurance or sick leave plan available in connection with employment. Written or unwritten employment policies and practices involving matters such as the commencement and duration of leave, the availability of extensions, the accrual of credits, and other benefits and privileges, reinstatement, and payment under any health or disability insurance or sick leave plan, formal or informal, shall be applied to disability due to pregnancy, childbirth or related medical conditions on the same terms and conditions as they are applied to other disabilities. “Health insurance benefits for abortion, except where the life of the mother would be endangered if the fetus were carried to term or where medical complications have arisen from an abortion, are not required to be paid by an employer; nothing herein, however, precludes an employer from providing abortion benefits or otherwise affects bargaining agreements in regard to abortion.”

The Pregnancy Discrimination Act requires that persons affected by pregnancy, childbirth and related medical conditions be treated the same as persons affected by other disabilities. To the extent that pregnancy-related conditions cause long term or permanent disabilities, employees affected by such disabilities must be accorded the same rights and benefits accorded to other employees with long term or permanent disabilities. For that reason, the word “temporary” is deleted from the subsection. The first sentence is modified to effect the deletion of the word “temporary.”

The word “abortifacient” is deleted from the first sentence and a new sentence is added to the subsection. These changes are made to reflect the fact that Congress did not require that health insurance be provided for abortions in all circumstances.

Finally, the phrase “pregnancy, childbirth, or related medical conditions” is used when appropriate to track the language of the statute.

§1604.10(d) is added, as follows: “Any fringe benefit program, or fund, or insurance program which is in effect on October 31, 1978, which does not treat women affected by pregnancy, childbirth, or related medical conditions the same as other persons not so affected but similar in their ability or inability to work, must be in compliance with the provisions of 1604.10(b) by April 30, 1979. In order to come into compliance with the provisions of 1604.10(b), there can be no reduction of benefits or compensation which were in effect on October 31, 1978, before October 31, 1979 or the expiration of a collective bargaining agreement in effect on October 31, 1978, whichever is later. “Any fringe benefit program implemented after October 31, 1978, must comply with the provisions of 1604.10(b) upon implementation.”

This addition is made to reflect the fact that Congress provided a grace period of 180 days to allow the amendment of fringe benefit programs in existing collective bargaining agreements prior to October 31, 1979, and that Congress further provided that neither benefits nor compensation could be reduced in order to effect compliance with the Act.

In addition, the Commission publishes herewith a list of questions and answers concerning the Pregnancy Discrimination Act. These respond to urgent concerns raised by employees, employers, unions and insurers who have sought the Commission’s guidance in understanding their rights and obligations under the Pregnancy Discrimination Act.

Fringe benefit programs subject to Title VII which existed on October 31, 1978, must be modified in accordance with the Pregnancy Discrimination Act no later than April 30, 1979. It is the Commission’s desire, therefore, that all interested parties be made aware of EEOC’s view of their rights and obligations sufficiently in advance.
of April 29, 1979, so that they may be in compliance by that date. For that reason, the Commission has determined that the amendment to 29 CFR § 1604.10 and the questions and answers, which will be appended to 29 CFR Part 1604, are not subject to the requirement that they be published before October 29, 1979. See § 6(b)(6) of Executive Order 12044.

The Commission has, however, received comments from interested members of the public and will continue to accept and consider such comments for a period of 30 days after publication of the amendment to 29 CFR § 1604.10 and the attached questions and answers. In addition, in accord with Executive Order 12007, the Commission has solicited the views of affected Federal agencies. If appropriate, the Commission will reconsider the views expressed within. The Commission wishes to emphasize that the fact that a woman may consider some of the views expressed below will not in any way excuse failure to comply with the Pregnancy Discrimination Act by the statutory deadlines.


Signed at Washington, D.C., this 6th day of March 1979.

E. Nonzo,
Chair, Equal Employment
Opportunity Commission.

1. 29 CFR § 1604.10 is amended to read as follows:

§ 1604.10 Employment policies relating to pregnancy and childbirth.

(a) A written or unwritten employment policy or practice which excludes from employment applicants or employees because of pregnancy, childbirth or related medical conditions is prima facie violation of Title VII.

(b) Disabilities caused or contributed to by pregnancy, childbirth, or related medical conditions, for all job-related purposes, shall be treated the same as disabilities caused or contributed to by other medical conditions, under any health or disability insurance or sick leave plan available in connection with employment. Written or unwritten employment policies and practices involving matters such as the commencement and duration of leave, the availability of extensions, the accrual of seniority and other benefits and privileges, reinstatement, and payment under any health or disability insurance or sick leave plan, formal or informal, shall be applied to disability due to pregnancy, childbirth or related medical conditions on the same terms and conditions as they are applied to other disabilities. Title VII insurance benefits for abortion, except where the life of the mother would be endangered if the fetus were carried to term or where medical complications have arisen from an abortion, are not required to be provided by an employer. Nothing herein, however, precludes an employer from providing abortion benefits or otherwise affects bargaining agreements in regard to abortion.

(c) Where the termination of an employee who is temporarily disabled is caused by an employment policy under which insufficient or no leave is available, such a termination violates the Act if it has a disparate impact on employees of one sex and is not justified by business necessity.

(d)(1) Any fringe benefit program, or fund, or insurance program which is in effect on October 31, 1978, which does not treat women affected by pregnancy, childbirth, or related medical conditions the same as other persons not so affected but similar in their ability or inability to work, must be in compliance with the provisions of § 1604.10(b) by April 29, 1979. In order to come into compliance with the provisions of § 1604.10(b), there can be no reduction of benefits or compensation which were in effect on October 31, 1978, before October 31, 1978 or the expiration of a collective bargaining agreement in effect on October 31, 1978, whichever is later.

(d)(2) Any fringe benefit program implemented after October 31, 1978, must comply with the provisions of § 1604.10(b) upon implementation.

2. The following questions and answers, with an introduction, are added to 29 CFR Part 1604 as an appendix:


INTRODUCTION

On October 31, 1978, President Carter signed into law the Pregnancy Discrimination Act (Pub. L. 95-555). The Act is an amendment to Title VII of the Civil Rights Act of 1964 which prohibits, among other things, discrimination in employment on the basis of sex. The Pregnancy Discrimination Act makes it clear that "because of sex" or "on the basis of sex," as used in Title VII, includes "because of pregnancy, childbirth, or related medical conditions." Therefore, Title VII prohibits discrimination in employment against women affected by pregnancy, childbirth or related medical conditions. The basic principle of the Act is that women affected by pregnancy and related medical conditions are entitled to the same rights and benefits that other applicants and employees on the basis of their ability or inability to work. A woman is therefore protected against such practices as being fired, or refused a job or promotion because she is pregnant, or has had an abortion. She usually cannot be forced to go on leave as long as she can still work. If other employees who take disability leave are entitled to get their jobs back when they are able to work again, so are women who have been unable to work because of pregnancy.

In the area of fringe benefits, such as disability benefits, sick leave and health insurance, the same principle applies. A woman unable to work for pregnancy-related reasons is entitled to disability benefits or sick leave on the same basis as employees unable to work for other medical reasons. Also, any health insurance coverage which excludes expenses for pregnancy-related conditions on the same basis as expenses for other medical conditions is not required to be provided by an employer. If the fetus were carried to term, or where medical complications have arisen from abortion, is not required except where the life of the mother would be endangered if the fetus were carried to term. Where medical complications have arisen from abortion.

Some questions and answers about the Pregnancy Discrimination Act follow. Although the questions and answers are not limited to the term "employer," the Act—and these questions and answers—apply also to unions and other entities covered by Title VII.

1. Q. What is the effective date of the Pregnancy Discrimination Act?

A. The Act became effective on October 31, 1978, except that with respect to fringe benefit programs in effect on that date, the Act will take effect 180 days thereafter, that is, April 29, 1979. To the extent that Title VII already required employers to treat persons affected by pregnancy-related conditions the same as persons affected by other conditions, and from failure to comply with the Pregnancy Discrimination Act, the Act does not change employee rights arising prior to October 31, 1978, or Act effective date. Most employer practices relating to pregnancy, childbirth and related conditions—whether concerning fringe benefits or other practices—were already controlled by Title VII prior to this Act. For example, Title VII has always prohibited an employer from firing, or refusing to hire or promote, a woman because of pregnancy or related conditions, and on those grounds to accord a woman on pregnancy-related leave the same seniority retention and accrual accorded to other disability leaves.

2. Q. If an employer has a sick leave policy in effect on October 31, 1978, by what date must the employer bring its policy into compliance with the Act?

A. With respect to payment of benefits, an employer has until April 29, 1979, to bring into compliance any fringe benefit or insurance program, including a sick leave policy, which was in effect on October 31, 1978. However, any such policy or program created after October 31, 1978, must be in compliance with the Act immediately.

With respect to all aspects of sick leave policy other than payment of benefits, such as eligibility for benefits, the period of time during which benefits can be accrued, the denial of seniority, credit for vacation, and remuneration of former job on return from sick leave, equality of treatment was required by Title VII of the Civil Rights Act of 1964, as amended, as of October 31, 1978. The Pregnancy Discrimination Act does not extend the Title VII requirements beyond this date.

3. Q. Must an employer provide benefits for pregnancy-related conditions to an employee whose pregnancy begins prior to April 29, 1979, and continues beyond that date?
A. As of April 29, 1979, the effective date of the Act's requirements, an employer must provide the same benefits for pregnancy-related conditions as it provides for other conditions, regardless of when the pregnancy began. Thus, disability benefits must be paid for all absences on or after April 29, 1979, resulting from pregnancy-related temporary disabilities to the same extent as they are payable for any other temporary disabilities. For example, if an employee gives birth before April 29, 1979, but is still unable to work on or after that date, she is entitled to the same disability benefits available to other employees. Similarly, medical insurance benefits must be paid for pregnancy-related expenses incurred on or after April 29, 1979.

If an employer requires an employee to be employed for a predetermined period prior to being eligible for insurance coverage, the period prior to April 29, 1979, during which a pregnant employee has been employed must be credited toward the eligibility waiting period on the same basis as for any other employee.

As to any programs instituted for the first time after October 31, 1978, coverage for pregnancy-related conditions must be provided in the same manner as for other medical conditions.

3. Q. Would the answer to the preceding question be the same if the employee became pregnant prior to October 31, 1978?
A. Yes.

5. Q. If, for pregnancy-related reasons, an employee is unable to perform the functions of her job, does the employer have to provide her an alternative job?
A. An employer may not single out pregnancy-related conditions for special procedures for determining an employee's ability to work. However, an employer may use any procedure used to determine the ability of all employees to work. For example, if an employer requires its employees to submit a doctor's statement concerning their ability to work before granting leave or paying sick benefits, the employer may require employees affected by pregnancy-related conditions to submit such statement. Similarly, if an employer's disability benefits must be obtained from personal physicians for absences due to other disabilities or return dates from other disabilities, it may require a doctor's statement from personal physicians for absences and return dates connected with pregnancy-related disabilities.

7. Q. Can an employer have a rule which prohibits an employee from returning to work for a predetermined length of time after childbirth?
A. No.

8. Q. If an employee has been absent from work as a result of a pregnancy-related condition and recovers, may her employer require her to remain on leave until after her baby is born?
A. No. An employee must be permitted to work at all times during pregnancy when she is able to work.

9. Q. May an employer hold open the job of an employee who is absent on leave because she is temporarily disabled by pregnancy-related conditions?
A. Unless the employee on leave has informed the employer that she does not intend to return to work, her job must be held open for her return on the same basis as jobs are held open for employees on sick or disability leave for other reasons.

10. Q. May an employer hold open an employee's seniority in the same manner as seniority during absences for medical conditions be different for employees affected by pregnancy-related conditions than for other employees?
A. No. An employer's seniority policy must be the same for employees absent for pregnancy-related conditions as for those absent for other medical reasons.

11. Q. For purposes of calculating such matters as vacations and pay increases, must an employer credit time spent on leave for pregnancy-related reasons differently than time spent on leave for other reasons?
A. No. An employer's policy with respect to crediting time for the purpose of calculating such matters as vacations and pay increases cannot treat employees on leave for pregnancy-related reasons less favorably than employees on leave for other reasons. For example, if employees on leave for medical reasons are credited with the time spent on leave when computing entitlement to vacation or pay raises, an employee on leave for pregnancy-related disability is entitled to the same kind of time credit.

12. Q. Must an employer hire a woman who is medically unable, because of a pregnancy-related condition, to perform a necessary function of a job?
A. An employer cannot refuse to hire a woman because of her pregnancy-related condition so long as she is able to perform the major functions necessary to the job. Nor can an employer refuse to hire her because of its preferences against pregnant workers or the preferences of co-workers, clients, or customers.

13. Q. May an employer limit disability benefits for pregnancy-related conditions to married employees?
A. No.

14. Q. If an employer has an all female workforce or job classification, must benefits be provided for pregnancy-related conditions?
A. Yes. If benefits are provided for other conditions, they must also be provided for pregnancy-related conditions.

15. Q. For what length of time must an employer who provides income maintenance benefits for temporary disabilities provide such benefits for pregnancy-related disabilities?
A. Benefits should be provided for as long as the employee is unable to work for medical reasons unless some other limitation is set for all other temporary disabilities, in which case pregnancy-related disabilities should be treated the same as other temporary disabilities.

16. Q. Must an employer who provides benefits for long-term or permanent disabilities also provide benefits for pregnancy-related conditions?
A. Yes. Benefits for long-term or permanent disabilities resulting from pregnancy-related conditions must be provided to the same extent that such benefits are provided for other conditions which result in long-term or permanent disabilities.

17. Q. If an employer provides benefits to employees on leave, such as installment purchase disability insurance, payment of premiums, and additional payments into pension, saving or profit sharing plans, must the same benefits be provided for those on leave for pregnancy-related conditions?
A. Yes. The employer must provide the same benefits for those on leave for pregnancy-related conditions as for those on leave for other reasons.

18. Q. Can an employee who is absent due to a pregnancy-related disability be required to exhaust vacation benefits before receiving sick leave pay or disability benefits?
A. No. If employees who are absent because of other disabling causes receive sick leave pay or disability benefits without any requirement that they first exhaust vacation benefits, the employer cannot impose this requirement on an employee absent for a pregnancy-related cause.

19. Q. If state law requires an employer to provide disability insurance for a specified period before and after childbirth, does such compliance with the state law fulfill the employer's obligation under the Pregnancy Discrimination Act?
A. Not necessarily. It is an employer's obligation to treat employees temporarily disabled by pregnancy in the same manner as employees affected by other temporary disabilities. Therefore, any restrictions imposed by state law on benefits for pregnancy-related disabilities, but not for other disabilities, do not excuse the employer from treating the individuals in both groups of employees the same. If, for example, a state law requires an employer to pay a maximum of 26 weeks' benefit before other than pregnancy-related ones but only six weeks for pregnancy-related disabilities, the employer must provide benefits for the additional weeks to an employee disabled by pregnancy-related conditions, up to the maximum provided other disabled employees.

20. Q. If a state or local government provides its own employees income maintenance benefits for disabilities, may it provide different benefits for disabilities arising from pregnancy-related conditions than for disabilities arising from other conditions?
A. No. State and local governments, as employers, are subject to the Pregnancy Discrimination Act in the same way as private employers and must bring their employment practices and programs into compliance with the Act, including disability and health insurance programs.

21. Q. Must an employer provide health insurance coverage for employees incapacitated by pregnancy-related conditions of the spouses of male employees? Of the dependents of all employees?
A. Where an employer provides no coverage for dependents, the employer is not required to institute such coverage. However,
If an employer’s insurance program covers the medical expenses of spouses of female employees, then it must equally cover the medical expenses of spouses of male employees, including those arising from pregnancy-related conditions.

But the insurance does not have to cover the pregnancy-related conditions of other dependents as long as it includes the pregnancy-related conditions of the dependents of male and female employees equally.

22. Q. Where an employer provides its employees a choice among several health insurance plans, must coverage for pregnancy-related conditions be offered in all of the plans?
   A. Yes. Each of the plans must cover pregnancy-related conditions. For example, an employee with a single coverage policy cannot be forced to purchase a more expensive family coverage policy in order to receive coverage for her own pregnancy-related condition.

23. Q. On what basis should an employee be reimbursed for medical expenses arising from pregnancy, childbirth or related conditions?
   A. Pregnancy-related expenses should be reimbursed in the same manner as are expenses incurred for other medical conditions. That is, the costs of medical expenses must be covered by the health insurance plan if they occur if the employer, such additional costs are the first incurred.

24. Q. May an employer limit payment of costs for pregnancy-related medical conditions to a specified dollar amount set forth in an insurance policy, collective bargaining agreement or other statement of benefits to which an employee is entitled?
   A. The amounts payable for the costs incurred for pregnancy-related conditions can be limited only to the same extent as are costs for other conditions. Maximum recoverable dollar amounts may be specified for pregnancy-related conditions if such amounts are similarly specified for other conditions, and so long as the specified amounts in all instances cover the same procedures or conditions. If an increase to the scheduled amount for other procedures, additional costs are paid for, either directly or indirectly, by the employer, such additional costs are the first incurred. Thus, if pregnancy-related costs are the first incurred under the policy, the employee is required to pay only the same deductible as would otherwise be required had other medical costs been the first incurred. Once this deductible has been paid, no additional deductible can be required for other medical procedures. If the usual deductible has already been paid for other medical procedures, no additional deductible can be required when pregnancy-related costs are later incurred.

25. Q. If a health insurance plan excludes the payment of benefits for any conditions existing at the time the insured’s coverage becomes effective (pre-existing condition clause), can benefits be denied for medical costs arising from a pregnancy existing at the time the coverage became effective?
   A. Yes. However, such benefits cannot be denied unless the pre-existing condition clause also excludes benefits for other pre-existing conditions in the same way.

26. Q. Can the added cost of bringing a health insurance plan into compliance with the Act be apportioned between the employer and employee?
   A. The added cost, if any, can be apportioned between the employer and employee in the same proportion that the cost of the fringe benefit plan was apportioned on October 31, 1978, whichever is later.

27. Q. May an employer discharge, refuse to hire or otherwise discriminate against a woman because she has had an abortion?
   A. No. An employer cannot discriminate in its employment practices against a woman who has had an abortion.

31. Q. Is an employer required to provide fringe benefits for abortions if fringe benefits are provided for other medical conditions?
   A. All fringe benefits other than health insurance, such as sick leave, which are provided for other medical conditions, must be provided for abortions. Health insurance, however, need be provided for abortions only where the life of the woman would be endangered if the fetus were carried to term or where medical complications arise from an abortion.

32. Q. If complications arise during the course of an abortion, as for instance excessive hemorrhaging, must an employer’s health insurance plan cover the additional costs due to the complications of the abortion?
   A. Yes. The plan is required to pay those additional costs attributable to the complications of the abortion. However, the employer is not required to pay for the abortion itself, except where the life of the mother would be endangered if the fetus were carried to term.

33. Q. May an employer elect to provide insurance coverage for abortions?
   A. Yes. The Act specifically provides that an employer is not precluded from providing benefits for abortions whether directly or through a collective bargaining agreement, but if an employer decides to cover the costs of abortion, the employer must do so in the same manner and to the same degree as it covers other medical conditions.

[FR Doc. 79-7232 Filed 3-8-79; 8:45 am]
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

CLASSIFICATION OF MEDICAL DEVICES

Development of General Provisions; Proposed Rules
The Medical Device Amendments of 1976 require 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.

The Agency is proposing that the final regulation concerning the classification of cardiovascular devices, which are being published elsewhere in the FEDERAL REGISTER. The preamble also describes the activities of the Cardiovascular Device Classification Panel, an FDA advisory committee, that makes recommendations to FDA concerning the classification of cardiovascular devices.

DATES: Comments by May 8, 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 office of the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT: Glenn A. Rahmoeller, Bureau of Medical Devices, Room 1460, Food and Drug Administration, 8757 Georgia Ave., Silver Spring, Md. 20910, 301-477-7555.

SUPPLEMENTARY INFORMATION:

The Medical Device Amendments of 1976 (Pub. L. 94-295, hereinafter called the amendments) 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. 355)), establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories (classes) are:

- Class I, general controls;
- Class II, performance standards; and
- 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 that is substantially equivalent to a device classified under this scheme, is 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 its availability to the public by notice published in the FEDERAL REGISTER of November 29, 1977 (42 FR 60792). At subsequent meetings, the Panel changed its previous recommendations concerning the classification of several devices. Summary minutes of these meetings have 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 form all other Panel meetings, verbatim transcripts of meetings held after May 28, 1976 (the date of enactment of the amendments), and all references cited in individual cardiovascular device proposed classification regulations. Interested persons may review these documents in the office of 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 CARDIOVASCULAR 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 cardiovascular devices. The Panel supplemented the list utilizing its members' knowledge of cardiovascular devices. The 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 September 29, 1977 (42 FR 46028). On August 9, 1976, the Panel and other preamendments device classification panels were recharter 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 Panel's deliberations, interested persons were given an opportunity to present their views, data, and other information concerning the classification of cardiovascular 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 former 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 subsequent meetings, the Panel changed its previous recommendations concerning the classification of several devices. Summary minutes of these meetings have 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 form all other Panel meetings, verbatim transcripts of meetings held after May 28, 1976 (the date of enactment of the amendments), and all references cited in individual cardiovascular device proposed classification regulations. Interested persons may review these documents in the office of 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.
PROPOSED RULES

13285

cardiovascular devices in use. Devices that were solely for experimental or investigational use or that were not generally available were not usually included. Although the Panel recommended that artificial hearts be classified into class III, none were commercially available at the time the law was enacted, and therefore artificial hearts have not been included in the list of cardiovascular devices, and no regulation is being proposed for them. The Panel recommended that pacemaker batteries be classified as a distinct device into class II. However, FDA believes that, because they are components of pacemaker pulse generators, the batteries should be regulated as a part of the pulse generators. Therefore, pacemaker batteries have been deleted from the list, and no regulation is proposed for them. Additional cardiovascular devices, which are not included in the list and which were commercially available before May 28, 1976, will be added to the list as necessary.

FDA is proposing to establish a new Part 870 in Title 21 of the Code of Federal Regulations. Part 870 will consist of sections identifying each cardiovascular device with a brief narrative description and stating the classification of that device. A list of the cardiovascular devices appears elsewhere in this preamble.

INDIVIDUAL CARDIOVASCULAR DEVICE CLASSIFICATION REGULATIONS

Elsewhere in this issue of the Federal Register, FDA is issuing 142 individual proposed regulations to classify each cardiovascular device. FDA is proposing to classify 2 cardiovascular devices into class I (general controls), 114 cardiovascular devices into class II (performance standards), and 25 cardiovascular 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) of the act (21 U.S.C. 360c(c)(2) and (d)(1)).

PUBLISHED PANEL RECOMMENDATIONS

Each published Panel recommendation concerning a cardiovascular device includes the information described below.

1. Identification. Both the Panel recommendation and the proposed FDA classification regulation include a brief identification statement in 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 §870.1, any manufacturer of a device which has a premarket notification submission under section 510(k) of the act and Part 807 of the regulations cannot show merely that the 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(d) of the act if it is not substantially equivalent to a preamendment device (or to a postamendment device that has already been reclassified from class III into class II) under section 513(i) of the act. 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 510.2 of the act. According to 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 section 510.2(j) (21 CFR 807.87), and whether the device is described in a classification regulation.

2. Recommended classification. Each Panel's recommendation describes the device, classifies it into a class other than class I, and states whether the device should be exempt from any requirements under certain sections of the act: section 510 (21 U.S.C. 360, registration), section 510(j) (21 U.S.C. 360(j), good manufacturing practice requirements), and section 520(f) (21 U.S.C. 360(f), good manufacturing practice requirements). The Panel did not recommend any exemptions for devices for which the Panel recommended classification into class I. Manufacturers and other interested persons may submit comments on the appropriateness of exempting manufacturers of particular class I devices from one or more of the requirements under sections 510, 519, and 520(f) of the act. These comments should be supported by data and views showing that the application of these requirements to manufacturers of a device is not necessary to assure that the device is safe and effective and in compliance with the act, and that, despite the exemption, FDA will be able to discharge its regulatory responsibilities under the act. Panel recommendation that a device be classified into class II includes the Panel's recommended priority ("high," "medium," 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," "medium," 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 agency priorities at this time.

3. Summary of reasons for recommendation. The summary of reasons for the Panel's recommendation explains why the Panel believes that a device should be classified into class I, II, or III. Except in those instances in which FDA's classification proposal differs from the Panel's recommendation, the agency provides a similar explanation 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 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 the Panel members' personal knowledge of, and familiarity with, the devices under review. The Panel particularly relied upon clinical experience and judgment when considering a simple device that had been used extensively and was accepted widely before the amendments were enacted. The legislative history of the amendments makes clear 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 that 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. Rep. No. 94-853, 94th Congress, 2d Session 40 (1976). The Commissioner has de-
thromboembolism, gaseous or particu-
larly, the Panel. The classification of a device is based, together with any additional risk to health presented by cardiovascular devices, on the potential for causing embolisms, obstructions or occlusions of a blood vessel by an air bubble (gas embolism), detached blood clot (thromboembolism) or other foreign body (particulate embolism). Many electrically operated devices can cause cardiac arrhythmias (disturbances of the normal rhythm of the heart) or electrical shock to the patient. The Panel stated that most devices in cardiac catheterization can cause perforation of the heart muscle or dissection of the catheter in which the device is inserted. Tissue and blood damage caused by a cardiovascular device may result from mechanical trauma, emission of excessive energy by the device, incompatibility of materials with the blood or tissue, or electrical and thermal burns. The Panel recognizes that infection is a hazard posed by any device which is required to be sterile, especially implanted devices. Yet, in many cases, the Panel did not list infection as a risk because it believes that assurance of sterility is addressed by general controls. Finally, the Panel recognizes that any device used to diagnose a patient’s condition can generate inaccurate diagnostic data, which may lead to a misdiagnosis and inappropriate therapy and, hence, may pose a significant risk to the patient’s health. Accordingly, this risk is noted in each of the documents for diagnostic devices.

Because the classification recommendations and FDA regulations may not identify all risks to health presented by cardiovascular devices, future regulations establishing performance standards under section 514 of the act (21 U.S.C. 360d) or requiring premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)) may identify additional risks to health to be addressed by FDA requirements.

5. Risks to health. In identifying the risks to health presented by cardiovascular devices, the Panel recognized that few devices are completely free of risk. The Panel listed the risks considered most significant, especially those that are unique to the individual device. Among the more frequently identified risks, the Panel listed thromboembolism, cardiac arrhythmias or electrical shock, cardiac perforation and vessel dissection, tissue or blood damage, and misdiagnosis. All cardiovascular devices that have a direct interface with the blood have the potential for causing embolisms, obstructions or occlusions of a blood vessel by an air bubble (gas embolism), detached blood clot (thromboembolism) or other foreign body (particulate embolism). Many electrically operated devices can cause cardiac arrhythmias (disturbances of the normal rhythm of the heart) or electrical shock to the physician, leading to iatrogenic (physician induced) complications in the patient. The Panel stated that most devices used in cardiac catheterization can cause perforation of the heart muscle or dissection of the catheter in which the device is inserted. Tissue and blood damage caused by a cardiovascular device may result from mechanical trauma, emission of excessive energy by the device, incompatibility of materials with the blood or tissue, or electrical and thermal burns. The Panel recognizes that infection is a hazard posed by any device which is required to be sterile, especially implanted devices. Yet, in many cases, the Panel did not list infection as a risk because it believes that assurance of sterility is addressed by general controls. Finally, the Panel recognizes that any device used to diagnose a patient’s condition can generate inaccurate diagnostic data, which may lead to a misdiagnosis and inappropriate therapy and, hence, may pose a significant risk to the patient’s health. Accordingly, this risk is noted in each of the documents for diagnostic devices.

Because the classification recommendations and FDA regulations may not identify all risks to health presented by cardiovascular devices, future regulations establishing performance standards under section 514 of the act (21 U.S.C. 360d) or requiring premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)) may identify additional risks to health to be addressed by FDA requirements.

PROPOSED CLASSIFICATION

Each proposed regulation to classify a cardiovascular 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 870 in which the device classification will be codified.

FDA 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 classification 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 performance standards or premarket approval requirements. In developing its advice concerning priorities ("high," "medium," or "low") of devices recommended for classification into class II or class III, the Panel compared the device with other cardiovascular 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 panel's 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 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 the 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)).

LIST OF CARDIOVASCULAR DEVICES

The following is a list of the cardiovascular devices that FDA is proposing to classify, 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.
### Subpart B—Cardiovascular Diagnostic Devices

<table>
<thead>
<tr>
<th>Section</th>
<th>Device</th>
<th>Docket No.</th>
<th>Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>870.1005</td>
<td>Arrhythmia detector and alarm</td>
<td>TN-1497</td>
<td>III</td>
</tr>
<tr>
<td>870.1090</td>
<td>Blood pressure alarm</td>
<td>TN-1460</td>
<td>II</td>
</tr>
<tr>
<td>870.1110</td>
<td>Blood pressure computer</td>
<td>TN-1469</td>
<td>II</td>
</tr>
<tr>
<td>870.1120</td>
<td>Blood pressure cuff</td>
<td>TN-1410</td>
<td>II</td>
</tr>
<tr>
<td>870.1130</td>
<td>Noninvasive blood pressure measurement system</td>
<td>TN-1411</td>
<td>II</td>
</tr>
<tr>
<td>870.1140</td>
<td>Venous blood pressure manometer</td>
<td>TN-1412</td>
<td>II</td>
</tr>
<tr>
<td>870.1150</td>
<td>Diagnostic intravascular catheter</td>
<td>TN-1413</td>
<td>II</td>
</tr>
<tr>
<td>870.1160</td>
<td>Continuous flush catheter</td>
<td>TN-1414</td>
<td>II</td>
</tr>
<tr>
<td>870.1170</td>
<td>Electrode recording catheter and electrode recording probe</td>
<td>TN-1415</td>
<td>II</td>
</tr>
<tr>
<td>870.1180</td>
<td>Fiberoptic oximeter catheter</td>
<td>TN-1416</td>
<td>II</td>
</tr>
<tr>
<td>870.1190</td>
<td>Flow-directed catheter</td>
<td>TN-1417</td>
<td>II</td>
</tr>
<tr>
<td>870.1200</td>
<td>Percutaneous catheter</td>
<td>TN-1418</td>
<td>II</td>
</tr>
<tr>
<td>870.1210</td>
<td>Steerable catheter</td>
<td>TN-1419</td>
<td>II</td>
</tr>
<tr>
<td>870.1220</td>
<td>Steerable catheter control system</td>
<td>TN-1420</td>
<td>II</td>
</tr>
<tr>
<td>870.1230</td>
<td>Catheter cannula</td>
<td>TN-1422</td>
<td>II</td>
</tr>
<tr>
<td>870.1240</td>
<td>Vessel dilator for percutaneous catheter dilation</td>
<td>TN-1423</td>
<td>II</td>
</tr>
<tr>
<td>870.1250</td>
<td>Catheter guide holder</td>
<td>TN-1425</td>
<td>I</td>
</tr>
<tr>
<td>870.1260</td>
<td>Catheter guide wire</td>
<td>TN-1426</td>
<td>II</td>
</tr>
<tr>
<td>870.1270</td>
<td>Catheter percutaneous introducer</td>
<td>TN-1427</td>
<td>II</td>
</tr>
<tr>
<td>870.1280</td>
<td>Catheter balloon repair kit</td>
<td>TN-1428</td>
<td>III</td>
</tr>
<tr>
<td>870.1290</td>
<td>True microphone</td>
<td>TN-1429</td>
<td>III</td>
</tr>
<tr>
<td>870.1300</td>
<td>Catheter tip occluder</td>
<td>TN-1430</td>
<td>III</td>
</tr>
<tr>
<td>870.1310</td>
<td>Catheter stylet</td>
<td>TN-1431</td>
<td>III</td>
</tr>
<tr>
<td>870.1320</td>
<td>Trocar</td>
<td>TN-1432</td>
<td>III</td>
</tr>
<tr>
<td>870.1330</td>
<td>Programmable diagnostic computer</td>
<td>TN-1433</td>
<td>III</td>
</tr>
<tr>
<td>870.1340</td>
<td>Single-function, preprogrammed diagnostic computer</td>
<td>TN-1434</td>
<td>III</td>
</tr>
<tr>
<td>870.1350</td>
<td>Densitometer</td>
<td>TN-1435</td>
<td>III</td>
</tr>
<tr>
<td>870.1360</td>
<td>Angiographic injector and syringe</td>
<td>TN-1436</td>
<td>III</td>
</tr>
<tr>
<td>870.1370</td>
<td>Indicator injector</td>
<td>TN-1437</td>
<td>III</td>
</tr>
<tr>
<td>870.1380</td>
<td>Suture sizer for injection</td>
<td>TN-1438</td>
<td>III</td>
</tr>
<tr>
<td>870.1390</td>
<td>External programmable pacemaker pulse generator</td>
<td>TN-1439</td>
<td>III</td>
</tr>
<tr>
<td>870.1400</td>
<td>Intracardiac blood flow pump</td>
<td>TN-1440</td>
<td>III</td>
</tr>
<tr>
<td>870.1410</td>
<td>Stethoscope</td>
<td>TN-1441</td>
<td>II</td>
</tr>
<tr>
<td>870.1415</td>
<td>Thermistor probe</td>
<td>TN-1442</td>
<td>II</td>
</tr>
</tbody>
</table>

### Subpart C—Cardiovascular Monitoring Devices

<table>
<thead>
<tr>
<th>Section</th>
<th>Device</th>
<th>Docket No.</th>
<th>Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>870.2000</td>
<td>Bioelectric amplifier and signal conditioner</td>
<td>TN-1443</td>
<td>II</td>
</tr>
<tr>
<td>870.2010</td>
<td>Transducer signal amplifier and signal conditioner</td>
<td>TN-1445</td>
<td>II</td>
</tr>
<tr>
<td>870.2020</td>
<td>Cardiovascular blood flowmeter</td>
<td>TN-1446</td>
<td>III</td>
</tr>
<tr>
<td>870.2030</td>
<td>Extracardiac blood flow probe</td>
<td>TN-1447</td>
<td>III</td>
</tr>
<tr>
<td>870.2040</td>
<td>Cardiac monitor (including cardiac electrometer and rate alarm)</td>
<td>TN-1448</td>
<td>III</td>
</tr>
<tr>
<td>870.2050</td>
<td>Apex cardiograph (electrocardiograph)</td>
<td>TN-1449</td>
<td>III</td>
</tr>
<tr>
<td>870.2060</td>
<td>Electrocardiograph</td>
<td>TN-1450</td>
<td>III</td>
</tr>
<tr>
<td>870.2070</td>
<td>Electrocardiograph lead switching adapter</td>
<td>TN-1451</td>
<td>III</td>
</tr>
<tr>
<td>870.2080</td>
<td>Electrocardiograph electrode</td>
<td>TN-1452</td>
<td>III</td>
</tr>
<tr>
<td>870.2090</td>
<td>Electrocardiograph surface electrode tester</td>
<td>TN-1453</td>
<td>III</td>
</tr>
<tr>
<td>870.2100</td>
<td>Electrocardiograph conducting media</td>
<td>TN-1454</td>
<td>III</td>
</tr>
<tr>
<td>870.2110</td>
<td>Phonocardiograph</td>
<td>TN-1455</td>
<td>III</td>
</tr>
<tr>
<td>870.2120</td>
<td>Vectorcardiograph</td>
<td>TN-1456</td>
<td>III</td>
</tr>
<tr>
<td>870.2130</td>
<td>Medical cathode-ray tube display</td>
<td>TN-1457</td>
<td>III</td>
</tr>
<tr>
<td>870.2140</td>
<td>Signal isolation system</td>
<td>TN-1458</td>
<td>III</td>
</tr>
<tr>
<td>870.2150</td>
<td>Line transit monitor</td>
<td>TN-1459</td>
<td>III</td>
</tr>
<tr>
<td>870.2160</td>
<td>Portable leakage current alarm</td>
<td>TN-1460</td>
<td>III</td>
</tr>
<tr>
<td>870.2170</td>
<td>Oscillograph</td>
<td>TN-1461</td>
<td>III</td>
</tr>
<tr>
<td>870.2180</td>
<td>Oscillograph</td>
<td>TN-1462</td>
<td>III</td>
</tr>
<tr>
<td>870.2190</td>
<td>Otterimeter</td>
<td>TN-1463</td>
<td>III</td>
</tr>
<tr>
<td>870.2200</td>
<td>Ear otterimeter</td>
<td>TN-1464</td>
<td>III</td>
</tr>
<tr>
<td>870.2210</td>
<td>Impedance phlebograph</td>
<td>TN-1465</td>
<td>III</td>
</tr>
<tr>
<td>870.2220</td>
<td>Impedance plethysmograph</td>
<td>TN-1466</td>
<td>III</td>
</tr>
<tr>
<td>870.2230</td>
<td>Hydraulic, pneumatic, and photoelectric plethysmograph</td>
<td>TN-1467</td>
<td>III</td>
</tr>
<tr>
<td>870.2240</td>
<td>Medical magnetic tape recorder</td>
<td>TN-1468</td>
<td>III</td>
</tr>
<tr>
<td>870.2250</td>
<td>Medical cathode-ray tube display</td>
<td>TN-1469</td>
<td>III</td>
</tr>
<tr>
<td>870.2260</td>
<td>Apex cardiographic transducer</td>
<td>TN-1470</td>
<td>III</td>
</tr>
<tr>
<td>870.2270</td>
<td>Extracardiac blood pressure transducer</td>
<td>TN-1471</td>
<td>III</td>
</tr>
<tr>
<td>870.2280</td>
<td>Heart sound transducer</td>
<td>TN-1472</td>
<td>III</td>
</tr>
<tr>
<td>870.2290</td>
<td>Catheter tip pressure transducer</td>
<td>TN-1473</td>
<td>III</td>
</tr>
<tr>
<td>870.2300</td>
<td>Ultrasonic transducer</td>
<td>TN-1474</td>
<td>III</td>
</tr>
<tr>
<td>870.2310</td>
<td>Vessel occlusion transducer</td>
<td>TN-1475</td>
<td>III</td>
</tr>
<tr>
<td>870.2320</td>
<td>Patient transducer and electrode cable (including connectors)</td>
<td>TN-1476</td>
<td>III</td>
</tr>
<tr>
<td>870.2330</td>
<td>Radionuclide physiological signal transmitters and receivers</td>
<td>TN-1477</td>
<td>III</td>
</tr>
<tr>
<td>870.2340</td>
<td>Telephone electrocardiograph transmitters and receivers</td>
<td>TN-1478</td>
<td>III</td>
</tr>
</tbody>
</table>
# PROPOSED RULES

## Subpart D—Cardiovascular Prosthetic Devices

<table>
<thead>
<tr>
<th>Code</th>
<th>Item Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>870.3220</td>
<td>Teflon® catheter...</td>
</tr>
<tr>
<td>870.3250</td>
<td>Vascular clip...</td>
</tr>
<tr>
<td>870.3260</td>
<td>Vena cava clip...</td>
</tr>
<tr>
<td>870.3290</td>
<td>Peripheral arterial embolization device...</td>
</tr>
<tr>
<td>870.3375</td>
<td>Intra-aortic balloon and control system...</td>
</tr>
<tr>
<td>870.3450</td>
<td>Vascular graft prosthesis of less than 6mm diameter...</td>
</tr>
<tr>
<td>870.3460</td>
<td>Vascular graft prosthesis of 6mm and greater diameter...</td>
</tr>
<tr>
<td>870.3470</td>
<td>Intraluminal catheter...</td>
</tr>
<tr>
<td>870.3480</td>
<td>Intraluminal catheter...</td>
</tr>
<tr>
<td>870.3490</td>
<td>Intraluminal catheter...</td>
</tr>
<tr>
<td>870.3510</td>
<td>Intraluminal catheter...</td>
</tr>
<tr>
<td>870.3530</td>
<td>Intraluminal catheter...</td>
</tr>
<tr>
<td>870.3550</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3560</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3570</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3580</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3590</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3600</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3610</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3620</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3630</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3640</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3650</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3660</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3670</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3680</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3690</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3700</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3710</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3720</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3730</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3740</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3750</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3760</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3770</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3780</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3790</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3800</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3810</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3820</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3830</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3840</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3850</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3860</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3870</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3880</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3890</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3900</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3910</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3920</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3930</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3940</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3950</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3960</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3970</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3980</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
<tr>
<td>870.3990</td>
<td>Cardiopulmonary bypass (PACP) device...</td>
</tr>
</tbody>
</table>

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
PROPOSED RULES

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 recommendation and a single proposed classification regulation. The following devices were considered by the Cardiovascular Device Classification Panel and by other panels:

1. The Neurological Device Classification Panel recommended that angiographic needles be classified into class I. The Cardiovascular Device Classification Panel recommended that catheter trocars 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 catheter trocars. Based upon the information provided in the Panel recommendations, the Commissioner is proposing that the device be classified into class II and is publishing the Panel recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

2. The Neurological Device Classification Panel recommended that angio graphic guide wires and accessories be classified into class I. The Radiological Device Classification Panel recommended that radiological catheter guide wire be classified into class II. The Cardiovascular Device Classification Panel recommended that cardiovascular guide wires 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 catheter guide wires. Based upon the information provided in the Panel recommendations, the Commissioner is proposing that the device be classified into class II and is publishing the Panel recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

3. The General and Plastic Surgery Device Classification Panel recommended that nonpowered central venous pressure monitors and nonpowered peripheral venous pressure monitors be classified into class I. The Cardiovascular Device Classification Panel recommended that venous blood pressure manometers 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 venous blood pressure manometers. Based upon the information provided in the Panel recommendations, the Commissioner is proposing that the device be classified into class II and is publishing the Panel recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

4. The General and Plastic Surgery Device Classification Panel recommended that direct stethoscopes and electronic amplified stethoscopes be classified into class I. The Cardiovascular Device Classification Panel recommended that stethoscopes 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 stethoscopes. Based upon the information provided in the Panel recommendations, the Commissioner is proposing that the device be classified into class II and is publishing the Panel recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

5. The Anesthesiology Device Classification Panel recommended that mechanical cardiac resuscitators be classified into class III. The General Hospital and Personal Use Device Classification Panel recommended that manual external cardiac compressors be classified into class III and that powered external cardiac compressors be classified into class II. The Cardiovascular Device Classification Panel recommended that external cardiac compressors be classified into class III. The Commissioner has determined that these devices are essentially the same. Therefore, the Commissioner is proposing a single regulation classifying external cardiac compressors. Based upon the information provided in the Panel recommendations, the Commissioner is proposing that the device be classified into class III and is publishing the Panel recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

6. The General and Plastic Surgery Device Classification Panel recommended that synthetic arterial graft prostheses (less than 6mm diameter) be classified into class III. The Cardiovascular Device Classification Panel recommended that vascular graft prostheses (less than 6mm diameter) be classified into class III. The Commissioner has determined that these devices are essentially the same. Therefore, the Commissioner is proposing a single regulation classifying vascular graft prostheses (less than 6mm diameter) into class III and is publishing the Panel recommendations in a proposal appearing elsewhere in this issue of the FEDERAL REGISTER.

7. The Cardiovascular Device Classification Panel and the other panels listed below recommended classification into class II for the following devices:

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
<table>
<thead>
<tr>
<th>Device</th>
<th>Other panel(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flow directed catheter</td>
<td>General and Plastic Surgery</td>
</tr>
<tr>
<td>Ballon-type cardiovascular catheter</td>
<td>General and Plastic Surgery</td>
</tr>
<tr>
<td>Diagnostic intravascular catheter</td>
<td>Neurological</td>
</tr>
<tr>
<td>Angiographic catheter</td>
<td>Dental</td>
</tr>
<tr>
<td>Cardiovascular catheter</td>
<td>General and Plastic Surgery</td>
</tr>
<tr>
<td>Opaque vascular catheter</td>
<td>Radiology</td>
</tr>
<tr>
<td>Blood pressure monitors</td>
<td></td>
</tr>
<tr>
<td>Internal arterial pressure monitor</td>
<td>General and Plastic Surgery</td>
</tr>
<tr>
<td>Atrial cardiac pressure monitor</td>
<td>General and Plastic Surgery</td>
</tr>
<tr>
<td>Ventricular cardiac pressure monitor</td>
<td>General and Plastic Surgery</td>
</tr>
<tr>
<td>Powered pulmonary artery pressure monitor</td>
<td>General and Plastic Surgery</td>
</tr>
<tr>
<td>Indwelling blood pressure monitor</td>
<td>Anesthesiology</td>
</tr>
<tr>
<td>Invasive neonatal blood pressure monitor</td>
<td>General Hospital and Personal Use</td>
</tr>
<tr>
<td>Single-function, preprogrammed diagnostic computer</td>
<td></td>
</tr>
<tr>
<td>Dye cardiac output monitor</td>
<td>General and Plastic Surgery</td>
</tr>
<tr>
<td>Thermal cardiac output monitor</td>
<td>General and Plastic Surgery</td>
</tr>
<tr>
<td>Trend cardiac output monitor</td>
<td>General and Plastic Surgery</td>
</tr>
<tr>
<td>Blood pressure cuff</td>
<td></td>
</tr>
<tr>
<td>Nonpowered external arterial pressure monitor</td>
<td>General and Plastic Surgery</td>
</tr>
<tr>
<td>Inflation cuff</td>
<td></td>
</tr>
<tr>
<td>Manual cuff inflating air pump</td>
<td>General and Plastic Surgery</td>
</tr>
<tr>
<td>Noninvasive blood pressure measurement system</td>
<td></td>
</tr>
<tr>
<td>Nonindwelling blood pressure monitor</td>
<td>Anesthesiology</td>
</tr>
<tr>
<td>Powered external arterial pressure monitor</td>
<td>General and Plastic Surgery</td>
</tr>
<tr>
<td>* Aneroid blood pressure manometer</td>
<td>General and Plastic Surgery</td>
</tr>
<tr>
<td>* Mercury blood pressure manometer</td>
<td>General and Plastic Surgery</td>
</tr>
<tr>
<td>Ultrasonic/doppler newborn blood pressure monitor</td>
<td>General and Plastic Surgery</td>
</tr>
<tr>
<td>Electrocardiograph</td>
<td></td>
</tr>
<tr>
<td>Electrocardiograph monitor</td>
<td>General and Plastic Surgery</td>
</tr>
<tr>
<td>Electrocardiograph monitor</td>
<td>Anesthesiology</td>
</tr>
<tr>
<td>Cardiovascular blood flowmeter</td>
<td></td>
</tr>
<tr>
<td>Transcutaneous ultrasonic blood flowmeter</td>
<td>Anesthesiology</td>
</tr>
<tr>
<td>Flowmeter cardiac output monitor</td>
<td>General and Plastic Surgery</td>
</tr>
<tr>
<td>Electromagnetic or Doppler, noninvasive blood flowmeter</td>
<td>Urology</td>
</tr>
<tr>
<td>Electrovascular blood flow probe</td>
<td></td>
</tr>
<tr>
<td>Indwelling blood flow transducer</td>
<td>Anesthesiology</td>
</tr>
<tr>
<td>Nonindwelling blood flow transducer</td>
<td>Anesthesiology</td>
</tr>
<tr>
<td>Cardiac monitor (including cardiotachometer and rate alarm)</td>
<td>Anesthesiology</td>
</tr>
<tr>
<td>Pulse rate monitor</td>
<td>General Hospital and Personal Use</td>
</tr>
<tr>
<td>Neonatal heart rate monitor</td>
<td></td>
</tr>
<tr>
<td>Impedance plethysmograph</td>
<td></td>
</tr>
<tr>
<td>Impedance plethysmography cardiac output monitor</td>
<td>General and Plastic Surgery</td>
</tr>
<tr>
<td>Extravascular blood pressure transducer</td>
<td>Anesthesiology</td>
</tr>
<tr>
<td>Nonindwelling blood pressure transducer monitor</td>
<td>Dental</td>
</tr>
<tr>
<td>Catheter tip pressure transducer</td>
<td></td>
</tr>
<tr>
<td>Indwelling blood pressure transducer monitor</td>
<td>Anesthesiology</td>
</tr>
<tr>
<td>Transducer signal amplifier and signal conditioner</td>
<td></td>
</tr>
<tr>
<td>Blood pressure monitor amplifier and associated electronics</td>
<td>Anesthesiology</td>
</tr>
<tr>
<td>Paper chart recorder</td>
<td></td>
</tr>
<tr>
<td>Ophthalmic analog and digital recorder</td>
<td>Ophthalmic</td>
</tr>
<tr>
<td>Vascular graft prosthesis (6mm and greater diameter)</td>
<td>General and Plastic Surgery</td>
</tr>
<tr>
<td>Synthetic arterial graft prosthesis (6mm and greater diameter)</td>
<td>General and Plastic Surgery</td>
</tr>
</tbody>
</table>

The Commissioner has determined that, by group as listed here, these devices are essentially the same. Therefore, the Commissioner is proposing a single regulation classifying each of the groups of devices listed above into class II, using the Cardiovascular Device Classification Panel designation, and is publishing the Panel recommendations in proposals appearing elsewhere in this issue of the Federal Register.

8. The Cardiovascular Device Classification Panel and the other Panels listed below made classification recommendations concerning the following devices:
The Commissioner is not at this time publishing the Cardiovascular Device Classification Panel recommendations to classify the devices listed above. The Commissioner will publish these recommendations and proposed classification regulations when he publishes the recommendations of the other Panels that reviewed the devices.

**ENVIRONMENTAL IMPACT**

The Commissioner has carefully considered the environmental effects of proposed §870.1 and of the proposed cardiovascular device classification regulations. Because the proposed actions will not significantly affect the quality of the human environment, the agency has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the office of 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. 350c, 371(a))), and under authority delegated to the Commissioner (21 CFR 5.1), the Commissioner proposes that Chapter I of Title 21 of the Code of Federal Regulations be amended by adding new Part 870, Subpart A, to read as follows:

**PART 870—CARDIOVASCULAR DEVICES**

**Subpart A—General Provisions**

Sec. 870.1 Scope.


Subpart A—General Provisions

§870.1 Scope.

(a) This part sets forth the classification of cardiovascular 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 cardiovascular 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 the more common use of the device, rather than in two or more subparts.

Interested persons may, on or before May 8, 1979, submit comments. 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.

DATES: Comments by May 8, 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:

Glenn A. Rahmoeuler, Bureau of Medical Devices (HFE-450), Food and Drug Administration, Department of Health, Education, and Welfare, 5757 Georgia Ave., Silver Spring, MD 20810, 301-427-7155.
A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, upon consideration of the information provided by the Commissioner, made the following recommendation with respect to the classification of arrhythmia detectors and alarms:

1. Identification: An arrhythmia detector and alarm is a system that monitors the electrocardiogram (ECG) and is designed to produce a visible or audible signal or alarm when an atrial or ventricular arrhythmia, such as a premature contraction or ventricular fibrillation, exists.

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 the arrhythmia detector and alarm be classified into class III (premarket approval). Although the device is neither life-supporting nor life-sustaining, diagnostic information derived from the use of the device may be critical to proper management of the patient. If the algorithms used to detect various cardiac arrhythmias are either inaccurate or inadequate, the resulting misdiagnosis can be life threatening. There is no consensus on the proper algorithms to be used in the device. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel also believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and, moreover, that there is insufficient information to establish a standard to provide such assurance. However, certain performance standards should be specified in specific applications of this device. Because this device is attached to the body through conducting electrodes, its electrical characteristics, e.g., electrical leakage current, need to meet certain requirements. In addition, the device will require special labeling to inform the user of the accuracy, reproducibility, or limitations on the ability of the device to detect cardiac arrhythmias.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. The Panel believes that, although the device itself is not life supporting or sustaining, information derived from the device, if inaccurate, would create a potentially life-threatening situation. The Panel also believes that data do not exist showing the safety and efficacy of the device and that clinical trials are now the method by which the safety and efficacy of the device can be established.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: Inadequate design of the ECG processing circuitry or program can lead to generation of diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the arrhythmia detector and alarm be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for use in primary diagnosis of certain critical cardiac arrhythmias, and thus it is of substantial importance in preventing impairment of human health. The Commissioner believes the device presents a potential unreasonable risk of illness or injury because, if the device is used as a primary alarm system rather than as a supplement to another diagnostic system, failure of the device may be fatal to the patient. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this 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 870 by adding new Subpart B including new § 870.1025, as follows:

Subpart B—Cardiovascular Diagnostic Devices

§ 870.1025 Arrhythmia detector and alarm.

(a) Identification. An arrhythmia detector and alarm is a system that monitors the electrocardiogram and is designed to produce a visible or audible signal or alarm when an atrial or ventricular arrhythmia, such as a premature contraction or ventricular fibrillation, exists.

(b) Classification. Class III (premarket approval).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6104 Filed 3-8-79 8:45 am]

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying blood pressure alarms into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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.

DATE: Comments by May 8, 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:
Glen A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.
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 Cardiovascular Device Classification Panel, properly used. This device is attached to the body through a blood pressure transducer and a catheter and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus, the electrical characteristics of this device, such as electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device’s performance characteristics, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device, if in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the electrical 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.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel’s recommendation and is proposing that the blood pressure alarm 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. Although blood pressure alarms are used both as diagnostic devices and as monitoring devices, they will be listed in the Part of the Code of Federal Regulations for cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a) 82 Stat. 1565, 90 Stat. 540-548 (21 U.S.C. 360c, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new §870.1100 as follows:

§870.1100 Blood pressure alarm.

(a) Identification. A blood pressure alarm is a device that accepts the signal from a blood pressure transducer amplifier, processes the signal, and emits an alarm when the blood pressure falls outside a preset upper or lower limit.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[FRC Doc. 79-6105 Filed 3-8-79, 8:45 a.m.]
Use Device Classification Panel, and the Anesthesiology Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of blood pressure devices:

1. Identification: A blood pressure computer is a device that accepts the electrical signal from a blood pressure transducer amplifier and indicates the systolic, diastolic, or mean pressure based on the input signal.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panels recommend that the blood pressure computer be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to health even when properly used. This device is attached to the body through a blood pressure transducer amplifier and a catheter and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of blood pressure, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is usually with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panels believe that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panels believe 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 recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (b) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications.

**PROPOSED RULES**

The Commissioner agrees with the Panels' recommendations and is proposing that the blood pressure computer 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. Because blood pressure measurement is an indication of cardiovascular function, this device will be listed in the Code of Federal Regulations under cardiovascular devices. Although blood pressure computers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 510(a), 52 Stat. 1065, 50 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 870 in subpart B by adding new § 870.1110 as follows:

§ 870.1110 Blood pressure computer.

(a) Identification. A blood pressure computer is a device that accepts the electrical signal from a blood pressure transducer amplifier and indicates the systolic, diastolic, or mean pressure based on the input signal.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5000 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.

**FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979.**
Surgery Device Classification Panel, FDA advisory committees, made the following recommendation with respect to the classification of blood pressure cuffs:

1. Identification: A blood pressure cuff is a device that has an inflatable bladder in an inelastic sleeve (cuff) with a mechanism for inflating and deflating the bladder. The cuff is used in conjunction with another device to determine a subject's blood pressure.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a priority.

3. Summary of reasons for recommendation: The Panels recommend that blood pressure cuffs be classified into class II because this device is neither life-supporting nor life-sustaining, but is hazardous to life or health even when properly used. If the design of the device is inadequate for accurate and precise measurement of blood pressure, the resulting misdiagnosis could have a significant negative effect on the patient's health. The mechanical design and performance characteristics of the device should be maintained at a generally accepted satisfactory level. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panels believe that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panels believe 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 recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Tissue trauma: Overinflation, or use of an improper size cuff, can cause unnecessary tissue trauma. (b) Misdiagnosis: Inadequate design of cuff size can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

Proposed Classification

The Commissioner agrees with the Panel's recommendations and is proposing that the blood pressure cuff 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. Because blood pressure measurement is an indication of cardiovascular function, this device will be listed in the Code of Federal Regulations under cardiovascular devices. Although blood pressure cuffs are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

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 870 in Subpart B by adding §870.1120 as follows:

§870.1120 Blood pressure cuff.

(a) Identification. A blood pressure cuff is a device that has an inflatable bladder in an inelastic sleeve (cuff) with a mechanism for inflating and deflating the bladder. The cuff is used in conjunction with another device to determine a subject's blood pressure.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20057, 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.


JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6107 Filed 3-8-79; 8:45 am]

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
vasive blood pressure measurement systems:

1. Identification: A noninvasive blood pressure measurement system is a device that provides a signal from which systolic, diastolic, mean, or any combination of the three can be derived through the use of transducers placed on the surface of the body.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panels recommend that noninvasive blood pressure measurement systems be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through surface transducers and can be electrically powered. It is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. If the design of the device is inadequate for accurate and precise measurement of blood pressure, the resulting misdiagnosis could have a significant negative effect on the patient's health. When functioning properly, the device emits an acceptable energy level into the body. Malfunction of the ultrasonic types of the device, however, may result in unsafe energy levels. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of blood pressure, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panels believe that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panels believe that 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. Because blood pressure measurement is an indication of cardiovascular function, this device will be listed in the Code of Federal Regulations under cardiovascular devices. Although noninvasive blood pressure measurement systems are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular devices because diagnosis is the more common use.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Cardiovascular Device Classification Panel cited three standards proposed by the medical community for blood pressure measurement equipment (Refs. 1 through 3).

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to serious complications. (b) Tissue damage: In devices that use an ultrasonic detection method, excessive ultrasonic energy output can cause tissue damage. (c) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (d) Tissue ischemia: Any system that allows prolonged cuff inflation can cause tissue ischemia (deficiency of blood supply to a portion of the body).

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panels' recommendations and is proposing that the noninvasive blood pressure measurement 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. Because blood pressure measurement is an indication of cardiovascular function, this device will be listed in the Code of Federal Regulations under cardiovascular devices. Although noninvasive blood pressure measurement systems are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular devices because diagnosis is the more common use.

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.


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, 571(a))) and under authority delegated to him (21 CFR 3.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new §870.1130 as follows:

§870.1130 Noninvasive blood pressure measurement system.

(a) Identification. A noninvasive blood pressure measurement system is a device that provides a signal from which systolic, diastolic, mean, or any combination of the three can be derived through the use of transducers placed on the surface of the body.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-505), Food and Drug Administration, Rm. 4-55, 5000 Fishers Lane, Rockville, MD 20852, 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.


JOSEPH P. HILL, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6108 Filed 3-8-79 8:45 am]
standards to assure the safety and effectiveness of the device. After 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 May 8, 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:

Glenn A Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, Silver Spring, MD 20810, 301-427-7559.

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 Cardiovascular Device Classification Panel and the General and Plastic Surgery Device Classification Panels; FDA advisory committees, made the following recommendations with respect to the classification of venous blood pressure manometers:

1. Identification: A venous blood pressure manometer is a device attached to a venous catheter to indicate manometrically the central or peripheral venous pressure.

2. Recommended classification: The Cardiovascular Device Classification Panel recommends class II (performance standards) and recommends that establishing a performance standard for this device be a low priority. The General and Plastic Surgery Device Classification Panel recommends class I (general controls) with no exemptions.

3. Summary of reasons for recommendation: The Cardiovascular Device Classification Panel recommends that venous blood pressure manometers be classified into class II because this device is not life-sustaining nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of blood pressure, the resulting misdiagnosis could have a significant negative effect on the patient's health. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of blood pressure, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Cardiovascular Device Classification Panel believes that general controls should not provide sufficient control over the performance characteristics of this device. The Cardiovascular Device Classification 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. The General and Plastic Surgery Device Classification Panel believes that general controls would provide sufficient control over the performance characteristics of the device and listed no risks to health for the device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Misdiagnosis: Inadequate design of calibration characteristics of the manometer can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Cardiovascular Device Classification Panel recommendation and is proposing that the venous blood pressure manometer 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 misdiagnosis listed as a risk to health by the Cardiovascular Device Classification Panel. 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. Because blood pressure measurement is an indication of cardiovascular function, this device will be listed in the Code of Federal Regulations under cardiovascular devices. Although venous blood pressure manometers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

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 870 in Subpart B by adding new § 870.1140 as follows:

§ 870.1140 Venous blood pressure manometer.

(a) Identification. A venous blood pressure manometer is a device attached to a venous catheter to indicate manometrically the central or peripheral venous pressure.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSPEH P. HILE, Associate Commissioner for Regulatory Affairs.

[21 CFR Part 870]
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 May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on the 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:

Glenn A. Rahmoeller, Bureau of Medical Devices (HF-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information on the development of the proposed regulation. The Cardiovascular Device Classification Panel, the General and Plastic Surgery Device Classification Panel, the Neurological Device Classification Panel, and the Radiological Device Classification Panel, FDA advisory committees, made the following recommendation with respect to the classification of diagnostic intravascular catheters:

1. Identification: An intravascular diagnostic catheter is a device used to record intracardiac pressures, to sample blood, and to introduce substances into the heart and vessels. Included in this generic group are right-heart catheters, left-heart catheters, and angiographic catheters, among others.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panels recommend that intravascular diagnostic catheters be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream, it must be designed and constructed to minimize foreign body reactions and disruption of normal blood flow. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The mechanical design of the device should also ensure adequate frequency response. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panels believe that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panels believe 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 recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device may contribute to thromboembolism and cleanliness may lead to potentially debilitating or fatal thromboembolism. (b) Cardiac perforation and vessel dissection: If the catheter or catheter tip is too big, or if the catheter is too stiff, cardiac perforation and vessel dissection may result. (c) Misdiagnosis: Inadequate mechanical design with regard to frequency response can lead to generation of inaccurate diagnostic data. If accurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

Proposed Classification

The Commissioner agrees with the Panels' recommendations and is proposing that the diagnostic intravascular 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. Because the device is more commonly used in cardiovascular catheterization procedures, the device will be listed in the Code of Federal Regulations under cardiovascular devices. Although diagnostic intravascular catheters are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.


(a) Identification. An intravascular diagnostic catheter is a device used to record intracardiac pressures, to sample blood, and to introduce substances into the heart and vessels. Included in this generic group are right-heart catheters, left-heart catheters, and angiographic catheters, among others.

(b) Classification. Class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because diagnosis is the more common use.

SUPPLEMENTARY INFORMATION: PREPARED RULES
FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 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-308), Food and Drug Administration, Room 4-45, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8787 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PROPOSED CLASSIFICATION

1. Identification: A continuous flush catheter is an attachment to a catheter-transducer system that permits continuous intravascular flushing at a slow infusion rate for the purpose of eliminating clotting, back-leakage, and waveform damping.

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 continuous flush catheter be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the design of the device is inadequate for accurate and precise measurement of physiological functions through the catheter system, the resulting misdiagnosis could have a significant negative effect on the patient’s health. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and biocompatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. Performance characteristics, including accuracy, reproducibility, and any limitations on the device’s ability to keep the catheter free of clots without inhibiting the measurement of any physiological function, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the 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 was based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal emboli. (b) Embolism: Pieces of the catheter that break or flake off may form potential debilitating or fatal emboli. (c) Tissue and blood damage: If the materials, surface finish, or cleanliness of this device are inadequate, damage to the blood and tissue may result. (d) Gas embolism: If the infusion solution that flushes through the catheter is exhausted, a potentially debilitating or fatal gas embolism may arise. (e) Hypervolemia: Overinfusion of the solution used to flush the catheter can lead to hypervolemia (abnormal increase in the blood plasma volume). (f) Misdiagnosis: Inadequate design with regard to possible degradation of the physiological waveform being measured can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel’s recommendation and is proposing that the continuous flush 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. Although continuous flush catheters are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 514(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 870 in Subpart B by adding new §870.1210 as follows:

§870.1210 Continuous flush catheter.

(a) Identification. A continuous flush catheter is an attachment to a catheter-transducer system that permits continuous intravascular flushing at a slow infusion rate for the purpose of eliminating clotting, back-leakage, and waveform damping.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-308), Food and Drug Administration, Room 4-45, 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.


JOSEPH P. HALE, Associate Commissioner for Regulatory Affairs.

(FR Doc. 79-6111 Filed 3-8-79; 8:45 am)
PROPOSED RULES

eters and electrode recording probes into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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.

DATE: Comments by May 8, 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, 5000 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Glenn A. Rahmoller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8767 Georgia Ave., Silver Spring, MD 20910, 301-427-7850.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electrode recording catheters and electrode recording probes:

1. Identification: Electrode recording catheters and electrode recording probes are devices used to detect an intracardiac electrocardiogram, or to detect cardiac output or left-to-right heart shunts. The devices may be unipolar or multipolar for electrocardiogram detection, or may be a platinum tipped catheter which senses the presence of a special indicator for cardiac output or left-to-right heart shunt determinations.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that electrode recording catheters and electrode recording probes be classified into class II because these devices are neither life-supporting nor life-sustaining, but are potentially hazardous to life or health even when properly used. Because the devices are placed directly in contact with the blood-fluid, material may be required to be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the devices should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The devices are used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of these devices. 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 the potential hazards associated with the inherent properties of these devices and on their personal knowledge of, and experience with, these devices.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in these devices and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Cardiac perforation and vessel dissection: If the catheter or catheter tip is rough or if the catheter is too stiff, cardiac perforation and vessel dissection may result. (c) Embolism: Pieces of the catheter that break or flake off may form potentially, debilitating or fatal emboli.

PROPOSED CLASSIFICATION
The Commissioner agrees with the Panel's recommendation and is proposing that electrode recording catheters and electrode recording probes 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 these devices. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of these devices. Although electrode recording catheters and electrode recording probes are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-544 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1120 as follows:

§870.1120 Electrode recording catheter and electrode recording probe.
(a) Identification. Electrode recording catheters and electrode recording probes are devices used to detect an intracardiac electrocardiogram, or to detect cardiac output or left-to-right heart shunts. The device may be unipolar or multipolar for electrocardiogram detection, or may be a platinum tipped catheter which senses the presence of a special indicator for cardiac output or left-to-right heart shunt determinations.

(b) Classification Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5000 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's 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.

Date: February 26, 1979.

JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[PR Doc. 79-6112 Filed 3-8-79; 8:45 a.m.]

[1110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1416]

MEDICAL DEVICES

Classification of Fiberoptic Oximeter 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 fiberoptic oximeter catheters into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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:
Glenn A. Rahmacker, Bureau of Medical Devices (HFA-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave, Silver Spring, MD 20910, 301-427-7598.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of fiberoptic oximeter catheters:

1. Identification: A fiberoptic oximeter catheter is a device used to estimate the oxygen saturation of the blood. It consists of two fiberoptic bundles that conduct light at a desired wavelength through blood and detect the reflected and scattered light at the distal end of the catheter.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the fiberoptic oximeter catheter be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The fiberoptic materials used in the device should allow the proper transmission of light energy to assure the accuracy of the results obtained from the system in which it is used. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Misdiagnosis: Inadequate design of the fiberoptic bundles can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in monitoring the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (b) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (c) Emboli: Pieces of the catheter that break or flake off may form potentially debilitating or fatal emboli. (d) Cardiac perforation and vessel dissection: If the catheter or catheter tip is rough, or if the catheter is too stiff cardiac perforation and vessel dissection may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the fiberoptic oximeter 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 to 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. Although fiberoptic oximeter catheters are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 21 Stat. 540-546 (21 U.S.C. 350c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1230 as follows:

§ 870.1230 Fiberoptic oximeter catheter.

(a) Identification. A fiberoptic oximeter catheter is a device used to estimate the oxygen saturation of the blood. It consists of two fiberoptic bundles that conduct light at a desired wavelength through blood and detect the reflected and scattered light at the distal end of the catheter.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


Joseph P. Hile,
Associate Commissioner,
for Regulatory Affairs.

[FEDERAL REGISTER, VOL. 44, NO. 45—FRIDAY, MARCH 9, 1979]
PROPOSED RULES

The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying percutaneous catheters into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[4110-03-M] [21 CFR Part 870]

MEDICAL DEVICES

Classification of Percutaneous 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 percutaneous catheters into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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.
PROPOSED RULES

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeeller, Bureau of Medical Devices (HFE-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave, Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of percutaneous catheters:

1. Identification: A percutaneous catheter is a device that is introduced into a vein or artery through the skin using a dilator and a sheath (introducer) or guide wire.

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 percutaneous catheters be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboembolism. (b) Embolism: Pieces of the catheter which break or flake off may form potentially debilitating or fatal emboli.

(c) Cardiac perforation and vessel dissection: If the catheter or catheter tip is rough, or if the catheter is too stiff, cardiac perforation and vessel dissection may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the percutaneous 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. Although percutaneous catheters are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 515, 701(a), 52 Stat. 1055, 56 Stat. 540-546 (21 U.S.C. 350c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new §870.1250 as follows:

§870.1250 Percutaneous catheter.

(a) Identification. A percutaneous catheter is a device that is introduced into a vein or artery through the skin using a dilator and a sheath (introducer) or guide wire.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE,
Associate Commissioner
for Regulatory Affairs.

[FPR Doc. 78-6115 Filed 3-6-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

Docket No. 78N-1419

MEDICAL DEVICES

Classification of pH Catheter 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 pH catheter probes into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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:

Glenn A. Rahmoeeller, Bureau of Medical Devices (HFE-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave, Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of pH catheter probes:

1. Identification: A pH catheter probe is a catheter with a special tip for measuring blood pH.
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 pH catheter probe be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. Certain performance characteristics of the pH catheter probe, such as electrical isolation, accuracy, and stability, should be maintained at an accepted level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (c) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli.

PROPOSED RULES

§870.1260 - pH catheter probe.

(a) Identification. A pH catheter probe is a catheter with a special tip for measuring blood pH.

(b) Classification. Class II (performance standards).

Interests persons may, on or before May 8, 1979 submit to the Hearing Clerk (FHA-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 by the public during office hours between the hours of 9 a.m. and 4 p.m., Monday through Friday.


JOSPEH P. HILE,
Associate Commissioner for Regulatory Affairs.

[F.R. Doc. 78-6116 Filed 3-6-79; 8:45 a.m.]
PROPOSED RULES

FEDERAL REGISTER, VOL 44, NO. 48—FRIDAY, MARCH 9, 1979

Section

13305


JOSEPH P. FRIED.
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6117 Filed 3-8-79; 8:45 am]

110-03-M

[21 CFR Part 870]

(Docket No. 78N-1421)

MEDICAL DEVICES

Classification of Steerable 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 steerable catheters into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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 (HPA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Glenn A. Rahmoeller, Bureau of Medical Devices (HFG-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8576 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of steerable catheters:

In the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

The Commissioner agrees with the Panel's recommendation and is proposing that the intracavitary phono-catheter system be classified into class II (performance standards). The Commissioner believes that there is sufficient information to establish a standard to provide such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 52 Stat. 840-856 (21 U.S.C. 360c, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new §870.1270 as follows:

§870.1270 Intracavitary phono-catheter system.

(a) Identification. An intracavitary phono-catheter system is a system that includes a catheter with an acoustic transducer and the associated device that processes the signal from the transducer; this device records bioacoustic phenomena from a transducer placed within the heart, blood vessels, or body cavities.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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 dockets number 870 and in brackets in the heading of this document. Received comments may be seen

The proposed classification is as follows:

PROPOSED CLASSIFICATION

The Panel recommends that the intracavitary phono-catheter system be classified into class II (performance standards). The Panel believes that there is sufficient information to establish a standard to provide such assurance.

The Commissioner proposes that the final regulation classify the device into class II (performance standards). The device is used with blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli.

Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications.

(b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

(c) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli.

(d) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

Class II (performance standards).

Interested persons may, on or before May 8, 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 dockets number 870 and 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.


JOSEPH P. FRIED.
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6117 Filed 3-8-79; 8:45 am]

110-03-M

[21 CFR Part 870]

(Docket No. 78N-1421)

MEDICAL DEVICES

Classification of Steerable 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 steerable catheters into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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 (HPA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Glenn A. Rahmoeller, Bureau of Medical Devices (HFG-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8576 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of steerable catheters:

...
The Commissioner proposes to amend the classification of steerable catheter systems by proposing to make the steerable catheter control systems into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device 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 the comments, the FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 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: Glenn A. Rahmoller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7659.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed rule. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of steerable catheter control systems:

1. Identification: A steerable catheter control system is a device that is connected to the proximal end of a steerable guide wire that controls the motion of the steerable catheter.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be of low priority.

3. Summary of reasons for recommendation: The Panel recommends that the steerable catheter control system be classified into class II because this device is neither life-sustaining nor life-supporting, but is potentially hazardous to life or health even when properly used. The mechanical design of the device is inadequate for proper steering of a catheter, use of the device could result in cardiac perforation or vessel dissection. Performance characteristics, including any limitations on the device's

PROPOSED RULES

1. Identification: A steerable catheter is a catheter used for diagnostic and monitoring purposes whose movements are directed by a steering control unit. The Panel recommends that establishing a performance standard for this device be of low priority.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be of low priority.

3. Summary of reasons for recommendation: The Panel recommends that the steerable catheter be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. The device is placed directly in contact with the bloodstream. It should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboembolism. (b) Embolism: Pieces of the catheter that break or flake off may form potentially debilitating or fatal emboli. (c) Cardiac perforation and vessel dissection: If the catheter or catheter balloon ruptures, or if the catheter is too stiff, cardiac perforation and vessel dissection may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the steerable 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. Although steerable catheters are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 50 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 870 in Subpart B by adding new §870.1280 as follows:

§§870.1280 Steerable catheter.

(a) Identification. A steerable catheter is a catheter used for diagnostic and monitoring purposes whose movements are directed by a steering control unit.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[FRL Doc. 79-6118 Filed 3-8-79; 8:45 a.m.]

[1110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1423]

MEDICAL DEVICES

Classification of Steerable Catheter Control 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 steerable catheter control systems into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device 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 the comments, the FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by May 8, 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:

Glenn A. Rahmoller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7659.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of steerable catheter control systems:

1. Identification: A steerable catheter control system is a device that is connected to the proximal end of a steerable guide wire that controls the motion of the steerable catheter.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be of low priority.

3. Summary of reasons for recommendation: The Panel recommends that the steerable catheter control system be classified into class II because this device is neither life-sustaining nor life-supporting, but is potentially hazardous to life or health even when properly used. The mechanical design of the device is inadequate for proper steering of a catheter, use of the device could result in cardiac perforation or vessel dissection. Performance characteristics, including any limitations on the device's...
mechanical ability to steer a catheter, should be maintained at a generally acceptable level. The device and its accessories must be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Cardiac perforation and vessel dissection: If the mechanical design of the device does not properly control the motion of the catheter to which the device is attached, cardiac perforation and vessel dissection may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the steerable catheter control 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. Although steerable catheter control systems are used both as diagnostic devices and as monitoring devices, they will be held in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

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 870 in Subpart B by adding new §870.1290 as follows:

§870.1290 Steerable catheter control system.

Identification. A steerable catheter control system is a device that is connected to the proximal end of a steerable guide wire that controls the motion of the steerable catheter.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6119 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

(Docket No. 78N-1423)

MEDICAL DEVICES

Classification of Catheter 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 catheter cannulas into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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.


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.

ADDRESSES: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FURTHER INFORMATION CONTACT:

Glenn A. Rahmoller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8737 Georgia Ave., Silver Spring, MD 20010, 301-227-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of catheter cannulas:

1. Identification: A catheter cannula is a hollow tube which is inserted into a vessel or cavity; this device provides a rigid or semirigid structure which can be connected to a tube or connector.

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 catheter cannula be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Tissue and blood damage: If the materials, surface finish, or cleanliness of the device are inadequate, damage to the blood and tissue may result.
**PROPOSED CLASSIFICATION**

The Commissioner agrees with the Panel's recommendation and is proposing that the catheter cannula 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. Although catheter cannulas are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

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 870 in Subpart B by adding new §870.1300 as follows:

§870.1300 Catheter cannula.

(a) Identification. A catheter cannula is a hollow tube which is inserted into a vessel or cavity; this device provides a rigid or semirigid structure which can be connected to a tube or connector.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


**JOSEPH P. HILE,**
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6120 Filed 3-8-79; 8:49 am]

---

**MEDICAL DEVICES**

**Classification of Vessel Dilators for Percutaneous Catheterization**

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed Rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying vessel dilators for percutaneous catheterization into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effective 30 days after the date of 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:**

Glenn A. Rahmoeller, Bureau of Medical Devices (HFX-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

**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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of vessel dilators for percutaneous catheterization:

1. Identification: A vessel dilator for percutaneous catheterization is a device which is placed over the guide wire and inserted into a vessel or cavity; this device provides a rigid or semirigid structure which can be connected to a tube or connector.

2. Recommended classification: Class II (performance standards): The Panel recommends that a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the vessel dilator for percutaneous catheterization be classified into class II because this device is neither life-sustaining nor life-supporting, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness which may affect the degree of compatibility. The mechanical design of the device should enable it to perform its function of enlarging the opening into the vessel with a minimum of tissue damage and without causing vessel dissection. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Vessel dissection: If the dilator is too stiff, vessel dissection may result. (b) Embolism: Pieces of the dilator which break off may form potentially debilitating or fatal embolism.

**PROPOSED CLASSIFICATION**

The Commissioner agrees with the Panel's recommendation, and is proposing that the vessel dilator for percutaneous catheterization 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.
Although the vessel dilator for percutaneous catheterization is used both as a diagnostic device and as a monitoring device, it will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

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 870 in subpart B by adding new § 870.1310 as follows:

§ 870.1310 Vessel dilator for percutaneous catheterization.

(a) Identification. A vessel dilator for percutaneous catheterization is a device which is placed over the guide wire to enlarge the opening in the vessel, and which is removed before sliding the catheter over the guide wire.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-79-6121 Filed 3-8-79; 8:45 am]

PROPOSED RULES

The Commissioner agrees with the Panel's recommendation and is proposing that the catheter guide holder be classified into class I (general controls). The Commissioner believes 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 870 in subpart B by adding new § 870.1320 as follows:

§ 870.1320 Catheter guide holder.

(a) Identification. A catheter guide holder is a tube that holds a spring guide during percutaneous techniques and during storage and sterilization.

(b) Classification. Class I (general controls).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-79-6122 Filed 3-8-79; 8:45 am]

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the catheter guide holder be classified into class I (general controls). The Commissioner believes 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 870 in subpart B by adding new § 870.1320 as follows:

§ 870.1320 Catheter guide holder.

(a) Identification. A catheter guide holder is a tube that holds a spring guide during percutaneous techniques and during storage and sterilization.

(b) Classification. Class I (general controls).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-79-6122 Filed 3-8-79; 8:45 am]

PROPOSED RULES

The Commissioner agrees with the Panel's recommendation and is proposing that the catheter guide holder be classified into class I (general controls). The Commissioner believes 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 870 in subpart B by adding new § 870.1320 as follows:

§ 870.1320 Catheter guide holder.

(a) Identification. A catheter guide holder is a tube that holds a spring guide during percutaneous techniques and during storage and sterilization.

(b) Classification. Class I (general controls).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-79-6122 Filed 3-8-79; 8:45 am]

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the catheter guide holder be classified into class I (general controls). The Commissioner believes 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 870 in subpart B by adding new § 870.1320 as follows:

§ 870.1320 Catheter guide holder.

(a) Identification. A catheter guide holder is a tube that holds a spring guide during percutaneous techniques and during storage and sterilization.

(b) Classification. Class I (general controls).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-79-6122 Filed 3-8-79; 8:45 am]
SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying catheter percutaneous introducers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 clas-

PROPOSED RULES

The Commissioner agrees with the recommendations of the Cardiovascular Device Classification Panel and the Radiological Device classification Panel and is proposing that the catheter guide wire be classified into class II (performance standards). The Commissioner believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device. The Panels believe that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panels believe 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. The Neurological Device Classification Panel believes that the device presents no potential hazard to health and that general controls are sufficient to control the safety and effectiveness of the device and recommends the device into class I (general controls).

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboembolism. (b) Embolism: Pieces of the catheter that break or flake off may form potentially debilitating or fatal emboli. (c) Cardiac perforation and vessel dissection: If the guide wire is rough or too stiff, cardiac perforation and vessel dissection may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the recommendations of the Cardiovascular Device Classification Panel and the Radiological Device classification Panel and is proposing that the catheter guide wire 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 thromboembolism, embolism, or cardiac perforation and vessel dissection listed as risks to health by the Panels. A performance standard would provide for future development of one or more performance standards to assure 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. Although guide wires are used in many different catheterization procedures, this device will be listed in the Code of Federal Regulations under cardiovascular devices because cardiovascular uses are more common.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 80 Stat. 540-546 (21 U.S.C. 380c, 311(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1330 as follows:

§ 870.1330 Catheter guide wire.

(a) Identification. A catheter guide wire is a coiled wire that is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner
for Regulatory Affairs.

[FR Doc. 79-6123 Filed 3-8-79; 8:45 am]
PROPOSED RULES

DATE: Comments by May 8, 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:
Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of catheter percutaneous introducers:

1. Identification: A catheter percutaneous introducer is a sheath used to facilitate placing a catheter through the skin into a vein or artery.

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 catheter percutaneous introducer be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, or maintained. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolic: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitative or fatal thromboemboli. (b) Embolism: Pieces of the introducer which break or flake off may form potentially debilitating or fatal emboli. (c) Vessel dissection: If the introducer or its tip is rough, or if the introducer is improperly designed, vessel dissection may result.

Proposed Classification

The Commissioner agrees with the Panel’s recommendation and is proposing that the catheter percutaneous introducer 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, 50 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 870 in Subpart B by adding new §870.1340 as follows:

§870.1340 Catheter percutaneous introducer.
(a) Identification. A catheter percutaneous introducer is a sheath used to facilitate placing a catheter through the skin into a vein or artery.
(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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 will submit single copies of documents; and shall be identified with the Hearing Clerk dock 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.


Joseph P. Hile, Associate Commissioner for Regulatory Affairs.

[4110-03-M]

[21 CFR Part 870]

Docket No. 78N-14281 - MEDICAL DEVICES

Classification of Catheter Balloon Repair Kits

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed rule classifying catheter balloon repair kits into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular 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 data. (FDA) Public comment is also solicited 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 May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation be 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:
Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.
A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of catheter balloon repair kits:

1. Identification: A catheter balloon repair kit is a device used to repair or replace the balloon of a balloon catheter. The kit contains the materials, such as glue and balloons, necessary to effect the repair or replacement.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the catheter balloon repair kit be classified into class III because the device presents a potential unreasonable risk of illness or injury. If the device fails to adequately repair a damaged balloon catheter, gas or particulate emboli are likely to occur which may present a substantial risk to health that is possibly debilitating or fatal. The Panel believes that these devices do not perform adequately. In addition, the Panel believes that sufficient data to establish adequate standards to provide reasonable assurance of the safety and effectiveness of the balloon repair kit, and that general controls alone would not provide sufficient control over the performance characteristics of this device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of safe use with the device. The Panel is not aware of any published literature on this device.

5. Risks to health: (a) Gas embolism: Balloon rupture caused by the repair material or a leak in the repair material can allow potentially debilitating or fatal gas emboli to escape into the bloodstream. (b) Embolism: Pieces of the balloon that break or flake off may form potentially debilitating or fatal emboli. (c) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness can lead to potentially debilitating or fatal thromboembolism. (d) Cardiac arrhythmias: Toxic substances released from the repair material (glue or other adhesive) can trigger cardiac arrhythmias (irregularities in heart rhythm).

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the catheter balloon repair kit be classified into class III (premarket approval). The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this 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 870 in Subpart B by adding new §870.1350 as follows:

§870.1350 Catheter balloon repair kit.
(a) Identification. A catheter balloon repair kit is a device used to repair or replace the balloon of a balloon catheter. The kit contains the materials, such as glue and balloons, necessary to effect the repair or replacement.
(b) Classification. Class III (premarket approval).

Interested persons may, on or before May 8, 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.


Joseph P. Hill, Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-6125 Filed 3-8-79; 8:45 am]
when properly used, and because there are insufficient information to establish the safety and effectiveness of the device. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to demonstrate that general controls will provide reasonable assurance of the safety and effectiveness of the device and, moreover, that there is not sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel recognizes the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in the device may lead to potentially debilitating or fatal thromboemboli. (b) Embolism: If the microspheres are too large or tend to clump together, they can lodge in a blood vessel and block the flow of blood to an organ. (c) Tissue damage: Tissue damage: Tissue damage can result from excessive radioactivity of the particles.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the trace microsphere be classified into class III (premarket approval). The Commissioner believes that the device needs to be provided with a use (diagnosis of blood flow disorders) which is of substantial importance in preventing impairment of human health. The device is intended to be implanted in the human body. The Federal Food, Drug, and Cosmetic 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 believes that instead the recommendation exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 50 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 870 in Subpart B by adding new §870.1360 as follows:

§870.1360 Trace microsphere.

(a) Identification. A trace microsphere is a radioactively tagged nonbiodegradable particle that is intended to be injected into an artery or vein and trapped in the capillary bed for the purpose of studying blood flow within or to an organ.

(b) Classification. Class III (premarket approval).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk, Bureau of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 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.


JOSEPH P. HILL, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6129 Filed 3-6-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1430]

PROPOSED RULES

MEDICAL DEVICES

Classification of Catheter Tip Occluders

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying catheter tip occluders into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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, Bureau of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of catheter tip occluders:

1. Identification: A catheter tip occluder is a device that is inserted into certain catheters to prevent flow through one or more orifices.

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 catheter tip occluder be classified into class II because this device is neither life-supporting but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted standard of adequate surface finish and cleanliness which may affect the degree of compatibility. The device should fit properly in the catheter in which it is used to avoid potential vessel perforation. The Panel believes that general controls alone would not provide sufficient control over the 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 the inherent properties of the device and on their personal knowledge of and experience with the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboembolism. (b) Cardiac perforation and vessel dissection: If the device is too small for the catheter in which it is used, it could protrude from the proximal end of the catheter and cause cardiac perforation and vessel dissection.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the catheter tip occluder 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(4)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1370 as follows:

§870.1370 Catheter tip occluder.
(a) Identification. A catheter tip occluder is a device that is inserted into certain catheters to prevent flow through one or more orifices.
(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.

PROPOSED RULES


Joseph R. Hile,
Associate Commissioner
for Regulatory Affairs.

[FR Doc. 79-6127 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

(Docket No. HFA-305)

MEDICAL DEVICES

Classification of Catheter Stylets

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying catheter styles into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 18, 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:

Glenn A. Rahmoeller, Bureau of Medical Devices (HPK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8707 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of catheter styles:

1. Identification: A catheter stylet is a wire that is run through a catheter or cannula to render it stiff.

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 catheter stylet be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream it should be designed and constructed to minimize foreign body reactions and disruption of normal blood flow. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The Panel believes that general controls alone would not provide sufficient control over the 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 the inherent properties of the device and on their personal knowledge of and experience with the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboembolism. (b) Cardiac perforation and vessel dissection: If the stylet is too rough or too stiff, cardiac perforation and vessel dissection may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the catheter stylet 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.

PROPOSED RULES

THE COMMISSIONER PROPOSES TO AMEND PART 870 IN SUBPART B BY ADDING NEW § 870.1380 AS FOLLOWS:

§ 870.1380 Catheter stylet.
(a) Identification. A catheter stylet is a wire that is run through a catheter or cannula to render it stiff.
(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to 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.


Joseph P. Hill, Associate Commissioner for Regulatory Affairs.

[21 CFR Part 870] [Docket No. 78N-1432]

MEDICAL DEVICES

Classification of Trocars

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying trocars into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class I, and 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.


The Commissioner 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:
Glen A. Rahmoeuler, Bureau of Medical Devices (HFA-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel and the Neurological Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of trocars:

1. Identification: A trocar is a sharp-pointed instrument used with a cannula for piercing a vessel or chamber to facilitate insertion of the cannula.

2. Recommended classification: The Cardiovascular 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 low priority. The Neurological Device Classification Panel recommends that this device be classified into class I (general controls) with no exemptions.

3. Summary of reasons for recommendation: The Cardiovascular Device Classification Panel recommends that the trocar be classified into class II because this device is neither life-supporting life-sustaining, nor is it potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream it should be designed and constructed to minimize disruption of normal blood flow and foreign body reaction. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness which may affect the degree of compatibility. If the device is not properly designed it can cause excessive damage to the vessel in which it is used. The Cardiovascular Device Classification Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Cardiovascular Device Classification Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device.

The Commissioner agrees with the Cardiovascular Device Classification Panel's recommendation and is proposing that the trocar 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 unnecessary damage to vessels listed as a risk to health by the Cardiovascular Device Classification Panel. 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. Although trocars are used in many different catheterization procedures, this device will be listed in the Code of Federal Regulations under cardiovascular devices because cardiovascular uses are more common.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 501(a), 516(a), 52 Stat. 1055, 90 Stat. 940-946 (21 U.S.C. 350c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1390 as follows:

§ 870.1390 Trocar.
(a) Identification. A trocar is a sharp-pointed instrument used with a cannula for piercing a vessel or chamber to facilitate insertion of the cannula.
(b) Classification. Class II (performance standards).
Interested persons may, on or before May 8, 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.


JOSEPH P. HILE,
Associate Commissioner
for Regulatory Affairs.

(FR Doc. 79-9129 Filed 3-6-79; 8:45 a.m.)

PROPOSED RULES

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying programmable diagnostic computers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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. 4-68, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Wel-
PROPOSED RULES

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 Cardiovascular Device Classification Panel, and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of single-function, preprogrammed diagnostic computers:

1. Identification: A single-function, preprogrammed diagnostic computer is a hard-wired computer that calculates a specific physiological or blood-flow parameter based on information obtained from one or more electrodes, transducers, or measuring devices.

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 believes that the single-function, preprogrammed diagnostic computer be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through transducers, electrodes, or catheters and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's preprogrammed function, should be maintained at a generally acceptable satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The recommendation of the General and Plastic Surgery Device Classification Panel relates specifically to cardiac output computers, while the Cardiovascular Device Classification Panel makes its recommendation or diagnostic computers of any cardiovascular parameter. The Panels believe that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panels believe 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 recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panels' recommendations and is proposing that the single-function, preprogrammed diagnostic computer 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 standards would provide reasonable assurance of the safety and effectiveness of the device. Because the device is used in general cardiovascular diagnosis and monitoring, the device will be listed in the Code of Federal Regulations under cardiovascular devices. Although single-function, preprogrammed diagnostic computers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular devices because diagnostic is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 549-546 (21 U.S.C. 301(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new §870.1435 as follows:

§870.1435 Single-function, preprogrammed diagnostic computer.

(a) Identification. A single-function, preprogrammed diagnostic computer is a hard-wired computer that calculates a specific physiological or blood-flow parameter based on information obtained from one or more electrodes, transducers, or measuring devices.

FEDERAL REGISTER, VOL. 44, NO. 45—FRIDAY, MARCH 9, 1979
PROPOSED RULES

Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE,
Associate Commissioner
for Regulatory Affairs.

[FR Doc. 79-6131 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1435]

MEDICAL DEVICES

Classification of Densitometers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying densitometers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the densitometer 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 May 8, 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:
Glenn A. Rahmoeue11, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of densitometers:

1. Identification: A densitometer is a device used to measure the transmission of light through an indicator in a sample of blood.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the densitometer be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining but is potentially hazardous to life and health even when properly used. This device is placed inline between a catheter and a withdrawal infusion pump and, in that position, continuously measures optical density, from which cardiac output may be determined. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of cardiac output, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications.

(b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner of Food and Drug Administration, Associate Commissioner for Regulatory Affairs, recommends that establishing a performance standard would provide reasonable assurance of the safety and effectiveness of the device. Further, the Commissioner 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 and Drug and Cosmetic Act (secs. 515, 701(a), 21 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 870 in Subpart B by adding new § 870.1450 as follows:

§ 870.1450 Densitometer.

(a) Identification. A densitometer is a device used to measure the transmission of light through an indicator in a sample of blood.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE,
Associate Commissioner
for Regulatory Affairs.
PROPOSED RULES

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1438]

MEDICAL DEVICES

Classification of Angiographic Injectors and Syringes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying angiographic injectors and syringes into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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, 5000 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Glen A. Rahmoller, Bureau of Medical Devices (HFR-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of angiographic injectors and syringes:

1. Identification: An angiographic injector and syringe is a device that consists of a syringe and a high-pressure injector which are used to inject contrast material into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography.

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 angiographic injector and syringe be classified into class II because this device is neither an implantable device nor a life-sustaining, but is potentially hazardous to life or health even when properly used. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's injection pressure, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. When the device is synchronized with ECG signal, proper timing of the injection is another important characteristic which should be controlled. Electrical leakage current is also a problem because the device is connected directly to the bloodstream via a catheter. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure and this may lead to iatrogenic complications. (b) Intramyocardial injection: If the pressure control is not accurate or does not properly limit the injection pressure, myocardial damage can result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the angiographic injector and syringe 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, the Commissioner proposes to amend Part 870 in Subpart B by adding new §870.1650 as follows:

§870.1650 Angiographic injector and syringes.

(a) Identification. An angiographic injector and syringe is a device that consists of a syringe and a high-pressure injector which are used to inject contrast material into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5000 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.


JoSEPH P. HIXE,
Associate Commissioner,
for Regulatory Affairs.

[FR Doc. 79-6133 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No.78-1437]

MEDICAL DEVICES

Classification of Indicator Injectors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying indicator injectors into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device
PROPOSED RULES

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 May 8, 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, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

Docket No. 78N-1428

MEDICAL DEVICES

Classification of Syringe Actuators for Injectors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying syringe actuators for injectors into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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.

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 Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of indicator injectors:

1. Identification: An indicator injector is an electrically or gas-powered device designed to inject accurately an indicator solution into the blood stream. This device may be used in conjunction with a densitometer or thermodilution device to determine cardiac output.

2. Recommended classification: Class II (performance standard). 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 indicator injectors be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through a catheter and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy and reproducibility, and any limitations on the device's injection pressure and rate of injection, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard would 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment which places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the indicator injectors 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 870 in Subpart B by adding new §870.1660 as follows:

§870.1660 Indicator injector.

(a) Identification. An indicator injector is an electrically or gas-powered device designed to inject accurately an indicator solution into the blood stream. This device may be used in conjunction with a densitometer or thermodilution device to determine cardiac output.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[4110-03-M]

[21 CFR Part 870]

(Docket No. 78N-1428)
PROPOSED RULES

FOR FURTHER INFORMATION CONTACT:
Glenn A. Rahmoeller, Bureau of Medical Devices (HFE-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8801 Morrissette Ave., Silver Spring, MD 20910, 301-427-7759.

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 Cardiovascular Disease Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of syringe actuators for injectors:

1. Identification. A syringe actuator for injectors is an electrical device that controls the timing of an injection by an angiographic or indicator injector and synchronizes the injection with the electrocardiograph (ECG) cycle. The Panel recommends that establishing a performance standard for this device be a low priority.

2. Summary of reasons for recommendation. The Panel recommends that the syringe actuator for injectors be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to health even when properly used. This device is attached to the body through ECG electrode leads and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. In addition, this device must properly sense the ECG and synchronize the injection to the correct portion of the heart cycle. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. Performance characteristics, including accuracy, reproducibility, and any limitations in the device's sensing of the ECG and synchronizing of the injection, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical 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.

3. Summary of data on which the recommendation is based. The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

4. Risks to health: Cardiac arrhythmias or electrical shock. Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Failure of the device to properly synchronize the injection with the cardiac cycle may also lead to cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to therapeutic complications.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the syringe actuator for injectors 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. 360a, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new §870.1670 as follows:

§870.1670 Syringe actuator for injectors.

(a) Identification. A syringe actuator for injectors is an electrical device that controls the timing of an injection by an angiographic or indicator injector and synchronizes the injection with the electrocardiograph signal.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE,
Associate Commissioner
for Regulatory Affairs.

[FR Doc. 79-6135 Filed 3-8-79; 8:45 am]

14110-05-A

[21 CFR Part 870]

(Docket No. 78N-1439)

MEDICAL DEVICES

Classification of External Programmable Pacemaker Pulse 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 external programmable pacemaker pulse generators into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Disease 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 May 8, 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:
Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Disease Classification Panel, an FDA advisory committee, made the following recommenda-
tion with respect to the classification of external programmable pacemaker pulse generators:

1. Identification: An external programmable pacemaker pulse generator is a device that can be programmed to produce one or more pulses at preselected intervals; this device is used in electrophysiological studies.

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 external programmable pacemaker pulse generators be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device fails to stimulate, or stimulates improperly, serious cardiac sequelae can occur. This device is attached to the body through stimulating electrodes and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Although the device releases an acceptable level of electrical energy into the body when functioning properly, unsafe energy levels may be released if the device malfunctions. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to stimulate the heart, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Failure to stimulate: An electronic circuit malfunction could cause failure to stimulate. (b) Improper stimulation: Improper sensing of the electrical activity of the heart, or electromagnetic interference from other sources, could lead to improper stimulation. Improper rate control or electronic circuit failure could cause improper stimulation rate. (c) Cardiac arrhythmias: A sensing failure resulting in excess electrical leakage current or stimulation of the heart during the vulnerable period of the cardiac cycle could cause cardiac arrhythmias.

**PROPOSED RULES**

**PROPOSED CLASSIFICATION**

The Commissioner agrees with the Panel's recommendation and is proposing that the external programmable pacemaker pulse 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. Although external programmable pacemaker pulse generators are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 560-566 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new §870.1750 as follows:

§870.1750 External programmable pacemaker pulse generator.

(a) Identification. An external programmable pacemaker pulse generator is a device that can be programmed to produce one or more pulses at preselected intervals; this device is used in electrophysiological studies.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


Joseph P. Hile, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6156 Filed 3-6-79; 8:45 am]
bloodstream and to withdraw blood samples for use in determining cardiac output.

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: Although withdrawal-infusion pumps can be life-supporting and life-sustaining, the Panel recommends that this device be classified into Class II. This device is attached to the body through an intravascular catheter and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device’s performance standards. Although the device can be life-supporting, the Commission believes that a performance standard is sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Commission believes that general controls by themselves are insufficient to control the risks to health of the device. Although withdrawal-infusion pumps are used as diagnostic devices and as therapeutic devices, they will be listed in the Code of Federal Regulations under cardiovascular diagnostic devices because diagnosis is the more common use.

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 870 in Subpart B by adding new §870.1800 as follows:

§870.1800 Withdrawal-infusion pump.

(a) Identification. A withdrawal-infusion pump is a device designed to inject accurately medications into the bloodstream and to withdraw blood samples for use in determining cardiac output.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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 dock number found in brackets in the heading of this document. Received comments may be seen in the above office during the hours of 9 a.m. and 4 p.m., Monday through Friday.
PROPOSED RULES

FDA Surgery Device Classification Panel, necessarily.

1. Identification: A stethoscope is a mechanical or electrically amplified device used to project the sounds associated with the heart, arteries, and veins.

2. Recommended classification: The Cardiovascular Device Classification Panel recommends that the stethoscope be classified into class II (performance standards) and that a performance standard for this device be a low priority. The General Hospital and Personal Use Device Classification Panel and the General and Plastic Surgery Device Classification Panel recommend that stethoscopes be classified into class I (general controls) with no exemptions.

3. Summary of reasons for recommendation: The Cardiovascular Device Classification Panel believes that the stethoscope be classified into class II because this device is neither life-supporting nor life-sustaining but is potentially hazardous to life or health even when properly used. This device is used routinely in a wide variety of diagnostic medical procedures. Performance characteristics, including adequate frequency response, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the 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 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, 30 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 870 in Subpart B by adding new §870.1875 as follows:

§870.1875 Stethoscope.

(a) Identification. A stethoscope is a mechanical or electrically amplified device used to project the sounds associated with the heart, arteries, and veins.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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's 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.


Joseph P. Hole, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6138 Filed 3-8-79; 8:45 am]
3. Summary of reasons for recommendations: The Panel recommends that thermodilution probes be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of cardiac output, the resulting misdiagnosis could have a significant negative effect on the patient’s health. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet an acceptable satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The panel recommends that the manufacturer provide such assurance. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the device.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel’s recommendation and is proposing that the thermodilution 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, 50 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 870 in Subpart B by adding new §870.1915 as follows:

§870.1915 Thermodilution probe.

(a) Identification. A thermodilution probe is a device that monitors cardiac output by use of thermodilution techniques; this device is commonly attached to a catheter that may have one or more probes.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


Joseph F. Hile, Associate Commissioner for Regulatory Affairs.

[FDR Doc. 79-139 Filed 3-8-79; 8:45 am]
proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed rule classifying transducer signal amplifiers and conditioners into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel and the Anesthesiology 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 May 8, 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:

Glenn A. Rahmooler, Bureau of Medical Devices (HIPK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, and the Anesthesiology Device Classification Panel, FDA advisory committees, made the following recommendation on the classification of transducer signal amplifiers and conditioners:

1. Identification: A transducer signal amplifier and conditioner is a device used to provide the excitation energy for the transducer and to amplify or...
condition the signal emitted by the transducer.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panels recommend that the transducer signal amplifiers and conditioners be classified into class II because, this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If signal amplification and conditioning are inadequate for accurate and precise measurement of a physiological function, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the patient's body and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirement characteristics, including accuracy, reproducibility, and any limitations on the device's electrical design should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panels believe that general controls we would provide sufficient control over the performance and electrical characteristics of this device. The Panels believe that a performance standard will provide reasonable assurance of the safety and effectiveness of the device. Because the transducer signal amplifier and signal conditioner is used to measure many cardiovascular functions, and because the recommendation of the Anesthesiology Device Classification Panel deals with the measurement of blood pressure, this device will be listed in the Code of Federal Regulations under cardiovascular devices. Although transducer signal amplifiers and conditioners are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.


(a) Identification. A transducer signal amplifier and conditioner is a device used to provide the excitation energy for the transducer and to amplify or condition the signal emitted by the transducer.

Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HUE, Associate Commissioner for Regulatory Affairs.

(FR Doc. 79–6141 Filed 3–8–78; 8:43 am)

[4110–03–M] [21 CFR Part 870] [Docket No. 78N–1445]

MEDICAL DEVICES

Classification of Cardiovascular Blood Flowmeters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiovascular blood flowmeters (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel, and the Anesthesiology Device Classification Panel, the Gastroenterology and Urology Device Classification Panel, the General and Plastic Surgery 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 May 8, 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: Glenn A. Rahmoeller, Bureau of Medical Devices (HFA–450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7559.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the de-
PROPOSED RULES

The Commissioner agrees with the Panels' recommendations and is proposing that the cardiovascular blood flowmeter 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. Because blood flow is an indicator of cardiovascular function, this device will be listed in the Code of Federal Regulations (CFR) under cardiovascular devices. Although cardiovascular blood flowmeters are used both as diagnostic devices and as monitoring devices, they will be listed in the CFR under cardiovascular monitoring devices because monitoring is the more common use.


(a) Identification. A cardiovascular blood flowmeter is a device that is connected to a flow transducer that energizes the transducer and processes and displays the blood flow signal.

(b) Classification. Class II (performance standards).
PROPOSED RULES

§870.2120 Extravascular blood flow probe.

(a) Identification. An extravascular blood flow probe is an extravascular ultrasonic or electromagnetic probe used in conjunction with a blood flowmeter to measure blood flow in a chamber or vessel.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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. Copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be included 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6143 Filed 3-2-79; 8:45 am]

MEDICAL DEVICES

Classification of Cardiac Monitors (Including Cardiotachometers and Rate Alarms)

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiac monitors (including cardiotachometers and rate alarms) into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the Anesthesiology 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.


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. 4-85, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoller, Bureau of Medical Devices (HPK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the Electrotherapy Device Classification Panel, FDA advisory committees, made the following recommendation regarding classification of cardiac monitors (including cardiotachometers and rate alarms):

1. Identification: A cardiac monitor (including a cardiotachometer and a rate alarm) is a device used to measure the heart rate from an analog signal produced by an electrocardiograph, vectorcardiograph, or blood pressure monitor. This device may sound an alarm when the heart rate falls outside preset upper and lower limits.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard will provide assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

3. Summary of reasons for recommendation: The Panels recommend that cardiac monitors be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health when properly used. Failure of the device to accurately measure heart rate could result in misdiagnosis that could have a significant negative effect on the patient's health. This device is attached to the body through a series of amplifiers, transducers, or electrodes and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of heart rate, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panels believe that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panels 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 recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disrupt the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, or if the processing circuitry is inadequate, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panels' recommendations and is proposing that the cardiac monitor (including a cardiotachometer and rate alarm) 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. Because cardiac monitoring indicates heart function, this device will be listed in the Code of Federal Regulations (CFR) under cardiovascular devices. Although cardiac monitors (including cardiotachometers and rate alarms) are used both as diagnostic devices and as monitoring devices, they will be listed in the CFR under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 360c, 371(a)), 52 Stat. 1055, 50 Stat. 1551 (21 U.S.C. 360c, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new §870.2300 as follows:

§870.2300 Cardiac monitor (including a cardiotachometer and a rate alarm).

(a) Identification. A cardiac monitor (including a cardiotachometer and a rate alarm) is a device used to measure the heart rate from an analog signal produced by an electrocardiograph, vectorcardiograph, or blood pressure monitor. This device may sound an alarm when the heart rate falls outside preset upper and lower limits.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-85, 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.


Joseph P. Hile, Associate Commissioner for Regulatory Affairs.

[F.R. Doc. 79-6144 Filed 3-8-79; 8:45 a.m.]

[4110-03-M]

[21 CFR Part 870]

(Docket No. 78N-1448)

Medical Devices

Classification of Apex Cardiographs (Vibrocardiographs)

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying apex cardiographs (vibrocardiographs) into class II (performance standards). The FDA is publishing the recommendation of the Cardiovascular 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 May 8, 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:
Glenn A. Rahmoller, Bureau of Medical Devices (HFZ-949), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7558.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of apex cardiographs (vibrocardiographs):

1. Identification: An apex cardiograph (vibrocardiograph) is a device used to amplify or condition the signal from an apex cardiographic transducer and to produce a visual display of the motion of the heart; this device also provides any excitation energy required by the transducer.

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 apex cardiographs be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of the heart motion, the resulting misdiagnosis could have a serious adverse effect on the patient's health. This device is attached to the body through a transducer and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of the heart motion should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disrupt the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION
The Commissioner agrees with the Panel's recommendation and is proposing that this apex cardiograph (vibrocardiograph) 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. Although apex cardiographs (vibrocardiographs) are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

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 870 in Subpart C by adding new §870.2310 as follows:

§870.2310 Apex cardiograph (vibrocardiograph).
(a) Identification. An apex cardiograph (vibrocardiograph) is a device used to amplify or condition the signal from an apex cardiographic transducer and to produce a visual display of the motion of the heart; this device also provides any excitation energy required by the transducer.
(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


J. JOSEPH P. HUELS, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6145 Filed 3-8-79; 8:45 am]

[110-03-M]

[21 CFR Part 870]

(Docket No. 78N-1449)

MEDICAL DEVICES
Classification of Ballistocardiographs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ballistocardiographs into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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:
Glenn A. Rahmoeuller, Bureau of Medical Devices, (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910. 301-427-7859.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of ballistocardiographs:

1. Identification: A ballistocardiograph is a device, including a supporting structure on which the patient is placed, that moves in response to blood ejection from the heart. The device often provides a visual display.

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 ballistocardiograph be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device fails to accurately measure cardiac function, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device directly supports the whole body of the patient and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of cardiac function, should be maintained at a generally accepted satisfactory level should be made known to the user through special labelling. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disrupt the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the ballistocardiograph 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. Although ballistocardiographs are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 U.S.C. 3553, 55 Stat. 1053, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a)(1))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new §870.2320 as follows:

§870.2320 Ballistocardiograph.
(a) Identification. A ballistocardiograph is a device, including a supporting structure on which the patient is placed, that moves in response to blood ejection from the heart. The device often provides a visual display.
(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


Joseph P. Hile, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6145 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1400]

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a public comment a proposed regulation classifying echocardiosgraphs into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device 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.


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:
Glenn A. Rahmoeuller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910. 301-427-7859.
5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (c) Tissue and blood damage: If the device is not designed properly, excessive ultrasonic energy can be released into the body at levels that can damage tissue and blood.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the echocardiograph 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. Although echocardiographs are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 50 Stat. 540-546, 21 U.S.C. 351, 355 et seq.) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new §870.2330 as follows:

§870.2330 Echocardiograph.

(a) Identification. An echocardiograph is a device that uses ultrasonic energy to create images of cardiovascular structures. It includes phased arrays and two-dimensional scanners.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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 to the Hearing Clerk. 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6147 Filed 3-5-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870] (Docket No. 78N-1451)

MEDICAL DEVICES

Classification of Electrocardiographs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electrocardiographs into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel, the Anesthesiology Device Classification Panel, and the General and Plastic Surgery 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.


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:

Glenn A. Rahmoller, Bureau of Medical Devices (HFA-450), Food and Drug Administration, Department of Health, Education, and Welfare, 200 Independence Ave., Silver Spring, MD 20910, 301-427-7550.

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 Cardiovascular Device Classification Panel, the Anesthesiology Device Classification Panel, and the General and Plastic Surgery Device Classification Panel made the following recommendations with respect to the classification of echocardiographs:

1. Identification: An echocardiograph is a device that uses ultrasonic energy to create images of cardiovascular structures. It includes phased arrays and two-dimensional scanners.

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 echocardiographs be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequately designed and precise imaging of cardiovascular structures, resulting in misinterpretations could have a significant negative effect on the patient's health. This device is attached to the body through an ultrasonic transducer which, when functioning normally, releases an acceptable energy level into the body. Malfunction of the device, however, may result in the misclassification of energy levels. In addition, the device is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, such as electrical leakage current, must be measured against the requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to image cardiovascular structures, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.
PROPOSED RULES

Electrocardiograph. A device used to process the electrical signal transmitted through two or more ECG electrodes and to produce a visual display of the electrical signal produced by the heart.

Misdiagnosis: If the zero or calibration control on the device is inaccurate or unstable, or if the frequency response of the device is inadequate, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

Proposed Classification

The Commissioner agrees with the Panels' recommendations and is proposing that the electrocardiograph 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. Because ECG's measure the electrical characteristics of the heart, this device will be listed in the Code of Federal Regulations (CFR) under cardiovascular devices. Although electrocardiographs are used both as diagnostic devices and as monitoring devices, they will be listed in the CFR under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 50 Stat. 540-546 (21 U.S.C. 360c, 371(a)) and under authority delegated to him (21 CFR 511), the Commissioner proposes that the final regulation classifying electrocardiograph lead switching adaptors into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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:
Glenn A. Rahmoeiler, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7569.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendations with respect to the classification of electrocardiograph (ECG) lead switching adaptors:

1. Identification: An electrocardiograph lead switching adaptor is a passive switching device to which ECG limb and chest leads may be attached. This device is used to connect various combinations of limb and chest leads to the output terminals in order to create standard lead combinations such as leads I, II, and III.

2. Need to meet certain criteria: 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 ECG lead switching adaptors be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to both the operator's health and the patient if used properly. If the device is designed so that it improperly connects the ECG leads, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through ECG electrodes and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, must meet certain requirements. Performance characteristics involving the design of the switching adaptor should be maintained at a generally accepted satisfactory level. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Misdiagnosis: Improper design of the switching adaptor and lack of standardization of the leads can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (b) Cardiac arrhythmias or electrical shock: Proper electrical isolation of the ECG leads by the device is necessary to prevent excessive electrical leakage current, which can disturb the normal electrophysiology of the heart and lead to the onset of cardiac arrhythmias.

**Proposed Classification**

The Commissioner agrees with the Panel's recommendation and is proposing that the electrocardiograph lead switching adaptor 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. Although electrocardiograph lead switching adaptors are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 512(a), 516, 515(b), 519 (21 U.S.C. 360a, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new §870.2350 as follows:

§870.2350 Electrocardiograph lead switching adaptor.

(a) Identification. An electrocardiograph lead switching adaptor is a passive switching device to which ECG limb and chest leads may be attached. This device is used to connect various combinations of limb and chest leads to the output terminals in order to create standard lead combinations such as leads I, II, and III.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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 include 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[4110-03-H]

[21 CFR Part 870]

(Docket No. 78N-1453)

**MEDICAL DEVICES**

Classification of Electrocardiograph 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 electrocardiograph electrodes into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 1979. A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electrocardiograph electrodes:

**FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979**
1. Identification: An electrocardiograph electrode is the electrical conductor which is applied to the surface of the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or vectorcardiogram.

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 electrocardiograph electrodes be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device fails to transmit accurately the electrical signal produced by the heart, the resulting misdiagnosis could have a significant negative effect upon the patient's health. Because the device is in direct contact with the skin, the materials used in the device should meet a generally accepted satisfactory level of tissue compatibility. Performance characteristics involving the device's ability to sense and transmit the electrical signal should also be maintained at a generally accepted satisfactory level. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Skin irritation: Irritants in the materials of which the device is made can lead to skin irritation. (b) Misdiagnosis: An improper electrode-medium combination creating an excessively high impedance, or a device design which allows excessive interference from subject movement, can lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the electrocardiograph 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. Although electrocardiograph electrodes are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

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 870 in Subpart C by adding new § 870.2360 as follows:

§ 870.2360 Electrocardiograph electrode.

(a) Identification. An electrocardiograph electrode which is applied to the surface of the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or vectorcardiogram.

(b) Classification. Class II (performance standard).

Interested persons may, on or before May 8, 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 by the public during regular office hours between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated February 26, 1979.

JOSEPH P. HILE
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6193 Filed 3-8-78; 8:45 am]

PAGE 13338

[PROPOSED RULES]

[13336]

[21 CFR Part 870]

[FR Doc. 79-6150 Filed 3-8-79; 8:45 am]

[13337]

MEDICAL DEVICES

Classification of ECG Surface Electrode 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 electrocardiograph (ECG) surface electrode testers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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:
Glenn A. Rahmoeller, Bureau of Medical Devices (HFE-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7659.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation regarding classification of ECG surface electrode testers:

1. Identification: An electrocardiograph surface electrode tester is a device used to test the function and application of ECG leads.

2. Recommended classification: Class II (performance standards). The Panel recommends that a performance standard for this device be a low priority.
3. Summary of reasons for recommendation: The Panel recommends that the ECG surface electrode tester be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through ECG electrodes and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. If the device is inadequate for accurate and precise indication of ECG electrode function, the resulting misdiagnosis could have a significant negative effect on the patient's health. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to test ECG electrodes, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the 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 the hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the ECG surface electrode 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 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 ECG surface electrode tester will be listed in the Code of Federal Regulations (CFR) under cardiovascular monitoring devices because the device is an accessory to ECG electrodes which are listed in the CFR under cardiovascular monitoring 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, 311(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2370 as follows:

§ 870.2370 ECG surface electrode tester.

(a) Identification. An electrocardiograph surface electrode tester is a device used to test the function and application of ECG electrodes.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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 issued for 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.


Joseph P. Hile
Associate Commissioner for Regulatory Affairs

(F) Reg. 79-1615 Filed 3-6-79; 8:45 am

[1110-3-M] [21 CFR Part 870]

(Docket No. 78N-1455)

MEDICAL DEVICES

Classification of Electrocardiograph Conducting 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 electrocardiograph conducting media into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 the 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 May 8, 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:

Glenn R. Rahmoeller, Bureau of Medical Devices (HFA-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of electrocardiograph conducting media:

1. Identification: Electrocardiograph conducting medium is the conductive paste or jelly that is applied to the surface of the body to transmit the electrical signal at the body surface to the electrocardiograph (ECG) electrode.

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 electrocardiograph conducting media be classified into class II because this device is neither life-supporting nor life-sustaining but is potentially hazardous to life or health even when properly used. Because the devices is in direct contact with the skin, the materials used in the device should meet a generally accepted satisfactory level of tissue compatibility. Performance characteristics involving the device's ability to transmit the electrical signal and the devices' compatibility with the electrocardiograph electrode should be maintained at a generally accepted satisfactory level.
The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Skin irritation: Irritants in the materials used in this device can cause skin irritation. (b) Misdiagnosis: An improper electrode-medium combination creating an excessively high impedance can lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel’s recommendation and is proposing that the electrocardiograph conducting media be classified into class II (performance standards). The Commissioner believes that 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. Although electrocardiograph conducting media are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 80 Stat. 540-546 (U.S.C. 360a, 371(a))) and under authority delegated to him (21 CFR Part 651), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2380 as follows:

§ 870.2380 Electrocardiograph conducting medium.

(a) Identification. Electrocardiograph conducting medium is the conductive paste or jelly that is applied to the surface of the body to transmit the electrical signal at the body surface to the electrocardiograph (ECG) electrode.

(b) Classification. Class II (performance standards).

- Interested persons may, on or before May 8, 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.


JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6152 Filed 3-8-79; 8:45 am]

4110–03–M

21 CFR Part 870

[Proposed]

Docket No. 78N-1456

MEDICAL DEVICES
Classification of Phonocardiographs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying phonocardiographs into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 1979. The Commission 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:
Glenn A. Rahmoeller, Bureau of Medical Devices (HPK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8777 Georgia Ave., Silver Spring, MD 20910, 301-427-7659.

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 Cardiovascular Device Classification Panel, an FDA advisory panel, made the following recommendation with respect to the classification of phonocardiographs:

1. Identification: A phonocardiograph is a device used to amplify or condition the signal from a heart sound transducer. This device furnishes the excitation energy for the transducer and provides a visual or audible display of the heart sounds.

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 phonocardiographs be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health when properly used. If this device is inadequate for accurate and precise measurement of heart sounds, the resulting misdiagnosis could have a significant negative effect on the patient’s health. This device is attached to the body through a heart sound transducer and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device’s measurement of heart sounds, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the 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
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.


JOSEPH P. HIZE, Associate Commissioner for Regulatory Affairs.

(FR Doc. 79-6153 Filed 3-8-78; 8:45 am)

[4110-03-M]

[21 CFR Part 870]

(Docket No. 78N-1457)

MEDICAL DEVICES

Classification of Vectorcardiographs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing, for public comment a proposed regulation classifying vectorcardiographs into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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. 4-05, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeiller, Bureau of Medical Devices (HFE-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-497-7059.

SUPPLEMENTARY INFORMATION:

PANEL RECOMMENDATION

A proposal elsewhere in this issue of Federal Register provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of vectorcardiographs:

1. Identification: A vectorcardiograph is a device used to detect, measure, and record the electrical signal transmitted through ECG electrodes and to produce a visual display of the magnitude and direction of the electrical signal produced by the heart.

2. Classification: Class II (performance standards). The Panel recommends that a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that vectorcardiographs be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life when used or even when in storage.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of car-
The Commissioner agrees with the Panel's recommendation and is proposing that the vectorcardiograph 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. Although vectorcardiographs are used both as diagnostic devices and as monitoring devices, they will be listed in the part of the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal, Food, Drug, and Cosmetic Act (secs. 513, 701(a)), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 380c, 371(a))) and under authority delegated to him (21 CFR 5.1.), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2400 as follows:

§ 870.2400 Vectorcardiograph.

(a) Identification. A vectorcardiograph is a device used to process the electrical signal transmitted through ECG electrodes and to produce a visual display of the magnitude and direction of the electrical signal produced by the heart.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HPA-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.

PROPOSED RULES


Joseph P. Hile,
Associate Commissioner
for Regulatory Affairs.

[FR Doc. 79-6154 Filed 3-8-78; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

(Docket No. 78N-1458)

MEDICAL DEVICES

Classification of Medical Cathode-Ray Tube Displays

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying medical cathode-ray tube displays into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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 (HPA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Glenn A. Rahmoeuer, Bureau of Medical Devices (HPK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8787 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendations with respect to the classification of medical cathode-ray tube displays:

1. Identification: A medical cathode-ray tube display is a device designed primarily to display selected biological signals. This device often incorporates special display features unique to a specific biological signal.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that medical cathode-ray tube displays be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise display of a designated physiological signal, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through catheters, transducers, electrodes, and amplifiers and is used in a clinical environment. Electrical leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's display of physiological signals, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device. Therefore, if 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, or the frequency response is inadequate, the device may generate inaccu-
rate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

**PROPOSED CLASSIFICATION**

The Commissioner agrees with the Panel’s recommendation and is proposing that the medical cathode-ray tube display 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. Although medical cathode-ray tube displays are used both as diagnostic devices and as monitoring devices, they will be listed in the part of the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

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 870 in Subpart C by adding new §870.2450 as follows:

§870.2450 Medical cathode-ray tube display.

(a) Identification. A medical cathode-ray tube display is a device designed primarily to display selected biological signals. This device often incorporates special display features unique to a specific biological signal.

Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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 at 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.

**PROPOSED RULES**


Joseph P. Hile, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6155 Filed 3-6-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

(Docket No. 78N-1459)

MEDICAL DEVICES

Classification of Signal Isolation 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 signal isolation systems into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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:

Glenn A. Rahmoller, Bureau of Medical Devices (HFA-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8737 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of signal isolation systems:

I. Identification. A signal isolation system is a device that electrically isolates the patient from equipment connected to the domestic power system. This isolation may be accomplished, for example, by transformer coupling, acoustic coupling, or optical coupling.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that signal isolation systems be classified into class II because this device is neither life-sustaining nor life-supporting but is potentially hazardous to life or health even when properly used. If the device fails to properly isolate the subject, or to adequately transmit the electrical signal from the patient to an electrode or electrode to the monitoring equipment, electrical shock and misdiagnosis are significant potential hazards to the patient’s health. The device is an interface between transducers and electrodes attached to the body and monitoring equipment connected to the domestic power system, and it is used in a clinical environment where excess electrical leakage current can be a serious hazard. Thus, the electrical characteristics of this device are subject to certain requirements. Performance for these characteristics, including electrical isolation, of electrical function, and any limitations on the device’s signal, will be the panel’s recommendation for a medium priority.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of and experience with the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Failure of the device to maintain electrical isolation can lead to the presence of excess electrical leakage current disturbing the normal electrophysiology of the heart and leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and
this can lead to iatrogenic complications. (b) Misdiagnosis: Inadequate frequency response and Inaccuracy or instability of calibration of a device with which a signal isolation system is used can cause the device to generate inaccurate or insufficient diagnostic data. If inaccurate or insufficient diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the signal isolation 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. Although signal-isolation systems are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 515, 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 870 in Subpart C by adding new § 870.2600 as follows:

§ 870.2600 Signal isolation system.
(a) Identification. A signal isolation system is a device that electrically isolates the patient from equipment connected to the domestic power system. This isolation may be accomplished, for example, by transformer coupling, acoustic coupling, or optical coupling.
(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5000 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.

PROPOSED RULES


JOSEPH P. HILE,
Associate Commissioner
for Regulatory Affairs.

(FRG Doc. 79-6150 Filed 3-8-79; 9:48 a.m.)

[4110-03-M]

[21 CFR Part 870]

(Docket No. 78N-1460)

MEDICAL DEVICES

Classification of Line Isolation 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 line isolation monitors into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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, the FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 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, 5000 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of line isolation monitors:

1. Identification: A line isolation monitor is a device used to monitor the-electrical-leakage current from a power supply electrically isolated from the domestic power supply.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

Summary of reasons for recommendation: The Panel recommends that line isolation monitors be classified into class II because the device is neither life-sustaining nor life-supporting, but is potentially hazardous to life or health when properly used. If the device fails to monitor accurately leakage current or to keep the power supply isolated, excessive leakage current could be released into the clinical environment, creating a potential hazard of electrical shock to the patient. Performance characteristics including the accurate monitoring of leakage current and any limitations on the device's ability to maintain power supply isolation should be contained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Cardiac arrhythmias or electrical shock: Failure to accurately monitor the electrical leakage current or failure of the device to keep the power supply isolated can lead to excessive leakage current, which can disturb the normal electrophysiology of the heart and lead to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician, during a catheterization or surgical procedure, and this can lead to iatrogenic complications.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the line isolation 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 Commis-
PROPOSED RULES

§ 870.2620 Line isolation monitor.
(a) Identification. A line isolation monitor is a device used to monitor the electrical leakage current from a power supply electrically isolated from the domestic power supply.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (FPA-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.


JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6157 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]
(Docket No. 78N-14613)

MEDICAL DEVICES
Classification of Portable Leakage Current Alarms

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying portable leakage current alarms into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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.


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 (FPA-305), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7599.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of portable leakage alarm:oj

1. Identification: A portable leakage current alarm is a device used to measure the electrical leakage current between any two points of an electrical system and to sound an alarm if the current exceeds a certain threshold.

2. Recommended classification: Class II (performance standards). The Panel recommends that a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that portable leakage current alarms be classified into class II because the device is neither life-sustaining nor lifesupporting, but is potentially hazardous to life or health even when properly used. If the device fails to detect excessive electrical leakage current, a potential hazard of electrical shock to the patient exists. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to measure electrical leakage current, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling.

The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Cardiac arrhythmias or electrical shock: An inaccuracy in the detection circuitry can lead to excessive electrical leakage current, which can disturb the normal electrophsiology of the heart and lead to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the portable leakage current alarm 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 can also control electrical leakage current, which can disturb the normal electrophsiology of the heart and lead to the onset of cardiac arrhythmias.

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 870 in Subpart C by adding new § 870.2640 as follows:

§ 870.2640 Portable leakage current alarm.
(a) Identification. A portable leakage current alarm is a device used to measure the electrical leakage current between any two points of an electrical system and to sound an alarm if the current exceeds a certain threshold.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (FPA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments to the Hearing Clerk (FPA-305), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7599.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFZ-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7599.
PROPOSED RULES

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 Cardiovascular Device Classification Panel, and FDA, having reviewed the comments received, made the following recommendation with respect to the classification of oscillometers:

1. Identification: An oscillometer is a device used to measure physiological oscillations of any kind, e.g., changes in the volume of arteries.

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 oscillometers be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through various types of transducers and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device’s measurement of a specific physiological parameter, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. If the device is inadequate for accurate and precise measurement of oscillations, the resulting misdiagnosis could have a significant negative effect on the patient’s health. The Panel believes that general controls alone would not provide sufficient control over the electrical 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero of calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel’s recommendation and is proposing that the oscillometer 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. Although oscillometers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

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 §1), the Commissioner proposes to amend Part 870 in Subpart C by adding a new §870.2675 as follows:

§870.2675 Oscillometer.

(a) Identification. An oscillometer is a device used to measure physiological oscillations of any kind, e.g., changes in the volume of arteries.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, 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.


JOSEPH P. HILE
Associate Commissioner
for Regulatory Affairs

[FR Doc. 79-6185 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1462]

MEDICAL DEVICES

Classification of Oscillometers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying oscillometers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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:

Glenn A. Rahmsoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8787 Georgia Ave., Silver Spring, MD 20910, 301-427-7759.
PROPOSED RULES

[4110-03-M]
[21 C.F.R. Part 870]

[DOCKET NO. 78N-1463]

MEDICAL DEVICES

Classification of Oximeters

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying oximeters into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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.

The Commissioner of Food and Drugs, and the Commissioner of Food and Drugs (HFA-305), 52 Stat. 1035, 50 Stat. 540-45, 41 U.S.C. 360c, 371 (a)) and under authority delegated to him (21 C.F.R. 5.1), the Commissioner proposes to amend Part 870 in subpart C by adding new §870.2700 as follows: §870.2700 Oximeter.

(a) Identification. An oximeter is a device used to transmit radiation at a known wavelength through blood and to measure the blood oxygen saturation based on the amount of reflected or scattered radiation. It may be used alone or in conjunction with a fiberoptic oximeter catheter.

(b) Classification. Class II (Performance standards).

INTERESTED PERSONS MAY, ON OR BEFORE 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

(FR Doc. 79-6160 Filed 3-6-79; 8:43 am)

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
PROPOSED RULES

Classification of Ear Oximeters

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify ear oximeters into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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.


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:

Glen A. Rahmoller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8787 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of ear oximeters:

1. Identification: An ear oximeter is an extravascular device used to transmit light at a known wavelength through blood in the ear. The amount of reflected or scattered light as indicated by this device is used to measure the blood oxygen saturation.

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 ear oximeters be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of blood oxygen saturation, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through transducers and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of blood oxygen saturation, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. Although the device releases into the body an acceptable energy level when functioning normally, unsafe energy levels may be released if the device malfunctions. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (c) Tissue damage and blood damage: Devices which emit energy into the body can emit such energy at levels which damage tissue and blood if the device is not properly designed.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the ear oximeter 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. Although ear oximeters are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-548 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2710 as follows:

§ 870.2710 Ear oximeter.

(a) Identification. An ear oximeter is an extravascular device used to transmit light at a known wavelength(s) through blood in the ear. The amount of reflected or scattered light as indicated by this device is used to measure the blood oxygen saturation.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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 brackeating 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.


JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FPR Doc. 79-6161 Filed 3-8-79; 8:45 am]
**PROPOSED RULES**

[4110–03–M]

[21 CFR Part 870]

[Docket No. 78N–1465]

**MEDICAL DEVICES**

Classification of Impedance Phlebographs

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying impedance phlebographs into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

**FOR FURTHER INFORMATION CONTACT:** Glenn A. Rahmoeller, Bureau of Medical Devices (HRP–450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

**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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of impedance phlebographs:

1. **Identification:** An impedance phlebograph is a device used to provide a visual display of the venous pulse or drainage by measuring electrical impedance changes in a region of the body.

2. **Recommended classification:** Class II (performance standards). The Panel recommends that a performance standard for this device be a high priority.

3. **Summary of reasons for recommendation:** The Panel recommends that impedance phlebographs be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of venous pulse or drainage, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through electrodes and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Although the device releases an acceptable energy level into the body when functioning normally, unsafe energy levels may be released if the device malfunctions. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of venous pulse or drainage, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical 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 recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. **Risks to health:** (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disrupt the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, or if the frequency response of the device is improper, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

**PROPOSED CLASSIFICATION**

The Commissioner agrees with the Panel's recommendation and is proposing that the impedance phlebograph 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. Although impedance phlebographs are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301(a), 513, 701(a)), 82 Stat. 1555, 50 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 870 in Subpart C by adding new § 870.2750 as follows:

- **§ 870.2750 Impedance phlebograph.**
  - (a) **Identification.** An impedance phlebograph is a device used to provide a visual display of the venous pulse or drainage by measuring electrical impedance changes in a region of the body.
  - (b) **Classification.** Class II (performance standards).

Interested persons may, on or before May 8, 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. 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.


[FR Doc. 79–6162 Filed 3–8–79; 8:45 am]

[4110–03–M]

[21 CFR Part 870]

[Docket No. 78N–1466]

**MEDICAL DEVICES**

Classification of Impedance 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 impedance plethysmographs into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel and the General and Plastic Surgery 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 May 8, 1979. The Commission 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:
Glenn A. Rahmaele, Bureau of Medical Devices (HEK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of impedance plethysmographs:

1. Identification: An impedance plethysmograph is a device used to estimate blood flow by measuring electrical impedance changes in a region of the body.

2. Recommended classification: Class II (performance standard). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panels recommend that impedance plethysmographs be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of blood flow, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through electrodes and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet the requirements. Although the device releases an acceptable energy level into the body when functioning normally, unsafe energy levels may be released if the device malfunctions. Performance characteristics including accuracy, reproducibility, and any limitations on the device's measurement of blood flow, should be maintained at a generally accepted satisfactory level and should be made known through special labeling. The Panels believe that general controls alone would not provide sufficient control over the performance and electrical 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 recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, or if frequency response of the device is improper, the device can generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION
The Commissioner agrees with the recommendations of the Panels and is proposing that the impedance plethysmograph be classified into class II standards. The Commissioner believes that a-performance standard is necessary for this device because general controls by themselves are insufficient to control the device. A performance standard would provide reasonable assurance of the device and the 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. Because the measurement of blood flow is an indicator of cardiovascular function, this device will be listed in the Code of Federal Regulations (CFR) under cardiovascular devices. Although impedance plethysmographs are used both as diagnostic devices and as monitoring devices, they will be listed in the CFR under cardiovascular monitoring devices because monitoring is the more common use.

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 870 in Subpart C by adding new § 870.2770 as follows:

§ 870.2770 Impedance plethysmograph.
(a) Identification. An impedance plethysmograph is a device used to estimate blood flow by measuring electrical impedance changes in a region of the body.
(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILLE, Associate Commissioner for Regulatory Affairs.

(30 FR 71-5163 Filed 3-6-79 8:45 am)
PROPOSED RULES


DATES: COMMENTS BY MAY 8, 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.


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 CARDIOVASCULAR DEVICE CLASSIFICATION PANEL, AN FDA ADVISORY COMMITTEE, MADE THE FOLLOWING RECOMMENDATION WITH RESPECT TO THE CLASSIFICATION OF HYDRAULIC, PNEUMATIC, AND PHOTOELECTRIC PLETHYSMOGRAPHS:

1. IDENTIFICATION: A HYDRAULIC, PNEUMATIC, AND PHOTOELECTRIC PLETHYSMOGRAPH IS A DEVICE USED TO ESTIMATE BLOOD FLOW IN A REGION OF THE BODY USING HYDRAULIC, PNEUMATIC, OR PHOTOELECTRIC MEASUREMENT TECHNIQUES.

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 HYDRAULIC, PNEUMATIC, AND PHOTOELECTRIC PLETHYSMOGRAPH BE CLASSIFIED INTO CLASS II BECAUSE THIS ELECTRICALLY POWERED DEVICE IS NEITHER LIFE-SUPPORTING NOR LIFE-SUSTAINING, BUT IS POTENTIALLY HAZARDOUS TO LIFE OR HEALTH EVEN WHEN PROPERLY USED. IF THE DEVICE IS INADEQUATE FOR ACCURATE AND PRECISE MEASUREMENT OF BLOOD FLOW, THE RESULTING MISDIAGNOSIS COULD HAVE A SIGNIFICANT NEGATIVE EFFECT ON THE PATIENT'S HEALTH. THIS DEVICE IS ATTACHED TO THE BODY THROUGH ELECTRICAL SENSORS AND IS USED IN A CLINICAL ENVIRONMENT WHERE EXCESSIVE LEAKAGE CURRENT CAN BE A SERIOUS HAZARD. THE ELECTRICAL CHARACTERISTICS OF THIS DEVICE, E.G., ELECTRICAL LEAKAGE CURRENT, NEED TO MEET CERTAIN REQUIREMENTS. PERFORMANCE CHARACTERISTICS INCLUDING ACCURACY, REPRODUCIBILITY, AND ANY LIMITATION ON THE DEVICE'S MEASUREMENT OF BLOOD FLOW, SHOULD BE MAINTAINED AT A GENERALLY ACCEPTED SATISFACTORY LEVEL AND SHOULD BE MADE KNOWN TO THE USER THROUGH SPECIAL LABELING. THE PANEL BELIEVES THAT GENERAL CONTROLS ALONE WOULD NOT PROVIDE SUFFICIENT CONTROL OVER THE PERFORMANCE AND ELECTRICAL CHARACTERISTICS OF THIS DEVICE. THE PANEL BELIEVES THAT A PERFORMANCE STANDARD WILL PROVIDE REASONABLE ASSURANCE OF THE SAFETY AND EFFECTIVENESS OF THE DEVICE.

PROPOSED CLASSIFICATION

THE COMMISSIONER AGREES WITH THE PANEL'S RECOMMENDATION AND IS PROPOSING THAT THE HYDRAULIC, PNEUMATIC, AND PHOTOELECTRIC PLETHYSMOGRAPH 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. ALTHOUGH HYDRAULIC, PNEUMATIC, AND PHOTOELECTRIC PLETHYSMOGRAPHS ARE USED BOTH AS DIAGNOSTIC DEVICES AND AS MONITORING DEVICES, THEY WILL BE LISTED IN THE CODE OF FEDERAL REGULATIONS UNDER CARDIOVASCULAR MONITORING DEVICES BECAUSE MONITORING IS THE MORE COMMON USE.

THE COMMISSIONER PROPOSES TO AMEND PART 870 IN SUBPART C BY ADDING NEW § 870.2780 AS FOLLOWS:

§ 870.2780 HYDRAULIC, PNEUMATIC, AND PHOTOELECTRIC PLETHYSMOGRAPHS

(a) IDENTIFICATION. A HYDRAULIC, PNEUMATIC, OR PHOTOELECTRIC PLETHYSMOGRAPH IS A DEVICE USED TO ESTIMATE BLOOD FLOW IN A REGION OF THE BODY USING HYDRAULIC, PNEUMATIC, OR PHOTOELECTRIC MEASURMENT TECHNIQUES.

(b) CLASSIFICATION. CLASS II (PERFORMANCE STANDARDS).

INTERESTED PARTIES 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.


JOSEPH P. HILE, ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
A medical magnetic tape recorder is a device used to record and play back signals from, for example, physiological amplifiers, signal conditioners, or computers. (b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit single copies of comments, four copies of all comments shall be submitted, except that if 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6165 Filed 3-8-79; 8:45 am]

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the medical magnetic tape recorder 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. Although medical magnetic tape recorders are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 30 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 870 in Subpart C by adding new § 870.2800 as follows:

§ 870.2800 Medical magnetic tape recorder.

(a) Identification. A medical magnetic tape recorder is a device used to record and play back signals from, for example, physiological amplifiers, signal conditioners, or computers.

(b) Classification. Class II (performance standards).

For further information contact:

Glenn A. Rahmoeiler, Bureau of Medical Devices (870X-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of medical magnetic tape recorders:

1. Identification: A medical magnetic tape recorder is device used to record and play back signals from, for example, physiological amplifiers, signal conditioners, or computers.

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 medical magnetic tape recorders be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the recording or playback of signals does not allow accurate and precise determination of a specific physiological function, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through transducers, catheters, or electrodes and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain characteristics, including accuracy, reproducibility, and any limitations on the device's recording of electrical signals, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrical physiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, or if the frequency response of the device is improper, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.
anance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue final classification standards for use in the future development of this device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 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:

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 Cardiovascular Device Classification Panel and the Ophthalmic Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of paper chart recorders:

1. Identification: A paper chart recorder is a device used to print on paper, and create a permanent record of, the signal from, for example, a physiological amplifier, signal conditioner, or computer.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panels recommend that paper chart recorders be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining but is potentially hazardous to life or health even when properly used. If the charted display provided by the device is inadequate for accurate and precise determination of a specific physiological parameter, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through transducers, catheters, or electrodes and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's recording of electrical signals, shall be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not properly assembled, used, and maintained. The Panels believe that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panels recommend that a performance standard with 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 basis on which the recommendation is based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device, and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to介绍。 (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, or if the frequency response of the device is improper, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the paper chart recorder 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. Because paper chart recorders are used most frequently with cardiovascular devices, this device will be listed in the Code of Federal Regulations under cardiovascular devices. Although paper chart recorders are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 50 Stat. 540-546 [21 U.S.C. 350c, 371(a)] and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2810 as follows:

§ 870.2810 Paper chart recorder.

(a) Identification. A paper chart recorder is a device used to print on paper, and create a permanent record of, the signal from, for example, a physiological amplifier, signal conditioner, or computer.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit comments 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 8 a.m. and 4 p.m., Monday through Friday.


Joseph P. Hele, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-8186 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[DOCKET No. 79N-1470]

MEDICAL DEVICES

Classification of Apex Cardiographic 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 apex cardiographic transducers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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:
Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

PROPOSED RULES

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of apex cardiographic transducers:

1. Identification: An apex cardiographic transducer is a device used to detect motion of the heart (acceleration, velocity, or displacement) by changes in the mechanical or electrical properties of the device.

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 apex cardiographic transducers be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the signal produced by the transducer is inadequate for accurate and precise measurement of heart movement, the resulting misdiagnosis could have a serious negative effect on the patient's health. This device is attached to the body through the skin and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to detect heart movement, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge and experience with the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the apex cardiographic 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. Although apex cardiographic transducers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 50 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 870 in Subpart C by adding new §870.2840 Apex cardiographic transducer, as follows:

(a) Identification. An apex cardiographic transducer is a device used to detect motion of the heart (acceleration, velocity, or displacement) by changes in the mechanical or electrical properties of the device.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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: February 26, 1979,

JOSPEH P. HILE,
Associate Commissioner for Regulatory Affairs.

(FR Doc. 79-8167 Filed 3-8-79; 8:45 am)

[4110-03-M]
[21 CFR Part 870]
(Docket No. 76N-1471)

MEDICAL DEVICES

Classification of Extravascular Blood Pressure 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 extravascular blood pressure transducers into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel and the Anesthesiology 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 May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal become effec-
PROPOSED RULES

PART 870 IN SUBPART C BY ADDING NEW § 870.2850 AS FOLLOWS:

§ 870.2850 Extravascular blood pressure transducer.

(a) Identification. An extravascular blood pressure transducer is a device used to measure blood pressure by changes in the mechanical or electrical properties of the device. The proximal end of the transducer is connected to a pressure monitor that produces an analog or digital electrical signal related to changes in the electrical or mechanical changes produced in the transducer.

(b) Classification. Class II (Performance Standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE,
Associate Commissioner
for Regulatory Affairs.

[FR Doc. 79-6168 Filed 3-8-79; 8:45 am]

MEDICAL DEVICES

Classification of Heart Sound 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 heart sound transducers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendations with respect to the classification of heart sound transducers:

1. Identification: A heart sound transducer is an external transducer which exhibits a change in mechanical or electrical properties in relation to sounds produced by the heart. This device may be used in conjunction with a phonocardiograph to record heart sounds.

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 heart sound transducer be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when used in a clinical environment where excessive leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the heart sound transducer be classified into class II (performance standards). The Commissioners 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. Although heart sound transducers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

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 870 in Subpart C by adding new § 870.2860 Heart sound transducer as follows:

§ 870.2860 Heart sound transducer.

(a) Identification. A heart sound transducer is an external transducer that exhibits a change in mechanical or electrical properties in relation to sounds produced by the heart. This device may be used in conjunction with a phonocardiograph to record heart sounds.

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE
Associate Commissioner for Regulatory Affairs.

[4110-03-M] [21 CFR Part 870] (Docket No. 78-N-1473)

MEDICAL DEVICES

Classification of Catheter Tip Pressure 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 catheter tip pressure transducers into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel and the Anesthesiology 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 May 8, 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 (HPA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.
FOR FURTHER INFORMATION CONTACT:
Glenn A. Rahmoller, Bureau of Medical Devices (HEK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, the Anesthesiology Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of catheter tip pressure transducers:

1. Identification: A catheter tip pressure transducer is a device incorporated into the distal end of a catheter. When placed in the bloodstream, its mechanical or electrical properties change in relation to changes in blood pressure. These changes are transmitted to accessory equipment for processing.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panels recommend that the catheter tip pressure transducer be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise measurement of blood pressure, the resulting miscalculation could have a significant negative effect on the patient’s health. This device is placed in direct contact with the bloodstream and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Materials used in the device should meet a generally acceptable level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. Performance characteristics, including accuracy, reproducibility, and any limitations on the device’s ability to measure blood pressure, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panels believe that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panels believe 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 Panels members based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disrupt the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician’s treatment may result in potentially debilitating of fatal thromboemboli. (c) Thromboemboli: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating of fatal thromboemboli. (d) Embolism: Pieces of the transducer or catheter which break or flake off may form potentially debilitating or fatal emboli. (e) Cardiac perforation and vessel dissection: If the catheter or catheter tip is rough, or if the catheter is too stiff, cardiac perforation and vessel dissection may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panels’ recommendations and is proposing that the catheter tip pressure 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. Because blood pressure measurement is an indication of cardiovascular function, this device will be listed in the Code of Federal Regulations (CFR) under cardiovascular devices. Although catheter tip pressure transducers are used both as diagnostic devices and as monitoring devices, they will be listed in the R under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat 540-546 (21 U.S.C. 350c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new § 870.2870 as follows:

§ 870.2870 Catheter tip pressure transducer.

(a) Identification. A catheter tip pressure transducer is a device incorporated into the distal end of a catheter. When placed in the bloodstream, its mechanical or electrical properties change in relation to changes in blood pressure. These changes are transmitted to accessory equipment for processing.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5500 Fisher 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.


JOSEPH P. HILE,
Associate Commissioner
for Regulatory Affairs.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979

PROPOSED RULES

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-14741]

MEDICAL DEVICES

Classification of Ultrasound 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 ultrasonic transducers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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...
PROPOSED RULES

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 May 8, 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: Glenn A. Rahmoeller, Bureau of Medical Devices (HFP-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8175 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of ultrasonic transducers:

1. Identification: An ultrasonic transducer is a device applied to the skin to transmit and receive ultrasonic energy that is used in conjunction with an echocardiograph to provide imaging of cardiovascular structures. This device includes phased arrays and two-dimensional scanning transducers.

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 ultrasonic transducers be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise cardiac imaging, the resulting misdiagnosis could have a significant negative effect on the patient’s health. This device is attached to the body through the skin and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, any limitations on the device's ability to provide cardiac imaging, and the level of ultrasonic energy injected into the body, should be maintained at generally accepted satisfactory levels and should be made known to users through special labeling. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (c) Tissue and blood damage: If the device is not properly designed, ultrasonic energy may be released into the body at levels that may damage tissue and blood.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel’s recommendation and is proposing that the ultrasonic 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. Although ultrasonic transducers are used both as diagnostic devices and as monitoring devices, they are within the scope of the Code of Federal Regulations, under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 50 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 870 in Subpart C by adding new § 870.2880 as follows:

§ 870.2880 Ultrasonic transducer.

(a) Identification. An ultrasonic transducer is a device applied to the skin to transmit and receive ultrasonic energy that is used in conjunction with an echocardiograph to provide imaging of cardiovascular structures. This device includes phased arrays and two-dimensional scanning transducers.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


Joseph P. Hile,
Associate Commissioner
for Regulatory Affairs.

[FR Doc. 79-6171 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

Docket No. 78N-1475

MEDICAL DEVICES

Classification of Vessel Occlusion 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 vessel occlusion transducers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of vessel occlusion transducers:

1. Identification: A vessel occlusion transducer is a device used to provide an electrical signal corresponding to sounds produced in a partially occluded vessel. This device includes motion, sound, and ultrasonic transducers.

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 vessel occlusion transducer be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the response of the transducer to the sounds is inadequate, the resulting misdiagnosis could have a significant negative effect on the patient's health. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to detect vessel occlusion, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is in direct contact with the surface of the body and may be used in a clinical environment where the transmission of electrical leakage current to the body presents a serious health hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to detect vessel occlusion, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the vessel occlusion 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 870 in Subpart C by adding new § 870.2890 as follows:

§ 870.2890 Vessel occlusion transducer.

(a) Identification. A vessel occlusion transducer is a device used to provide an electrical signal corresponding to sounds produced in a partially occluded vessel. This device includes motion, sound, and ultrasonic transducers.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


Joseph P. Hile,
Associate Commissioner
for Regulatory Affairs.

[FR Doc. 79-6172 Filed 3-5-79; 8:45 a.m.
FRIDAY, MARCH 9, 1979

4110-03-M]

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoller, Bureau of Medical Devices (HFX-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. 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 870 in Subpart C by adding new § 870.2890 as follows:

§ 870.2890 Vessel occlusion transducer.

(a) Identification. A vessel occlusion transducer is a device used to provide an electrical signal corresponding to sounds produced in a partially occluded vessel. This device includes motion, sound, and ultrasonic transducers.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


Joseph P. Hile,
Associate Commissioner
for Regulatory Affairs.

[FR Doc. 79-6172 Filed 3-5-79; 8:45 a.m.
FRIDAY, MARCH 9, 1979

4110-03-M]

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoller, Bureau of Medical Devices (HFX-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. 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 870 in Subpart C by adding new § 870.2890 as follows:

§ 870.2890 Vessel occlusion transducer.

(a) Identification. A vessel occlusion transducer is a device used to provide an electrical signal corresponding to sounds produced in a partially occluded vessel. This device includes motion, sound, and ultrasonic transducers.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


Joseph P. Hile,
Associate Commissioner
for Regulatory Affairs.

[FR Doc. 79-6172 Filed 3-5-79; 8:45 a.m.
FRIDAY, MARCH 9, 1979

4110-03-M]

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoller, Bureau of Medical Devices (HFX-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. 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 870 in Subpart C by adding new § 870.2890 as follows:

§ 870.2890 Vessel occlusion transducer.

(a) Identification. A vessel occlusion transducer is a device used to provide an electrical signal corresponding to sounds produced in a partially occluded vessel. This device includes motion, sound, and ultrasonic transducers.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


Joseph P. Hile,
Associate Commissioner
for Regulatory Affairs.

[FR Doc. 79-6172 Filed 3-5-79; 8:45 a.m.
FRIDAY, MARCH 9, 1979

4110-03-M]

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoller, Bureau of Medical Devices (HFX-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.
tive 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:
Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, after a review of the information and on the advice of an advisory committee, made the following recommendation with respect to the classification of patient transducer and electrode cables (including connector):

1. Identification: A patient transducer and electrode cable (including connector) is an electrical conductor used to transmit signals from, or power or excitation signals to, patient-connected electrodes or transducers.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that patient transducers and electrode cables (including connectors) be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through electrodes or transducers and is used in a clinical environment where transmission of excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. The Panel believes that each type of cable connector should be standardized uniquely so that, for example, an electrocardiograph cable cannot be connected to a pressure transducer cable connector where the transducer excitation signal may cause the heart to fibrillate. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the 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 the panel's good understanding with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Failure to transmit signal or intermittent transmission or electrical leakage: Poor mechanical design of the conductor and insulating material, and the inability of the device to withstand sterilization cycles may lead to signal transmission failures or electrical leakage.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the patient transducer and electrode cable (including connector) 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. Although patient transducer and electrode cables (including connector) are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. sections 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new §870.2900 as follows:

§870.2900 Patient transducer and electrode cable (including connector).

(a) Identification. A patient transducer and-electrode cable (including connector) is an electrical conductor used to transmit signals from, or power or excitation signals to, patient-connected electrodes or transducers.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


Joseph P. Heile,
Associate Commissioner for Regulatory Affairs.

[4110-03-M] [21 CFR Part 870] (Docket No. 78N-1477)

MEDICAL DEVICES

Classification of Radiofrequency Physiological Signal Transmitters and Receivers

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 physiological signal transmitters and receivers into class II (performance standards).

The FDA is also publishing the recommendation of the Cardiovascular 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, the FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 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:
Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.
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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendations with respect to the classification of radiofrequency physiological signal transmitters and receivers:

1. Identification: A radiofrequency physiological signal transmitter and receiver is a device used to condition a physiological signal so that it can be transmitted via radiofrequency from one location to another, e.g., a central monitoring station. The received signal is reconditioned by the device into its original format so that it can be displayed.

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 radiofrequency physiological signal transmitters and receivers be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through transducers or electrodes and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. If the data conditioning or transmission is inadequate for such rate and precise measurement of a given physiological signal, the resulting misdiagnosis could have a significant negative effect on the patient’s health. Performance characteristics including effective data transmission and any limitations on the device’s performance characteristics should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Misdiagnosis: Inadequate frequency response of the transmitter-receiver system can lead to loss of data in transmission or to the generation of inaccurate diagnostic data. Inaccuracy or instability of zero or calibration can also lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (c) Interference with or from other medical devices: Electromagnetic interference to or by the radiofrequency signal can lead to a malfunction of this device or other devices in the immediate vicinity.

(d) Tissue damage: Excessive radiofrequency energy can possibly cause tissue damage.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel’s recommendation and is proposing that the radiofrequency physiological signal transmitter and receiver 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. Although radiofrequency physiological signal transmitters and receivers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 514, and 516, 21 U.S.C. 355c, 355d, and 355j, respectively) (21 U.S.C. 355(l), 355(r), and 355(s)) and under authority delegated to him (21 CFR 5.1) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new §870.2910 Radiofrequency physiological signal transmitters and receivers.

(a) Identification. A radiofrequency physiological signal transmitter and receiver is a device used to condition a physiological signal so that it can be transmitted via radiofrequency from one location to another, e.g., a central monitoring station. The received signal is reconditioned by the device into its original format so that it can be displayed.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (FIA-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.


Joseph P. Hile, Associate Commissioner for Regulatory Affairs.
[FR Doc. 79-6174 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1478]

MEDICAL DEVICES

Classification of Telephone Electrocardiograph Transmitters and Receivers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying telephone electrocardiograph transmitters and receivers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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.


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:
Glenn A. Rahmoe, Bureau of Medical Devices (HPK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of telephone electrocardiograph transmitters and receivers:

1. Identification: A telephone electrocardiograph transmitter and receiver is a device used to condition an ECG signal so that it can be transmitted via a telephone line to another location. This device also includes a receiver that reconditions the received signal into its original format so that it can be displayed. The device includes devices used to transmit and receive pacemaker 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 telephone electrocardiograph transmitters and receivers be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through ECG electrodes and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. If the data conditioning or transmission is inadequate for accurate and precise measurement of the ECG or heart rate, the resulting misdiagnosis could have a significant negative effect upon the patient's health. Performance characteristics, including effective data transmission and any limitations on the device's performance characteristics, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of and experience with the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the occurrence of cardiac arrhythmias. (b) Misdiagnosis: Inadequate frequency response of the transmitter-receiver system can lead to loss of data in transmission or to the generation of inaccurate diagnostic data. Inaccuracy or instability of zero or calibration can also lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION
The Commissioner agrees with the Panel's recommendation and is proposing that the telephone electrocardiograph transmitter and receiver 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. Although telephone electrocardiograph transmitters and receivers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 506c, 371(a))) and under authority delegated to him (21 CFR 3.1), the Commissioner proposes to amend Part 870 in Subpart C by adding new §870.2220 as follows:

§870.2220 Telephone electrocardiograph transmitters and receivers.

(a) Identification. A telephone electrocardiograph transmitter and receiver is a device used to condition an ECG signal so that it can be transmitted via a telephone line to another location. This device also includes a receiver that reconditions the received signal into its original format so that it can be displayed. The device includes devices used to transmit and receive pacemaker signals.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20851, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-8175 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

(Docket No. 78N-1470)

MEDICAL DEVICES

Classification of Vascular 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 vascular clips into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 ac-
PROPOSED RULES

DATE: Comments by May 8, 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 (HPA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 20201 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of vascular clips:

1. Identification: A vascular clip is an implanted extravascular device designed to occlude, by compression, blood flow in small blood vessels.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that vascular clips be classified into class II because this implanted device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's tensile and grasp strength, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. Although the device is an implant, 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, this device. In addition, the Panel found further support for their recommendation in the medical literature. This literature includes a review of over 40 types of malleable, screw, and spring clips (Ref. 1) in which 3 types of hazards associated with the device are cited. The main hazard noted is tissue damage due to a severing of the vessel (Ref. 1) or the application of excess pressure (Ref. 2). Both types of tissue damage can result from poor mechanical design. Slippage is another hazard associated with poor mechanical design and is especially prominent with clips that are not grooved (Refs. 1 through 5). A third hazard is ineffective occlusion of the vessel when the pressure originally applied is reduced because of material creep (stress relief in a material due to plastic deformation occurring over a long period of time). This hazard is associated most frequently with plastic clips. Vascular clips serve the same function as suture or hemostatic clamps and apparently are most valuable when used in relatively inaccessible areas (Ref. 3).

5. Risks to health: (a) Tissue damage: Damage to the vessel may result because of poor mechanical design of the device or tissue incompatibility of the materials used in the device. (b) Bleeding from loss of occlusion: The occlusion caused by the device may become ineffective due to material creep. (c) Bleeding due to clip slippage: May be due to either material creep or poor mechanical design of the device.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the vascular 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, although the device is an implant, 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 (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.


Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 50 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 870 by adding new Subpart D and new §870.3250 as follows:

Subpart D—Cardiovascular Prosthetic Devices

§870.3250 Vascular clip.

(a) Identification. A vascular clip is an implanted extravascular device designed to occlude, by compression, blood flow in small blood vessels.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HPA-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.


Joseph P. Hele, Associate Commissioner for Regulatory Affairs.

FPR Doc. 79-6176 Filed 3-8-79; 8:45 am

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-14801]

MEDICAL DEVICES

Classification of Vena Cava 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 vena cava clips into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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.

DATE: Comments by May 8, 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 (HPA-305), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, Maryland 20910, 301-427-7559.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFX-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, Maryland 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation as to the classification of vena cava clips:

1. Identification: A vena cava clip is an implanted extravascular device designed to occlude partially the vena cava for the purpose of inhibiting the flow of thromboemboli through that vessel.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the vena cava clip be classified into class II because this implanted device is neither life-sustaining, nor life-sustaining, but is potentially hazardous to life or health even when properly used. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. Performance characteristics, including accuracy, reproducibility, and biocompatibility, are significant. In addition, 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 recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Panel found further support for their recommendations in the medical literature. This review included a comparison of the four commonly used methods of vena cava interruption: ligation (simple occlusion), plication (narrowing by surgical technique), filter placement, and clipping. The vena cava clip has no blood-material interface. Because it is only partially occlusive it causes less hemodynamic alteration than does ligation (Refs. 2, 4 through 6, 8 through 11, and 13). Tissue damage, however, may result from poor mechanical design. Clips with teeth on both jaws, for example, are more likely to snag or tear the vena cava or surrounding structures (Ref. 7). A large, large product produced in the cava during coughing or sneezing tend to dislocate a clip that does not permit secure closure (Ref. 7). Finally, ineffective occlusion can result as the original pressure applied by a plastic clip is reduced by material creep (stress relief due to plastic deformation of the material over a long time period). While the percentage of embolism recurrence varies from report to report, it is generally agreed that these clips are at least as safe and effective as ligation, plication, or filtering (Refs. 1, 2, 6, 8, 9, 11, and 14).

5. Risks to health: (a) Tissue damage: Damage to the vessel may occur sufficiently to affect the mechanical design of the device or tissue incompatibility of the materials used in the device. (b) Recurrent thromboembolism: Relaxation of the device due to material creep can lead to recurrent pulmonary thromboemboli, which can be debilitating or fatal.

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.


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 870 in Subpart D by adding new § 870.3260 as follows:

§ 870.3260 Vena cava clip.

(a) Identification. A vena cava clip is an implanted extravascular device designed to occlude partially the vena cava for the purpose of inhibiting the flow of thromboemboli through that vessel.

(b) Classification. Class II (performance standards).

Interested persons may, on or before March 8, 1979, submit to the Hearing Clerk (HFA-303), 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.


JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

(FR Doc. 79-6177 Filed 3-6-79; 8:45 am)

[4110-03-M]

[21 CFR Part 870]
(Docket No. 78N-1481)

MEDICAL DEVICES

Classification of Peripheral Arterial 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 peripheral arterial embolization devices into class III (premarket approval). The FDA is also publishing the recommendations of the Cardiovascular 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 March 8, 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-303), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Glenn A. Rahmoller, Bureau of Medical Devices (HFA-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-622-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of peripheral arterial embolization devices:

1. Identification: A peripheral arterial embolization device is an intravascular implant used to occlude certain arteries to halt blood flow in arteries supplying certain types of abdominal tumors (e.g., nephroma, hepatoma) or to control internal hemorrhage.

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 peripheral arterial embolization device be classified into class III because the Panel believes that premarket approval is necessary to assure the safety and effectiveness of this device and because the device is an implant that presents a potential unreasonable risk of illness or injury. If the device fails to halt blood flow when used to control internal hemorrhaging, the resulting continued bleeding can be debilitating or fatal. Migration of the device can lead to halting the blood supply to healthy tissue. The Panel believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and, moreover, that there is insufficient 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness can lead to potentially debilitating or fatal thromboembolism. (b) Inadvertent embolization and infarction: If the design of the device makes proper positioning difficult, erroneous placement or migration could occur and cause a potentially debilitating infarction of healthy tissue. (c) Vessel perforation: If the surface of the device is rough or sharp, or if the device causes excessive inflammation, vessel perforation can lead to progressive granulomatous inflammation: The materials used in the device or the mechanical design of the device can lead to progressive granulomatous inflammation localized tissue response characterized by a tumor-like mass. (d) Infection: By design, the device could have obscured areas of contamination, making sterilization difficult and possibly leading to infections.

Proposed Classification

The Commissioner agrees with the Panel’s recommendation and is proposing that the peripheral arterial embolization device be classified into class III (premarket approval). The Commissioner believes the device is purposed or represented to be for a use in treatment of tumors and control of internal hemorrhage, which is of substantial importance in preventing impairment of human health. The device is intended to be implanted into the human body. The Commissioner believes the device presents a potential unreasonable risk of illness or injury because the device may inadvertently halt blood flow to a normal, healthy section of tissue. The Federal Food, Drug, and Cosmetic 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 device’s safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a per-
The Commissioner proposes to amend Part 870 in Subpart D by adding new §870.3300 as follows:

§870.3300 Peripheral arterial embolization device.

(a) Identification. A peripheral arterial embolization device is an intravascular implant used to occlude certain arteries to halt blood flow in arteries supplying certain types of abdominal tumors (e.g., nephroma, hepatoxoma) or to control internal hemorrhage.

(b) Classification. Class III (premarket approval).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-6178 Filed 3-9-78; 8:45 am]

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiovascular intravascular filters: 1. Identification: An intravascular filter is an implant that is placed in the inferior vena cava for the purpose of preventing pulmonary thromboembolism (blood clots generated in the lower limbs and broken loose into the bloodstream) from flowing into the right side of the heart and the pulmonary circulation.

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 cardiovascular intravascular filters be classified into class III because the device is an implant used for a life-sustaining purpose. The materials used in the device and its design should minimize thromboembolic complications and the tendency to perforate the vena cava. The device should allow as much venous blood to return to the right heart as possible. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel also believes that a performance standard would provide assurance of the safety and effectiveness of the device and, moreover, that there is not 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 the potential hazards associated with the inherent properties of the device, their personal knowledge of, and experience with, the device, and the fact that the device is an implant used for a life-sustaining purpose.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboembolism. (b) Vena cava perforation: Improper design of the mechanical fixation of the device to the vein can cause perforation of the vena cava. (c) Decreased venous return to the right heart: The hemodynamic design of the device is associated with the possibility of a serious reduction in the amount of blood return to the right heart.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiovascular intravascular filters be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (prevention of pulmonary thromboembolism) in supporting or sustaining human life. The device is intended to be implanted into the human body. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify an implant or a life-supporting or life-sustaining device into class III unless the Commissioner determines that premmarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness.

In this case, the Commissioner has determined that premmarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 50 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 870 in Subpart D by adding new §870.3375 as follows:

§870.3375 Cardiovascular intravascular filter.

(a) Identification. An intravascular filter is an implant that is placed in...
the inferior vena cava for the purpose of preventing pulmonary thromboembolism (blood clots generated in the lower limbs and broken loose into the blood stream) from flowing into the right side of the heart and the pulmonary circulation.

(b) Classification. Class III (premarket approval).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILDE, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6179 Filed 3-8-79; 8:45 am]

MEDICAL DEVICES

Classification of Vascular Graft Prostheses of Less Than 6 Millimeters in Diameter

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying vascular graft prostheses of less than 6 millimeters (mm) diameter as a device used to replace sections of small arteries. These grafts are commonly constructed of woven or knitted materials such as Dacron and Teflon.

1. Identification: A vascular graft prosthesis of less than 6 millimeters (mm) diameter is a device used to replace sections of small arteries. These grafts are commonly constructed of woven or knitted materials such as Dacron and Teflon.

2. Recommended classification: Class III (premarket approval). The Panels recommend that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panels recommend that vascular graft prostheses of less than 6 mm in diameter be classified as a Class III device that is implanted and is life-sustaining. The Panels believe that artificial grafts of less than 6 mm diameter have not performed as well as the alternatives of endarterectomy and autogenous vein grafting. The reasons for this poorer performance are not known. Material or mechanical properties can have a substantial effect upon the behavior of the device, but until data exist showing safety and efficacy related to physical, chemical, and material properties, clinical trials are necessary to establish the safety and effectiveness of the device. The Panels believe that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panels do not believe that sufficient scientific and medical data exist to establish standards to assure the safety and efficacy of this implanted device.

4. Summary of data on which the recommendation is based: The members of the Panels based their recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Panels found further support for their recommendations in the medical literature.

The following complications were cited in the literature reviewed by the Panels: thromboembolic complications (Refs. 1 through 6); failure to heal properly, including insufficient or excessive tissue ingrowth resulting in failure to incorporate the graft in the neointima (Refs. 2, 4, and 6) and stenosis (Refs. 7, 8); material or mechanical failures (Refs. 4, 5, 9, and 10); hemorrhage (Ref. 14); sarcoma (Ref. 15); late infection (Ref. 16); and aneurysms and dilation of the prosthesis or "false aneurysm" (Refs. 2, 4, 9, and 19). Material and mechanical failures include kinking (Refs. 4 and 5) and dilation (Refs. 4, 5, 9, and 10). Some more recent experimental projects have shown promise for increased safety and efficacy in small artery and venous applications. These include the use of electrically conductive materials (Ref. 7), heparinization (Ref. 21), biological preparations of artificial grafts (Ref. 1), and expanded polytetrafluorethylene (Refs. 17 and 18). Despite this progress, premarket approval is warranted for this device because clinical trials are still needed to establish safety and efficacy.

6. Risks to health: (a) Clot formation: Material incompatibility with the blood can lead to clot formation. (b) Ripping of the graft: An improper design of the graft can lead to ripping of the graft when punctured with a surgical needle. (c) Dilation: Dilation can result from insufficient or mechanical failures of the material or from improper design of the weaves or knit pattern of the graft. (b) Blood seepage: In the medical literature clotting of the graft can cause seepage or leakage of blood through the graft wall.
PROPOSED RULES

The Commissioner agrees with the Panel's recommendation and is proposing that the vascular graft prosthesis of less than 6 mm diameter be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for use as an artificial replacement of the aorta or other supporting or maintaining human life. The device is intended to be implanted into the human body. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify an implant or a life supporting or life sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary.

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.


Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 80 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 870 in Subpart D by adding new §870.3450 as follows:

§870.3450 Vascular graft prosthesis of less than 6 millimeters in diameter.

(a) Identification. A vascular graft prosthesis of less than 6 millimeters (mm) diameter is a device used to replace sections of small arteries. These grafts are commonly constructed of woven or knitted materials such as Dacron and Teflon.

(b) Classification. Class III (premarket approval).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6180 Filed 3-8-79; 8:45 am]

MEDICAL DEVICES

Classification of Vascular Graft Prostheses of 6 Millimeters and Greater Diameter

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying vascular graft prostheses of 6 millimeters (mm) and greater diameter into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel and the General and Plastic Surgery 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.


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.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of vascular graft prostheses of 6 mm and greater diameter:

1. Identification: A graft is commonly constructed of woven or knitted materials such as Dacron and Teflon.

2. Recommended classification: Class II (performance standards). The Panels recommend that establishing a standard to control the risks to health. A performance standard is necessary for this device because general controls alone would not provide sufficient control over the performance characteristics of this device. The Panels believe that a performance standard would provide reasonable assurance of the safety and effectiveness of this implanted device and, moreover, 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 recommendations on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Panels found further support for their recommendations in the medical literature.

In the literature reviewed by the Panels, the following complications were cited: thromboembolic complications (Refs. 1 through 6); failure to heal properly, including insufficient or excessive tissue ingrowth, resulting in failure to incorporate in neointima (Refs. 2, 4, and 6) and stenosis (Refs. 7 and 8); material or mechanical failures (Refs. 4, 5, and 9 through 13); hemolysis (Ref. 14); sarcoma (Ref. 15); late infection (Ref. 16); aneurysm and dilation of the prosthesis or "false aneurysm" (Refs. 2, 4, 9, and 19). Material and mechanical failures include kinking (Refs. 4 and 5) and dilatation (Refs. 2, 4, 9, and 19). Loss of tensile strength of these grafts was reported to occur by (a) rupture or tearing of the graft when punctured with a surgical needle. (c) Dilatation: dilatation can result from insufficient physical or mechanical stress of the material or from improper design of the weave or knit pattern of the graft. (d) Blood seepage or leakage: inadequate precipitating of the graft can cause seepage or leakage of blood through the graft wall.

The proposed classification is an implant, there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Because the device is used solely in cardiovascular surgery, this device will be listed in the Code of Federal Regulations under cardiovascular devices.

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.


PROPOSED RULES

§ 870.3460 Classification of Intracardiac Patches and Pledgets Made of Polypropylene, Teflon, or Dacron

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying intracardiac patches and pledgets made of polypropylene, Teflon, or Dacron into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel (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.


The Commissioner of Food and Drugs proposes to amend Part 870 in Subpart D by adding new § 870.3460 as follows:

§ 870.3460 Vascular graft prostheses of 6 millimeters and greater diameter.

(a) Identification. A vascular graft prosthesis of 6 millimeters (mm) and greater diameter is a device used to replace sections of arteries. These grafts are commonly constructed of woven or knitted materials such as Dacron and Teflon.

(b) Classification. Class II (performance standards).

Comments on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5000 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.


JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[PR Doc. 79-6181 Filed 3-8-79; 8:45 am]
PROPOSED RULES

The Commissioner agrees with the Panel's recommendation and is proposing that intracardiac patches and pledges made of polypropylene, Teflon, or Dacron 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, although the device is an implant, 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 (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.


JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[4110-03-M]

[21 CFR Part 870]
(Docket No. S8-F-14671)

MEDICAL DEVICES
Classification of Intrac-Aortic Balloon and Control 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 the intra-aortic balloon and control system into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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, 5000 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Glenn A. Rahmoeiler, Bureau of Medical Devices (HEK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTAL INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification:
of intra-aortic balloon and control systems:

1. Identification: An intra-aortic balloon and control system is a device that consists of an inflatable balloon, which is placed in the aorta to improve cardiovascular functioning during certain life-threatening emergencies, and a control system for regulating the inflation and deflation of the balloon. The control system, which monitors and is synchronized with the electrocardiogram (ECG), provides a means for setting the inflation and deflation of the balloon with the cardiac cycle.

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 the intra-aortic balloon and control system be classified into class III because the device is life-supporting, and because the Panel believes that there is insufficient medical and scientific information to establish a standard to assure the safety and effectiveness of the device. The Panel stated that controversy exists as to whether the device is even beneficial in many situations in which it is used, and that it is difficult to use the device safely and effectively. The Panel believes that accurate and precise labeling and directions for use are especially critical. The Panel is concerned that the various components of the device would not function properly if its modular components were poorly matched. The balloon of the device is used within the main artery of intensive care patients to aid the heart in pumping blood throughout the body. Because this portion of the device is in contact with internal tissues and blood, the materials used with it require special controls. Because the device is typically electrically powered and portions of the device may be in direct contact with the heart, the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. If the design of the device is inadequate for accurate and precise blood pumping, a resulting failure could lead to death.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during placement or use of the balloon pump, and this may lead to iatrogenic complications. (b) Ineffective cardiac assist: Failure to sense or synchronize on heartbeat or failure to inflate and deflate at the proper intervals can lead to improper or ineffective pumping of blood. (c) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness can lead to potentially debilitating or fatal thromboembolism. (d) Aortic rupture of dissection: Improper sizing or overinflation of the balloon can cause a rupture in the main artery. (e) Limb ischemia: Improper operation of the device which restricts blood flow to the peripheral vascular tree results in tissue ischemia (deficiency of blood supply to a portion of the body) in the limbs. (f) Embolism: Balloon rupture or a leak in the balloon can cause potentially debilitating or fatal gas embolism to escape into the bloodstream. (g) Hemolysis: Poor material-blood compatibility or excessive disruption of the normal hemodynamic flow patterns can cause hemolysis (destruction of red blood cells).

PROPOSED RULES

§ 870.3335 Intra-aortic balloon and control system.

(a) Identification. An intra-aortic balloon and control system is a device that consists of an inflatable balloon, which is placed in the aorta to improve cardiovascular functioning during certain life-threatening emergencies, and a control system for regulating the inflation and deflation of the balloon. The control system, which monitors and is synchronized with the electrocardiogram, provides a means for setting the inflation and deflation of the balloon with the cardiac cycle.

(b) Classification. Class III (premarket approval).

Interested persons may, on or before May 8, 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, which 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 February 26, 1979.

JOSEPH P. HILL, Associate Commissioner for Regulatory Affairs.

[4110-03-M]

[21 CFR Part 870]

(Docket No. 78N-1488)

MEDICAL DEVICES

Classification of Ventricular Assist 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 ventricular bypass (assist) devices into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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 (HPA-305), Food and Drug Administration, Department of Health, Education, and Welfare, 5137 Georgia Ave., Silver Spring, MD 20857.

FOR FURTHER INFORMATION CONTACT: Glenn A. Rahmeoller, Bureau of Medical Devices (HPK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8137 Georgia Ave., Silver Spring, MD 20857.

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 Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of ventricular bypass (assist) devices:

1. Identification: A ventricular bypass (assist) device is a device that assists the left or right ventricle in maintaining circulatory blood flow. These devices are either totally or partially implanted in the body.

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 ventricular bypass (assist) device be classified into class III because the device is an implant used in a life-supporting situation. It is powered by either a pneumatic, hydraulic, or electrical source, and failure of the power source can lead to death. In addition, physical, chemical, and biological properties of materials used in the blood-contacting surfaces of the device have not been fully established, and there are divergent opinions about these materials. At this time, the device is primarily investigational. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel also believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and, moreover, that there is not sufficient information to establish a standard to provide such assurance. For these reasons, the Panel believes that premarket approval is necessary to assure the safety and effectiveness of this device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the use of this device, their personal knowledge of, and experience with, the device, and the experimental nature of the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness can lead to potentially debilitating or fatal thromboembolism. (b) Excessive hemolysis: Poor design of the hemodynamic characteristics of the device can lead to excess hemolysis. (c) Failure to support life: Inaccurate pressure or flow control or improper synchronization can impede the ability of the device to support life. (d) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during the placement or use of the device, and this can lead to iatrogenic complications. (e) Interference with other organs: Because of its size and the location of its implantation, the device may interfere with the functioning of other organs. (f) Damage to blood vessels: The mechanical design of the attachments is associated with the possibility of damage to blood vessels at attachment points. (g) Inability to maintain long-term support: Low fatigue life of the materials used, or poor quality control in construction, can lead to premature breakdown of the device.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the ventricular bypass (assist) device be classified into class III (premarket approval). The Commissioner notes the controversy surrounding the development of the left ventricular assist device, including differing philosophies among experts in the field involving optimum materials, hemodynamic performance, and power source. The Commissioner also cites the work presented on December 12-14, 1977, at the Devices and Technology Branch Contractor's Conference of the National Heart, Lung, and Blood Institute as indicative of the investigational nature of this device. This document is on file in the office of the Hearing Clerk, Food and Drug Administration. The Commissioner believes the device is purposed or represented to be for use (maintaining circulation in certain case of heart failure) in supporting or sustaining human life. The device is intended to be implanted in the human body. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify an implant or a life supporting or life sustaining device in 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 believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 50 Stat. 540-546 (21 U.S.C. 360c, 37(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 810 in Subpart D by adding new § 870.3545 as follows:

§ 870.3545 Ventricular bypass (assist) devices.

(a) Identification. A ventricular bypass (assist) device is a device that assists the left or right ventricle in maintaining circulatory blood flow. These devices are either totally or partially implanted in the body.

(b) Classification. Class III (premarket approval).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HPA-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.


Joseph P. Hile, Associate Commissioner for Regulatory Affairs.
MEDICAL DEVICES
Classification of External Pacemaker Pulse Generators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration is issuing for public comment a proposal to reclassify externalpacemaker pulse generators into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular 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 1978.

DATE: Comments by May 8, 1979. The Commissioner of Food and Drugs proposes that the final rule, 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:
Glenn A. Rahmoeuser, Bureau of Medical Devices, (HFZ-458), Food and Drug Administration, Department of Health, Education, and Welfare, 8777 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of external pacemaker pulse generators:

1. Identification: An external pacemaker pulse generator is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device, which is used outside the body, is used as a temporary substitute for the heart's intrinsic pacing system until a permanent pacemaker can be implanted, or to control irregular heartbeats in patients following cardiac surgery or a myocardial infarction. The device may have adjustments for impulse strength, duration, R-wave sensitivity, and other pacing variables.

PROPOSED RULES

PROPOSED RULES

The Commissioner agrees with the Panel's recommendation and is proposing that the external pacemaker pulse generator be classified into class III (premarket approval). The Commissioner believes the device is properly represented to be for a use (maintaining heart function by electrical stimulation) in supporting or sustaining human life. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify a life-supporting or life-sustaining device into class III unless the Commissioner determines that premarket approval is not required to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls alone will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 50 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 870 in Subpart D by adding new § 870.3600 as follows:

§ 870.3600 External pacemaker pulse generator.

(a) Identification. An external pacemaker pulse generator is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device, which is used outside the body, is used as a temporary substitute for the heart's intrinsic pacing system until a permanent pacemaker can be implanted, or to control irregular heartbeats in patients following cardiac surgery or a myocardial infarction. The device may have adjustments for impulse strength, duration, R-wave sensitivity, and other pacing variables.

(b) Classification. Class III (premarket approval).

Interested persons may, on or before (insert date 60 days after date of publication in the Federal Register) 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
PROPOSED RULES

13873

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.


JOSEPH P. HILE
Associate Commissioner
for Regulatory Affairs.

[4110-03-M]

[21 CFR Part 870]
(Docket No. 78N-1490)

MEDICAL DEVICES
Classification of Implantable Pacemaker Pulse 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 implantable pacemaker pulse generators into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to provide for the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of implantable pacemaker pulse generators:

1. Identification: An implantable pacemaker pulse generator is a device that has a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device is used as a substitute for the heart's intrinsic pacing system to correct both intermittent and continuous cardiac rhythm disorders. This generic term includes triggered, inhibited, and asynchronous devices implanted in the human body.

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 the implantable pacemaker pulse generator be classified in class III because the device is implanted and life-supporting and presents a potential unreasonable risk of illness or injury. This device is intended to be used over a period of years to pace a heart with a natural pacing defect surgically implanted. In patients with heart pacing or conduction defects, the patient may be totally dependent upon this device for their continued survival. The Panel states that, although a natural or artificial life-sustaining cardiac rhythm device is a life-supporting or life-sustaining human life. The device is intended to be implanted in the human body. The Federal, Food, Drug, and Cosmetic Act requires the Commissioner to classify an implant or a life-sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 380c, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new §870.3610 as follows:

§870.3610 Implantable pacemaker pulse generator.

(a) Identification. An implantable pacemaker pulse generator is a device that has power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. This device is used as a substitute for the heart's intrinsic pacing system to correct both intermittent and continuous cardiac rhythm disorders. This generic term includes triggered, inhibited, and asynchronous devices implanted in the human body.

(b) Classification. Class III (premarket approval).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, 301-427-7620.

FEDERAL REGISTER, VOL. 44, NO. 45—FRIDAY, MARCH 9, 1979
SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. According to the Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation regarding classification of pacemaker lead adaptors:

1. Identification: A pacemaker lead adaptor is a device used to adapt a pacemaker lead so that it can be connected to a pacemaker pulse generator produced by a different manufacturer.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the pacemaker lead adaptor be classified into class III because the device is implanted, life-supporting, and presents a potential unreasonable risk of illness or injury. This device electrically and mechanically connects a pacemaker lead to a different manufacturer's pacemaker. It serves a vital purpose and is generally used when a pacemaker is replaced by another pacemaker made by a different manufacturer. Materials used in the device should meet a generally accepted satisfactory level of tissue compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The Panel believes that the device can create a hazard to the life of the patient if it is not manufactured or employed properly. The device is used with other devices in a system that may be hazardous if not satisfactorily used, used, and maintained. The Panel believes that there are insufficient medical, engineering, and scientific data to establish performance standard to assure the safety and effectiveness of this life-supporting device, and, therefore, that premarket approval is necessary.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device, their personal knowledge of, and experience with, the device, and the life-supporting function of the device.

5. Risks to health: (a) Improper pacing: Poor mechanical or electrical design could cause a failure to properly pace the patient's heart. (b) Failure to pace: Electrical or mechanical incompatibility leading to conductor breakage or electrochemical corrosion can cause failure to pace the patient's heart. Also, the use of poor sealant materials that allow water to enter into the electrical junction between the pacemaker and its pacing lead diverts the current from the heart and causes failure to pace. (c) Tissue damage: Insufficiently biocompatible materials can lead to adverse tissue reactions.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the pacemaker lead adaptor be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (maintaining heart function by electrical stimulation) in supporting or sustaining human life. The device is intended to be implanted in the human body. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify an implant or a life-supporting or life-sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this 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 870 in Subpart D by adding new § 870.3620 as follows:

§ 870.3620 Pacemaker lead adaptor.

(a) Identification. A pacemaker lead adaptor is a device used to adapt a pacemaker lead so that it can be connected to a pacemaker pulse generator produced by a different manufacturer.

(b) Classification. Class III (premarket approval).

Interested persons may, on or before May 8, 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.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
PROPOSED RULES


JOSEPH P. HILE,
Associate Commissioner
for Regulatory Affairs

[FR Doc. 79-6187 Filed 3-8-79; 8:45 am]

1. Identification: A pacemaker generator function analyzer is a device that is connected to a pacemaker pulse generator to test any or all of the generator's parameters, including pulse duration, pulse amplitude, pulse rate, and sensing threshold.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that pacemaker generator function analyzers be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Failure of the device to perform its analysis function may lead to improper cardiac pacing or cardiac arrhythmias. Performance characteristics, including accuracy, reproducibility, and any limitations of the device's measurement of pacemaker generator function, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Cardiac arrhythmias or improper pacing: Inability of the device to accurately measure the pacemaker's performance parameters may result in the implantation of an inappropriate or poorly functioning pacemaker.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the pacemaker generator function 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 (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 3.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3630 as follows:

§ 870.3630 Pacemaker generator function analyzers.

(a) Identification. A pacemaker generator function analyzer is a device that is connected to a pacemaker pulse generator to test any or all of the generator's parameters, including pulse duration, pulse amplitude, pulse rate, and sensing threshold.

(b) Classification. Class II (performance standards).

Interested persons, may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-455), 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.


JOSEPH P. HILE,
Associate Commissioner
for Regulatory Affairs.

[FR Doc. 79-6188 Filed 3-8-79; 8:45 am]

MEDICAL DEVICES

Classification of Indirect Pacemaker Generator Function 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 indirect pacemaker generator function analyzers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
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 May 8, 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, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

FOR FURTHER INFORMATION CONTACT:
Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of Indirect pacemaker generator function analyzers:

1. Identification: An indirect pacemaker generator function analyzer is an electrically powered device that is used to determine pacemaker function or pacemaker battery function by periodically monitoring an implanted pacemaker's pulse rate and pulse width. The device is noninvasive, and it detects pacemaker pulse rate and pulse width via external electrodes in contact with the patient's 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 indirect pacemaker generator function analyzer be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the body through surface electrodes and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Failure of the device to perform its analysis function may lead to improper cardiac pacing or cardiac arrhythmias. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of pacemaker generator function, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical 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 the potential hazards associated with the inherent properties of this device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, which can lead to onset of cardiac arrhythmias. (b) Misdagnosis: Inadequate design of the device affecting its ability to sense pacemaker generator function can lead to inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the indirect pacemaker generator function 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 (secs. 513, 701(a), 21 Stat. 1055, 90 Stat. 540-548 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new §870.3640 as follows.

§870.3640 Indirect pacemaker generator function analyzer.

(a) Identification. An indirect pacemaker generator function analyzer is an electrically powered device that is used to determine pacemaker function or pacemaker battery function by periodically monitoring an implanted pacemaker's pulse rate and pulse width. The device is noninvasive, and it detects pacemaker pulse rate and width via external electrodes in contact with the patient's skin.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit comments by mail to the Hearing Clerk (HFA-305), Food and Drug Administration, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6189 Filed 3-8-79; 8:45 am]

MEDICAL DEVICES

Classification of Pacemaker Polymeric Mesh Bags

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pacemaker polymeric mesh bags into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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.
PROPOSED RULES

PROPOSED RULES

PROPOSED RULES

FOR FURTHER INFORMATION CONTACT:
Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8731 Georgia Ave., Silver Spring, MD 20910, 301-427-7898.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of pacemaker polymeric mesh bags:

1. Identification: A pacemaker polymeric mesh bag is a device used to hold a pacemaker pulse generator. It is designed to create a stable implant environment for the generator.

2. Recommended classification: Class II (performance standards). The Panel recommends establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the pacemaker polymeric mesh bag be classified into class II because this implanted device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Materials used in the device should meet a generally accepted satisfactory level of tissue compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of tissue ingrowth. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Panel reviewed the following information from the medical literature. The fabric mesh bag used with cardiac pacemaker polymeric mesh takes advantage of tissue ingrowth to stabilize, and to prevent migration of, the pacemaker generator. While the phenomenon of tissue ingrowth into porous materials is well-known, it is usually described in passing without great detail and is not reported in controlled studies. Lee and Neville (Ref. 1) claim that, as of 1971, internal mounting of artificial organs had received much attention in the medical literature. However, both We- solowski (Ref. 2), In 1962, and Braunwald and Bull (Ref. 3), in 1969, indicated that an increase in porosity of fabrics increases the ingrowth activity in the body. The phenomenon of tissue ingrowth of artificial hearts, vascular prostheses or artificial heart valves, Lindenaue et al. (Ref. 4) also indicated better tissue ingrowth in more porous materials, and cited a leak-rate porosity value and tissue ingrowth correlation. In general, the vascular graft literature recognizes and discusses tissue ingrowth. Many uses of fabrics for tissue fixation have been listed by Lee and Neville (Ref. 1), including heart valves, vascular grafts, artificial tendons, percutaneous A-V shunt seals, and artificial breasts among many other applications. Some concerns expressed by Skelton (Ref. 5) included specification of polymer properties, composites, additives, and fabric configuration (i.e., weave, knit, velour, etc.). These concerns are also being addressed by various voluntary standards groups.

5. Risks to health: Tissue damage: Tissue damage can occur by an adverse reaction to the material, infection, tearing of tissue, mechanical failure of the bag, and failure of the bag to contain or restrain the pacemaker.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel’s recommendation and is proposing that the pacemaker polymeric mesh bag be classified into class II (performance standards). In arriving at this decision the Commissioner has reviewed additional information from the medical literature and has found that the phenomenon of tissue ingrowth into porous implanted material is well characterized in controlled animal studies and well documented in clinical experience. The phenomenon has been utilized in fixation and stabilization of prostheses in vascular surgery (Ref. 2), heart valve replacement (Ref. 3), intracranial lens replacement (Ref. 6), muscle and tendon repair (Refs. 7 and 8), artificial joints in bone (Refs. 7 and 8), and percutaneous vascular access (Ref. 9). The rate of tissue ingrowth in relation to pore size, and percent porosity of the implant was studied and reported by Hubert et al. (Ref. 8). Brals and Braunwald (Ref. 10) reported on a method for accelerating tissue ingrowth into fabrics implanted in the heart. Dunn et al. (Ref. 7) demonstrated the mechanical strength of the matrix formed by the porous implant and tissue ingrowth. Electron microscopy scanning (Refs. 11 and 12) and histologic examination (Refs. 7, 9, 10, and 13) of porous materials implanted in various tissues, including bone, muscle and soft tissue, have thoroughly demonstrated tissue ingrowth into porous prostheses, and the mechanical testing of ingrown tissue (Refs. 7 and 8) has proven the value of this phenomenon in fixation and stabilization of prostheses. The phenomenon of tissue ingrowth has even provided a means for the development and investigation of autologous arterial grafts (grafts in which the donor and recipient are the same individual) by growing fibrous tissue in a porous fabric surrounding a solid plastic mold (Ref. 14). 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 although the device is an implant, 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 (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.


PROPOSED RULES

[4110-03-M] [21 CFR Part 870]
[Docket No. 76N-1486]

MEDICAL DEVICES

Classification of Pacemaker Chargers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pacemaker chargers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 to the Hearing Clerk (HFA-305), Food and Drug Administration, Department of Health, Education, and Welfare, 5130 Georgia Avenue, Silver Spring, MD 20910, must be received no later than May 8, 1979.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Department of Health, Education, and Welfare, 5130 Georgia Avenue, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT:
Glenn A. Rahmoeiler, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 5130 Georgia Avenue, Silver Spring, MD 20910.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation regarding classification of pacemaker-chargers:

- Identification: A pacemaker charger is a device used to recharge the batteries of a rechargeable pacemaker.
- Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.
- Summary of reasons: The Panel recommends that pacemaker chargers be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached directly to the surface of the body and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's recharging capability, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Pacemaker slowy stops functioning: Failure of the device to recharge the battery or a misinterpretation of the amount of recharging can cause the pacemaker to fail prematurely due to battery depletion. (c) Tissue burn: Thermal burns to the tissues adjacent to the pacemaker can result from overcharging the device. (d) Failure of the pacemaker: Overcharging the device can lead to damage to the pacemaker and result in pacemaker failure.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the pacemaker charger 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 agrees with the Panel's recommendation that the device be classified into class II (performance standards).
sioner 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 870 in Subpart D by adding new §870.3670 as follows:

§ 870.3670 Pacemaker charger.

(a) Identification. A pacemaker charger is a device used transcutaneously to recharge the batteries of a rechargeable pacemaker.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 8500 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-611 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

(Docket No. 78N-1497)

MEDICAL DEVICES

Classification of Permanent and Temporary Pacemaker 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 permanent and temporary pacemaker electrodes into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular 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.


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, 8500 Fishers Lane, Rockville, MD 20857.

FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeuler, Durebtn of Medical Devices (HFR-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of permanent and temporary pacemaker electrodes:

1. Identification: Permanent and temporary pacemaker electrodes are flexible insulated electrical conductors with one end connected to a pacemaker pulse generator and the other end applied to the heart. The device is used to transmit a pacing electrical stimulus from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the pulse generator.

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 permanent and temporary pacemaker electrodes be classified into class III because this device is life-sustaining, and there is insufficient scientific and medical data to develop a standard to assure the safety and effectiveness of the device. The electrode is implanted into the body and can be in direct contact with the blood. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility. The electrode provides an adequate surface finish and cleanliness, which may affect the degree of compatibility. The device provides an electrical path between a pacemaker and the heart. An interruption or short circuit of this path could interfere with proper pacing of the heart. Certain characteristics of the device must be maintained by proper construction and storage. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of and experience with, the device. The Panel found further support for their recommendation in the medical literature. The electrode lead transmits the electrical signal from the pulse generator to the heart and directly stimulates the myocardium. Several varieties of electrode design are used to fulfill the role of the electrode lead. The two basic categories of electrodes are endocardial and myocardial. More than 90 percent (Ref. 1) of all pacemaker implants use the endocardial type. Although they are of two general types (bipolar and monopolar), endocardial electrode leads are of a number of geometrical configurations designed to reduce the current density, displacement and corrosion. Some experimental endocardial electrodes, such as the differential current density electrode and the capacitor electrode, have been developed to minimize electrode corrosion and tissue reaction problems. Myocardial electrode leads also are available in many forms, including cork-screw-mesh and suture types, which are secured by sutures or a combination of electrode cardiac and tissue ingrowth into the mesh. Myocardial electrode leads can be used alone as a monopolar system, or in pairs as a bipolar system, and they can be made in bipolar single lead form. The terms monopolar and bipolar actually refer to the number of poles located at the heart and not to the total number of poles, since all pacemakers have both a cathode and an anode. In the monopolar system the cathode is on the lead at the heart and the anode is a metal plate on the generator package. The medical literature lists the following materials used in pacemaker electrodes and leads: cardiac electrode-palladium-platinum-iridium; lead insulation-silicone rubber and Teflon. Lead wires are usually manufactured from various forms of multiple helical coils or multiple strands to reduce breakage by distributing stress during flexion throughout the wire.
and, by providing redundancy, preventing a single break from causing conduction failure. The complication most frequently listed in the medical literature is lead fracture (Refs. 1 through 4, 6 through 8, 13, and 16), which is something that breaks down into wire breakage and insulation breakage. Roy (Ref. 1) discusses the use of helically coiled wires to increase the longevity of pacemaker leads, but states that no optimum design has yet been determined in clinical trials. With increasing battery life, leads will need to withstand an increased number of flexion cycles and may need to be redesigned to ensure safety. Grogler, et al., (Ref. 29) indicates a lead breakage rate of 6.6 percent in endocardial leads; Green (Ref. 7) indicates a breakage rate of 23.4 percent for an older lead design and 1.2 percent in an older, endocardial lead design. Another problem frequently mentioned in the medical literature is electrode displacement (Refs. 2 through 4, 7, 8, 14, and 16). Although the configuration of the lead can be designed so that displacement is reduced, improper placement at the time of surgery can also cause displacement (Ref. 4). Hence, this problem is complexly related to both design and operative procedure. Grogler's (Ref. 2) results indicate a dislocation rate of 11 percent. Related to electrode displacement is the problem of diaphragmatic contractions, which can be caused by a malpositioned electrode stimulating the phrenic nerve (Refs. 3 and 4). The third most commonly cited complication is "exit block" (Refs. 2 through 4, 6, 7, 14, and 16), which is the failure to achieve pacing due to a rise in the stimulation threshold to a current value above the generator's output. This condition is caused by the natural development of a nonconductive, fibrous tissue sheath around the electrode tip. Threshold rise occurs after all-electrode lead, as that displacement is reduced, improper placement at the time of surgery can also cause displacement (Ref. 4). If the sheath that is formed can be minimized, then threshold rise is also reduced and "exit block" can be reduced in turn. Grogler's (Ref. 2) results indicate that "exit block" occurs 1.6 percent of the time; Green (Ref. 7) shows "exit blocks" of 1 to 8 percent for endocardial leads and 5 to 8 percent for myocardial leads. Green's 8 percent figure is for an older electrode design; the newer designs tested showed a 1 to 2 percent incidence of "exit block." Another complication listed in the literature is cardiac perforation (Refs. 2, 4, 6, 8, 13, and 16). Its incidence is reported to be between 0.7 percent (Ref. 2) and 7.1 percent (Ref. 4). Perforation has also been reported to lead to diaphragm contractions (Ref. 6). Infection is generally listed as an electrode complication (Refs. 4, 6, 8, and 10), although this problem is usually surgical (Ref. 2). Other problems less frequently mentioned are knotting of lead wire (Ref. 6), corrosion leading to gas generation at the electrodes (Refs. 1 and 9), arrhythmias (Refs. 6 and 7), and subpapillary infarction (Ref. 3). Small surface area electrodes used in demand pacing have been found to fail to sense properly and thus cause loss of pacing (Ref. 15). Although these problems are less common, they can cause serious complications. For example, thrombotic developments can easily become emboils leading to pulmonary infarction. In summary, there are many problems in cardiac pacing that are directly or indirectly related to electrode lead design. Grogler (Ref. 2) has reported lead complications, not including infection, in 20.4 percent of the 770 leads in the study. In that study, it has been shown that small surface area electrodes reduce the threshold current, thus reducing current drain and increasing pacing life. However, Grogler et al. (Ref. 2) have reported that the same electrodes, when used with demand pacemakers, can fail to sense demand properly and cause loss of pacing. This would indicate a strong need for matching electrode to generator. Currently proposed standards (Ref. 16) merely address dimensions and dimensional tolerances, and performance limits as tested by various accelerated bench tests. These proposals do not deal with lead displacement, cardiac perforation, "exit block," thrombosis, and other complications that comprise 13.8 percent of the complications noted in Grogler's study (Ref. 2). In discussing electrode lead choice, Roy (Ref. 1) states, "Accelerated bench testing cannot duplicate all the in situ conditions. To a large extent, the choice awaits long term in vivo statistics." The following information has been placed in the office of the Hearing Clerk (HPA-305), Rm. 4-65, 5600 Fisher Lane, Rockville, Md. 20857, and may be seen by interested persons, from 8 a.m. to 4 p.m., Monday through Friday.

PROPOSED RULES


JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6192 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

(Docket No. 78N-1498)

MEDICAL DEVICES

Classification of Pacemaker Test Magnets

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pacemaker test magnets under the Medical Device Amendments of 1976.

The Commissioner of Food and Drugs is issuing this proposal in response to a request by the Cardiovascular Device Classification Panel for a performance standard for pacemaker test magnets.

The panel recognizes the need for a classification of pacemaker test magnets so that adequate standards can be established for testing devices that are used to test pacemaker function.

The panel also recognizes that the safety and effectiveness of the device will be dependent on the design and development of the device.

The panel recommends that classifying pacemaker test magnets into class II (performance standards) be considered.

The panel also recommends that the pacemaker test magnet be classified into class II.

The panel believes that general controls alone would not provide sufficient control over the 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 found further support for their recommendation in the medical literature. The risks cited in the literature reviewed by the panel are failure of the magnet to cause the pacemaker to reversion to a fixed rate (Ref. 1) and inadequate design of the device with regard to magnetic strength (Ref. 2).

5. Risks to health: (a) Misdiagnosis: Inadequate design of the device with regard to magnetic strength can lead to inaccurate assessment of pacemaker function. If an inaccurate assessment of pacemaker function is used in managing the patient, the physician may prescribe a course of treatment which places the patient at risk unnecessarily.

(b) Improper pacemaker operation: When a magnet is used to induce continuous operation of the pacemaker pulse generator and cause an inhibited or triggered generator to revert to asynchronous operation.

5. Risks to health: (a) Misdiagnosis: Inadequate design of the device with regard to magnetic strength can lead to inaccurate assessment of pacemaker function. If an inaccurate assessment of pacemaker function is used in managing the patient, the physician may prescribe a course of treatment which places the patient at risk unnecessarily.

(b) Improper pacemaker operation: When a magnet is used to induce continuous operation of the pacemaker pulse generator and cause an inhibited or triggered generator to revert to asynchronous operation.

5. Risks to health: (a) Misdiagnosis: Inadequate design of the device with regard to magnetic strength can lead to inaccurate assessment of pacemaker function. If an inaccurate assessment of pacemaker function is used in managing the patient, the physician may prescribe a course of treatment which places the patient at risk unnecessarily.

(b) Improper pacemaker operation: When a magnet is used to induce continuous operation of the pacemaker pulse generator and cause an inhibited or triggered generator to revert to asynchronous operation.

5. Risks to health: (a) Misdiagnosis: Inadequate design of the device with regard to magnetic strength can lead to inaccurate assessment of pacemaker function. If an inaccurate assessment of pacemaker function is used in managing the patient, the physician may prescribe a course of treatment which places the patient at risk unnecessarily.

(b) Improper pacemaker operation: When a magnet is used to induce continuous operation of the pacemaker pulse generator and cause an inhibited or triggered generator to revert to asynchronous operation.

5. Risks to health: (a) Misdiagnosis: Inadequate design of the device with regard to magnetic strength can lead to inaccurate assessment of pacemaker function. If an inaccurate assessment of pacemaker function is used in managing the patient, the physician may prescribe a course of treatment which places the patient at risk unnecessarily.

(b) Improper pacemaker operation: When a magnet is used to induce continuous operation of the pacemaker pulse generator and cause an inhibited or triggered generator to revert to asynchronous operation.

5. Risks to health: (a) Misdiagnosis: Inadequate design of the device with regard to magnetic strength can lead to inaccurate assessment of pacemaker function. If an inaccurate assessment of pacemaker function is used in managing the patient, the physician may prescribe a course of treatment which places the patient at risk unnecessarily.
during surgery, failure to revert may be life-threatening.

Proposed Classification

The Commissioner agrees with the Panel recommendation and is proposing that the pacemaker test magnet 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, although the device can be life-supporting, 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 (advice) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.


Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546, 21 U.S.C. 360e, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new §870.3590 as follows:

§870.3590 Pacemaker test magnet.

(a) Identification. A pacemaker test magnet is a device used to test an inhibited or triggered type of pacemaker pulse generator which causes an inhibited or triggered generator to revert to asynchronous operation.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20807, written comments regarding this proposed rule. 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.


Joseph P. Hile, Associate Commissioner for Regulatory Affairs.

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1499]

MEDICAL DEVICES

Classification of Pacemaker Programmers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pacemaker programmers into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular 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 dated at a time 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 May 8, 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:

Glenn A. Rahmoller, Bureau of Medical Devices (HFK-460), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 "Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of pacemaker programmers:

1. Identification: A pacemaker programmer is a device used to change noninvasively one or more of the electrical operating characteristics of a pacemaker.

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: Because the Panel recommends that pacemakers be classified into class III, they also recommend class III for pacemaker programmers. The Panel believes that premarket approval is necessary to assure the safety and effectiveness of this life-supporting device. The Panel noted that because this device must be designed to operate with a specific pacemaker as a system, the same level of control is necessary for both devices. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and, moreover, that there are insufficient data 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Improper pacemaker operation: Inadequate design of the device's programming function can cause the pacemaker to lose its sensing or pacing ability, or to pace at an improper rate. (c) Misdiagnosis: Inadequate design of the device's ability to sense pacemaker function can lead to the generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (d) Inability to change pacing therapy: Inadequate matching of the programmer to the pacemaker could lead to a situation where the pacemaker could not be programmed, thereby preventing a needed change in pacing therapy and placing the patient at risk unnecessarily.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is pro-
proposing that the pacemaker programmer be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (maintaining heart function by electrical stimulation) in supporting or sustaining human life. The Commissioner also believes the device is purported or represented to be for a use in controlling the electrical output of a programmable implanted pacemaker with substantial importance in preventing impairment of human health. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify a life-supporting or life-sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 510, 701(a), 82 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 870 in Subpart D by adding new § 870.3700 as follows:

§ 870.3700 Pacemaker programmer.

(a) Identification. A pacemaker programmer is a device used to change noninvasively one or more of the electrical operating characteristics of a pacemaker.

(b) Classification. Class III (premarket approval).

"Interested persons may, on or before May 8, 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.


Joseph P. Hill
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-8194 Filed 3-8-79; 8:45 am]"
not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 50 Stat. 540-546 (21 U.S.C. 350, 351), and authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new §870.3710 as follows:

§870.3710 Pacemaker repair and replacement materials.

(a) Identification. Pacemaker repair and replacement materials are adhesives, sealants, screws, crimps, and other materials used to repair a pacemaker lead or to reconnect a pacemaker lead to a pacemaker pulse generator.

(b) Classification. Class III (premarket approval).

Interested persons may, on or before May 8, 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 proposed rule. 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.


JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6155 Filed 2-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78-N-1501]

MEDICAL DEVICES

Classification of Pacemaker Electrode Function 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 pacemaker electrode function testers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 consideration of public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.


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:

Glen A. Rahmoeller, Bureau of Medical Devices (HFP-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

A proposal - elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of pacemaker electrode function testers:

1. Identification: A pacemaker electrode function tester is a device which is connected to an implanted pacemaker lead that supplies an accurately calibrated, variable pacing pulse for measuring the patient's pacing threshold and the intracardiac R-wave potential.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The panel recommends that pacemaker electrode function testers be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Failure of the device to accurately measure pacing threshold can lead to pacing failures due to excessive or insufficient charge, energy, or current delivered through the electrode. This device is attached to the body through the pacemaker electrode lead and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics including accuracy and reproducibility and any limitations on the device's ability to measure pacing threshold and R-wave amplitude should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. Although the device releases an acceptable level of energy into the body when functioning properly, unsafe energy levels may be released if the device malfunctions. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that control general alone would not provide sufficient control over the performance and electrical 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic data. If inaccurate diagnostic data are used in monitoring the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (b) Cardiac arrhythmias: Excessive charge, energy, or current supplied to the heart because of inaccurate calibration, or a sensing failure (for inhibited type pacemakers) due to inaccurate calibration, or as a result of cardiac arrhythmias. Also, excessive electrical leakage current can disturb the normal electrophysiology of the heart, thus leading to the onset of cardiac arrhythmias.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the pacemaker electrode function tester be classified into class II (performance standards). The Commissioner believes that performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance stand-
The Commissioner agrees with the Panel's recommendation and is proposing that pacemaker service tools be classified into class I (general controls). 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 870 in Subpart D by adding new § 870.3720 as follows:

§ 870.3720 Pacemaker electrode function tester.
(a) Identification. A pacemaker electrode function tester is a device which is connected to an implanted pacemaker lead that supplies an accurately calibrated, variable pacing pulse for measuring the patient's pacing threshold and the intracardiac R-wave potential.
(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-450), 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.


Joseph P. Hile,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6196 Filed 3-8-79; 8:45 am]

[4110-03-M]
[21 CFR Part 870]
(Docket No. 78N-1502)

MEDICAL DEVICES
Classification of Pacemaker Service Tools
AGENCY: Food and Drug Administration.
ACTION: Proposed rule.
SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed rule classifying pacemaker service tools into class I (general controls). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 1979. The Commission of Food and Drugs proposes that the final regulation be issued on or before September 1, 1979. The classification is based upon the lack of potential hazards associated with the device and on their personal knowledge of, and experience with, the device.

Risks to health: None identified.

FOR FURTHER INFORMATION CONTACT:
Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8717 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of pacemaker service tools:

1. Identification: Pacemaker service tools are devices, such as screwdrivers and Allen wrenches, used to repair a pacemaker lead or to reconnect a pacemaker lead to a pacemaker generator.
2. Recommended classification: Class I (general controls).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-450), 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.


Joseph P. Hile,
Associate Commissioner for Regulatory Affairs.
PROPOSED RULES

The Commissioner agrees with the Panel’s recommendation and is proposing that the annuloplasty ring be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (correction of heart valve insufficiency) in supporting or sustaining human life. The device is intended to be implanted in the human body. The Food, Drug, and Cosmetic Act requires the Commissioner to classify an implant or a life supporting or life sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device’s safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 70(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 870 in Subpart D by adding new §870.3880 as follows:

§870.3880 Annuloplasty ring.

(a) Identification. An annuloplasty ring is a rigid or flexible ring implanted around the mitral or tricuspid heart valve for reconstructive treatment of valvular insufficiency.

(b) Classification. Class III (premarket approval).

Interested persons may, on or before May 8, 1979 submit their comments 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.


JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[4110-03-M]

[21 CFR Part 870]

[Dockets No. 78N-1501]

MEDICAL DEVICES
Classification of Carotid Sinus 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 carotid sinus nerve stimulators into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular 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 may be received at the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glaen A. Rahmoeiler, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8707 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of annuloplasty rings:

1. Identification: An annuloplasty ring is a rigid or flexible ring implanted around the mitral or tricuspid heart valve for reconstructive treatment of valvular insufficiency.

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 the ring be classified into class III because the device is implanted and is life-supporting. The Panel believes that premarket approval is necessary to assure the safety and effectiveness of this implanted device. The device is used for correction of valvular insufficiency and, if not designed properly, presents a potential unreasonable risk of illness, injury, or death. The Panel also believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and, moreover, that there is not 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Tissue and blood damage: If the materials, surface finish, or cleanliness of the device are inadequate, damage to the blood and tissue may result. (b) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (c) Embolism: Pieces of the ring that break or flake off may form potentially debilitating or fatal emboli. (d) Dilatation of the heart eventually leading to intractable heart failure. The mechanical design of the device does not provide an adequate means of correcting valvular insufficiency. The condition will persist causing dilation of the heart and eventually leading to intractable heart failure.
PROPOSED RULES

Glenn A. Rahmoeller, Bureau of Medical Devices (HFZ-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of carotid sinus nerve stimulators:

1. Identification: A carotid sinus nerve stimulator is an implantable device used to decrease arterial pressure by stimulating Hering's nerve at the carotid sinus.

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 carotid sinus nerve stimulator be classified into class III because, although this device is neither life-supporting nor life-sustaining, it presents a potential unreasonable risk to life or health even when properly used and because it is an implant. A carotid sinus nerve-stimulating type consists of an implanted stimulator with electronics in contact with the carotid sinus nerve. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The device presents some potential hazards either by electrical shock or through failure to perform as a result of a power source failure. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to reduce blood pressure by Hering's nerve stimulation, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel also believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and that there is not 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 the following hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Tissue and blood damage: If the materials, surface finish, or cleanliness of this device are inadequate, damage to the blood and tissue may result. (b) Inability to control blood pressure: Failure of the device to operate properly can prevent effective control of elevated blood pressure.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the carotid sinus nerve stimulator be classified into class III (premarket approval). The Commissioner believes the device is purported to be for a use in controlling chronic high blood pressure, which is of substantial importance in preventing impairment of human health. The device is intended to be implanted in the human body. 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 device's safety and effectiveness. In this case, the Commissioner determines that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this 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 8 a.m. to 4 p.m., Monday through Friday.


Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 80 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 870 in Subpart D by adding new § 870.3850 as follows:

§ 870.3850 Carotid sinus nerve stimulator.

(a) Identification. A carotid sinus nerve stimulator is an implantable device used to decrease arterial pressure by stimulating Hering's nerve at the carotid sinus.

(b) Classification. Class III (premarket approval).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305n), 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.


Joseph P. Hile, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6199 Filed 5-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[DOCKET NO. 78N-1505]

MEDICAL DEVICES

Classification of Replacement Heart Valves

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying replacement heart valves into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class III. The effect of classifying a device be classified 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. The actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 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-305n), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.
FOR FURTHER INFORMATION CONTACT:
Glenn A. Rahmoeiller, Bureau of Medical Devices (HFE-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

PANEL RECOMMENDATION

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of replacement heart valves:

1. Identification: A replacement heart valve is a device intended to perform the function of any of the heart's natural valves. This generic device class includes valves constructed of prosthetic materials, biologic valves (e.g., porcine valves), or valves constructed of a combination of prosthetic and biologic materials.

2. Recommended Classification: Class III (premarket approval). The Panel recommends that premarket approval of this device by a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the replacement heart valve be classified into class III because this device is an implant that is life-supporting and life-sustaining. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. Performance characteristics, including blood flow properties and mechanical strength, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device, that there is not sufficient information to establish a standard to provide such assurance and, therefore, that premarket approval is necessary for this device.

4. Summary of data on which recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge and experience with the device. In addition, the Panel found further support for their recommendation in the medical literature. Because the Panel conducted an extensive literature search in the medical literature, only a small sample of the literature reviewed is cited here (Refs. 1 through 10).

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Excessive regurgitation, excessive hemolysis, improper hemodynamic operation, excessive obstruction, and valve degeneration: Poor valve design can cause one or more of these conditions.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the replacement heart valve be classified into class III (premarket approval).

The Commissioner believes the device is purposed or represented to be for a use (correction of heart valve defects) in supporting or sustaining human health. The device is intended to be implanted in the human body. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify an implant or a life-supporting or life-sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the device's safety and effectiveness and that insufficient information exists to establish a performance standard to provide this 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.


Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 501(a), 501(i), 505, 21 U.S.C. 350a, 350c(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 810 in Subpart D by adding new § 870.3925 as follows:

§ 870.3925 Replacement heart valve.

(a) Identification. A replacement heart valve is a device intended to perform the function of any of the heart's natural valves. This generic device class includes valves constructed of prosthetic materials, biologic valves (e.g., porcine valve), or valves constructed of a combination of prosthetic and biologic materials.

(b) Classification. Class III (premarket approval).

Interests persons may, on or before May 8, 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.


JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.
PROPOSED RULES

MEDICAL DEVICES

Classification of Prosthetic Heart Valve Holders

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying prosthetic heart valve holders into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation 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:
Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-217-7658.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of prosthetic heart valve holders:

1. Identification: A prosthetic heart valve holder is a device used to hold a replacement heart valve while it is being sutured into place. The Commissioner recommends that the prosthetic heart valve holder be classified into class II because the device is neither life-supporting nor life-sustaining but is potentially hazardous to life or health even when properly used. The device is used with other devices in a system that may be hazardous if not assembled, used, and maintained in a satisfactory fashion. The device should be designed so that it will not cause damage to the replacement heart valve. The Panel believes that general controls alone would not provide sufficient control over the 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.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the prosthetic heart valve holder be classified into class II because the device is neither life-supporting nor life-sustaining but is potentially hazardous to life or health even when properly used. The device is used with other devices in a system that may be hazardous if not assembled, used, and maintained in a satisfactory fashion. The device should be designed so that it will not cause damage to the replacement heart valve while it is being sutured into place.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge, training, and experience with the device.

5. Risks to health: Valve failure: Replacement valve damage, causing the valve to function improperly or to have a shortened service life, can be caused by poor mechanical design of the valve holder and by use of incompatible materials for the valve and valve holder. If the replacement valve is damaged, valve failure and the necessity for a hazardous corrective reoperation may occur.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the prosthetic heart valve holder 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. Although prosthetic heart valve holders are used both as diagnostic devices and as monitoring devices, they will be listed in this code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use.

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 870 in Subpart D by adding new §870.3935 as follows:

§870.3935 Prosthetic heart valve holder.

(a) Identification. A prosthetic heart valve holder is a device used to hold a replacement heart valve while it is being sutured into place.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE
Associate Commissioner for Regulatory Affairs.

[CFR Doc. 79-5201 Filed 3-8-79; 8:45 am]

MEDICAL DEVICES

Classification of Prosthetic Heart Valve Sizers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying prosthetic heart valve sizers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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.

FEDERAL REGISTER, VOL. 44, NO. 45—FRIDAY, MARCH 9, 1979
The Commissioner agrees with the Panel's recommendation and is proposing that the prosthetic heart valve sizer 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. Although prosthetic valve sizers are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the more common use. Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 50 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 870 in Subpart D by adding new § 870.3945 Prosthetic heart valve sizer.

(a) Identification. A prosthetic heart valve sizer is a device used to measure the size of the natural valve opening to determine the size of the appropriate replacement heart valve.

(b) Classification. Class II (performance standards).

Interested persons may, or or before May 8, 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.

FOR FURTHER INFORMATION CONTACT:
Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of endomyocardial biopsy devices:

1. Identification: An endomyocardial biopsy device is a device used to

on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that heart valve sizers be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device is inadequate for accurate and precise determination of proper valve size, the resulting misdiagnosis could have a significant negative effect on the patient's health. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to measure heart valve size should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the 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...
remove samples of tissue from the inner wall of the heart.

2. Explanation: 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 endomyocardial biopsy device be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility or, and experience with the 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 reasons for the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Panel found further support for their recommendation in the medical literature. Use of an endomyocardial biopsy device was first described by Sakakibara and Kanno in 1962 (Ref. 1). Since that time, the device has been modified by others (Refs. 2 through 5). Introduction of an endomyocardial biopsy device involves the insertion of a biopsy (an instrument for removing a small fragment of tissue) via a percutaneous catheter to the desired endomyocardial site in either the right or left heart (Refs. 1 through 10). The procedure of biopsy holds an established place in medical practice and the efficacy of this device does not appear to be questioned (Refs. 1 through 10). The most serious hazards associated with the use of this biopsy device involve the risk of perforation and hemorrhage of the endomyocardial wall (Refs. 6 through 8). Tricuspid perforation has been reported in dogs (Ref. 8). Perforation and hemorrhage can be accompanied by pericardial tamponade (compression of the heart due to accumulation of fluid within the sac surrounding the heart) (Refs. 7 and 8), which is an immediate life-threatening complication. These hazards are predominately related to device use and occur most frequently when the biopsy is advanced to the endomyocardial wall with its jaws closed. This configuration apparently renders the shape of the biopsy “bulletlike” and permits endomyocardial entry even when minimal pressure is applied (Ref. 6). The incidence of perforation and hemorrhage is significantly reduced by advancing the biopsy with its jaws open. Other hazards associated with the use of this device are embolization and transient chest pain (Figs. 4, 5, and 7). The incidence of embolization is apparently lower in patients who are receiving anticoagulant drugs (Ref. 7) than in patients who are not (Ref. 7). Temporary right bundle branch block of the left ventricle (Ref. 7) can occur during one study of 1054 patients (more than 100 biopsy procedures) resulted in the incidence of complications in both ventricles (Ref. 7, table IV). A Stanford University study involving over 600 biopsy procedures demonstrated no significant morbidity and no mortality associated with the use of the endomyocardial biopsy device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboembolism. (b) Embolism: Improper mechanical design can cause premature release of the bioptome and it becomes an embolus. (c) Damage to heart tissue: Endomyocardial hemorrhage, perforation of the heart, and cardiac arrhythmias can all result from improper mechanical design.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel’s recommendation and is proposing that the endomyocardial biopsy 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 such assurance. Although endomyocardial biopsy devices are used both as diagnostic devices and as monitoring devices, they will be listed in the Code of Federal Regulations under cardiovascular monitoring devices because monitoring is the most common use.

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.


Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513,
PROPOSED RULES

701(a), 52 Stat. 1055, 99 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 870 by adding Subpart E and new § 870.4075 as follows:

Subpart E—Cardiovascular Surgical Devices

§ 870.4075 Endomyocardial biopsy device.

(a) Identification. An endomyocardial biopsy device is a device used to remove samples of tissue from the inner wall of the heart.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit single copies of comments, or write to the Hearing Clerk, Hearing Office, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[IFR Doc. 79-8240 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1509]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Accessory Equipment

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass accessory equipment into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 Adjudgments of 1976.

DATES: Comments by May 8, 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 (HPA-303), Food and Drug Administration, Rm. 4-55, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glen A. Rahmoeller, Bureau of Medical Devices (HFK-459), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass accessory equipment:

1. Identification: Cardiopulmonary bypass accessory equipment is equipment that includes devices having no contact with blood-material that are used in the cardiopulmonary bypass circuit to support, adjoin, or connect components, or to aid in the setup of the extracorporeal line, e.g., an oxygenator mounting bracket or system priming equipment.

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 cardiopulmonary bypass accessory equipment be classified into class II because this device is neither life-sustaining nor life-sustaining, but is potentially hazardous to life or health even when properly used. This equipment plays an important role in the setup and function of the cardiopulmonary bypass circuit. Failure of the equipment to perform its intended purpose could lead to serious hazards such as cessation of perfusion (passage of fluid through the vessels of an organ) or cessation of oxygenation (oxygen uptake by the blood). Performance characteristics should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, or maintained. This equipment does not include any devices that have been classified individually as items of cardiopulmonary bypass equipment under other regulations in this section. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cessation of perfusion: Failure of the device due to poor mechanical design can require temporary cessation of the perfusion.

(b) Cessation of oxygenation: Failure of the device due to poor mechanical design can require temporary cessation of oxygenation.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass accessory equipment 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 such assurance.

Therefore, under the Federal Food, Drug and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 99 Stat. 540-546 (21 U.S.C. 360e, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4200 as follows:

§ 870.4200 Cardiopulmonary bypass accessory equipment.

(a) Identification. Cardiopulmonary bypass accessory equipment is equipment that includes devices having no contact with blood-material that are used in the cardiopulmonary bypass circuit to support, adjoin, or connect components, or to aid in the setup of the extracorporeal line, e.g., an oxygenator mounting bracket or system priming equipment.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk, Hearing Office, 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.
PROPOSED RULES

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 Cardiovascular Device classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass bubble detectors:

1. Identification: A cardiopulmonary bypass bubble detector is a device used to detect bubbles in the arterial return line of the cardiopulmonary bypass circuit.

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 cardiopulmonary bypass bubble detector be classified into class II because this device is neither life-sustaining but is potentially hazardous to life or health even when properly used. If the device is used for accurate and precise detection of gas emboli, the resulting misdiagnosis could have a significant negative effect on the patient's health. Performance characteristics, including accuracy, reproducibility, and any limitations on the device’s ability to detect bubbles, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device releases an acceptable energy level into the bloodstream when functioning normally. If the device malfunctions, however, unsafe energy levels may be released, especially if the device utilizes ultrasonic techniques. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge and experience with the device.

5. Risks to health: (a) Tissue and blood damage: If not properly designed, devices that release ultrasonic energy into the body could release such energy at levels which may damage tissue and blood. (b) Gas embolism: Failure of the device to detect gas emboli in the extracorporeal circuit can allow potentially debilitating or fatal gas emboli to enter the patient's circulation.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel recommendation and is proposing that the cardiopulmonary bypass bubble detector 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 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 870 in Subpart E by adding new § 870.4205 as follows:

§ 870.4205 Cardiopulmonary bypass bubble detector.

(a) Identification. A cardiopulmonary bypass bubble detector is a device used to detect bubbles in the arterial return line of the cardiopulmonary bypass circuit.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.
PROPOSED RULES

[4110-03-M]  [21 CFR Part 870]  [Docket No. 78N-1510]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass
Vascular Catheters, Cannulas, and Tubing

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass vascular catheters, cannulas, and tubing into class II. The effect of classifying a device into class II (performance standards) is to provide for the 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 May 8, 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 Fisher Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Glenn A. Rathsaller, Bureau of Medical Devices (HFA-450), Food and Drug Administration, Department of Health, Education, and Welfare, 2001 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendations with respect to the classification of cardiopulmonary bypass vascular catheters, cannulas, and tubing:

1. Identification: Cardiopulmonary bypass catheters, cannulas, and tubing are devices used in cardiopulmonary bypass surgery to cannulate the vessels, perfuse the coronary arteries, and interconnect the catheters and cannulas with an oxygenator and the accessory bypass equipment.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a medium priority. 3. Summary of reasons for recommendation: The Panel recommends that cardiopulmonary bypass vascular catheters, cannulas, and tubing be classified into Class II because these devices are neither life-supporting nor life-sustaining, but play an important role in the treatment of patients with respect to the classification of the devices. These actions are being taken under the Medical Device Amendments of 1976.

4. Risks to health: (a) Thromboemboli: Inadequate blood compatibility of the materials used in these devices and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Tissue and blood damage: If the materials, surface finish, or cleanliness of these devices are inadequate, damage to the blood and tissue may result. (c) Loss of blood: Lack of integrity of the connections between these devices and adapters and connectors used to join these devices together causes blood leakage.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that cardiopulmonary bypass vascular catheters, cannulas, and tubing be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for these devices 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 such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1065, 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 870 in subpart E by adding new § 870.4210 as follows:

§ 870.4210 Cardiopulmonary bypass vascular catheters, cannulas, and tubing.

(a) Identification. Cardiopulmonary bypass vascular catheters, cannulas, and tubing are devices used in cardiopulmonary surgery to cannulate the vessels, perfuse the coronary arteries, and interconnect the catheters and cannulas with an oxygenator, and the accessory bypass equipment.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fisher 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.


JOSEPH P. HILE
Associate Commissioner for Regulatory Affairs

[FR Doc. 79-6551 Filed 3-6-79; 8:45 am]

[4110-03-M]  [21 CFR Part 870]  [Docket No. 78N-1511]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass
Heart-Lung Machine Consoles

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass heart-lung machine consoles into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classi-
PROPOSED RULES

fled into class II. The effect of classifying a device into class II is to provide for the development of 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 to be taken under the Medical Device Amendments of 1976.

DATES: Comments by May 8, 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: Glenn A. Rahmoller, Bureau of Medical Devices (HFR-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7659.

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 Cardiovascular Device Classification Panel, an FDA Advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass heart-lung machine consoles:

1. Identification: A cardiopulmonary bypass heart-lung machine console is a device that consists of a control panel and the electrical power and control circuitry for a heart-lung machine. The console is designed to interface with the basic units used in a gas exchange system, including the pumps, oxygenator, and heat exchanger.

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 cardiopulmonary bypass heart-lung machine console be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. The device is electrically powered and presents a potential hazard to the patient either by power failure or electrical leakage current. Thus, the electrical characteristics of the device, e.g., electrical leakage current, need to meet certain requirements. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard will provide a 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias of electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician, during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Failure to provide sufficient power to the life-support equipment: If the device cannot operate within the expected range of line voltage, it may fail to provide sufficient power to the cardiopulmonary bypass circuit and cause the circuit to cease working.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass heart-lung machine console 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 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 870 in Subpart E by adding new §870.4220 as follows:

§870.4220 Cardiopulmonary bypass heart-lung machine console.

(a) Identification. A cardiopulmonary bypass heart-lung machine console is a device that consists of a control panel, and the electrical power and control circuitry for a heart-lung machine. The console is designed to inter-

face with the basic units used in a gas exchange system, including the pumps, oxygenator, and heat exchanger.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[21 CFR Part 870]

[8:45 am]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Defoamers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass defoamers into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
PROPOSED RULES

5. Risks to health: (a) Blood damage: If the materials, finish, or cleanliness of this device are inadequate, damage to the blood may result. (b) Gas embolism: Inability of the device to adequately remove gas bubbles from the blood can allow potentially debilitating or fatal gas emboli to escape into the bloodstream.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass defoamer be classified into class III (premarket approval). The Commissioner believes the device is purposed or represented to be for a use in removing gas bubbles from the blood in the cardiopulmonary bypass circuit which is of substantial importance in preventing impairment of human health. The Commissioner believes the device presents a potential unreasonable risk of illness or injury because if the device fails to remove gas bubbles from the blood, a potentially debilitating or fatal gas embolism could result. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this 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. 306c, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new §870.4230 as follows:

§870.4230 Cardiopulmonary bypass defoamer.
(a) Identification. A cardiopulmonary bypass defoamer is a device used in conjunction with an oxygenator during cardiovascular bypass surgery to remove gas bubbles from the blood.
(b) Classification. Class III (premarket approval).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6253 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

(Docket No. 79N-1513)

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Heat Exchangers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass heat exchangers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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.

DATE: Comments by May 8, 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:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass heat exchangers:

"FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979"
PROPOSED RULES

1. Identification: A cardiopulmonary bypass heat exchanger is a device, consisting of a heat exchange system, used in extracorporeal circulation to warm or cool the blood or profusion fluid flowing through the device.

2. Recommended classification: Class II (performance standards). The Panel recommends establishing a performance standard for this device as a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass heat exchanger be classified into class II (performance standards) because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. The device is attached to the body through an extracorporeal blood circuit and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus if the device is electrically powered, the electrical characteristics of the device, including leakage current, need to meet certain requirements. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. When the device transfers heat between one fluid and the blood, integrity of the separation of the two fluids must be maintained. The device should protect against the release of unsafe energy levels into the body. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's heat transfer characteristics, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: If the device is electrically powered, excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization procedure, and this may lead to intracardiac complications. (b) Blood loss or contamination: The integrity of the fluid channels must be maintained to prevent leakage between the blood and water sides of the device causing either loss of blood into the water or contamination of the blood by the water. (c) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboembolism. (d) Blood damage: If the materials, surface finish, or cleanliness of this device are inadequate, damage to the blood may result. Also, excessive or uncontrolled heat transfer due to physical properties of the materials used in the device or to a mismatch of the heat exchanger and temperature controller can cause blood damage. (e) Infection: Sterility of the device must be ensured to prevent infection.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass heat exchanger 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 such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 510, 515, 520(a), 522(a), 526, 540, 548, 551(j), 552, 553, 554, 558, 562, 563, 564 (21 U.S.C. 360a, 361(b)(3)(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new §870.1240 as follows:

§870.1240 Cardiopulmonary bypass heat exchanger.

(a) Identification. A cardiopulmonary bypass heat exchanger is a device consisting of a heat exchange system, used in extracorporeal circulation to warm or cool the blood or profusion fluid flowing through the device.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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 or surgical procedure, and this may be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found 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.


Joseph P. Hale, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6254 Filed 3-8-79; 8:45 am]

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary temperature controllers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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: Glenn A. Rahmoler, Bureau of Medical Devices (HFA-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the de-
development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass temperature controllers:

1. Identification: A cardiopulmonary bypass temperature controller is a device used to control the temperature of the fluid entering and leaving a heat exchanger.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass temperature controller be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the cardiopulmonary bypass circuit through the heat exchanger and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to control temperature should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient performance and electrical characteristics of this device. The Panel believes that a performance standard will 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 such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 80 Stat. 549-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4250 as follows:

§ 870.4250 Cardiopulmonary bypass temperature controller.

(a) Identification. A cardiopulmonary bypass temperature controller is a device used to control the temperature of the fluid entering and leaving a heat exchanger.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearng 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's 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.


Joseph P. Hille,
Associate Commissioner for Regulatory Affairs.
pieces of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. It is used in the arterial return line.

2. Recommended classification: Class III (premarket approval). The Panel recommends that the cardiopulmonary bypass arterial line blood filter be classified as class III because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used, and because there are insufficient data to establish the safety and effectiveness of the device. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize foreign body reactions and disruption of normal blood flow characteristics, including accuracy, reproducibility, and any limitations on the device’s filtration efficiency, should be maintained at a generally accepted satisfactory level. The Commissioner believes the device presents a potential risk of embolism: Inability of the device to filter the amount of blood flowing through it during a cardiopulmonary bypass operation could lead to inadequate flow or excessive pressure gradient. For this reason, the Commissioner believes the device is purported or represented to be a cause of detrimental alterations in pulmonary physiology (Refs. 3 through 6). Dr. Clark (Ref. 1) summarizes the problem as follows: "A second major consideration is that of high removal of gas to microemboli. Although oxygen and carbon dioxide are the two gases used during extracorporeal circulation, the net outward effects of small (less than 20-30 micron) microbubbles have not been documented to date for two reasons. First, It is very difficult to generate uniform size bubbles in the size range of 25 to 50 microns, and the bubble size may not remain constant in a non-Newtonian turbulent flow field. Second, no highly accurate on-line, continuous noninvasive system for measurement of size and total particles per unit time has appeared. Consequently, the total number by size and the distribution of types of microemboli in the arterial line, i.e., gas, protein solids, and non-protein solids, have not been ascertained. In summary, the pathophysiologic data and the means by which to obtain that data are still lacking.

Most investigators state that blood filters are invaluable for removing harmful aggregates induced by extracorporeal circulation (Refs. 2 and 6 through 10). However, adequate filter capacity and effective filtration are important for this application, as obstruction could be a serious hazard to the patient. Although fresh in vivo blood has very few of the filterable elements per unit (500 milliliters), the high flow rate in an arterial line (3 to 5 liters per minute) and its pulsing can cause problems due to excessive turbulence and high frequency vibration in the filter. This can cause platelet and fibrin destruction resulting in a clogged filter just when an adequate flow of blood is needed the most (Refs. 6 and 8). Arterial circuit application requires a special design to reduce turbulence and a greatly increased capacity to handle the added flow rate and time needed for an operation. Filters on the market as of 1975 seem to do a good job for short periods of time (less than 4 hours) on dogs weighing 20 to 30 kilograms (Ref. 9). However, Heimbeck's studies (Ref. 7) indicate that line filters experiencing blood flows of 3 to 5 liters per minute that are not designed for such flows may actually generate or retain emboli which are released into the systemic circulation causing neurologic, pulmonary, and renal complications. From this data and their experience, the Panel concluded that there do not exist sufficient safety and effectiveness data on which adequate performance standards could be based.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device may lead to thromboemboli. (b) Inadequate blood flow: Inadequate capacity of the device to filter the amount of blood flowing through it during a cardiopulmonary bypass operation could lead to inadequate flow or excessive pressure gradient. (c) Embolic complications: Inability of the device to properly filter particles can lead to platelet and fibrin destructions. (d) Gas embolism: Inability of the device to properly filter microbubbles from the extracorporeal circulation is associated with gas embolism.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass arterial line blood filter be classified into class III (premarket approval).

The Commissioner believes the device is purported or represented to be a use in removing emboli from the blood in the cardiopulmonary bypass circuit which is of substantial importance in preventing impairment of human health. The Commissioner believes the device presents a potential unreasonable risk of illness or injury because if the device fails to remove emboli from the blood, a potentially debilitating or fatal embolism may result. The Commissioner believes that insufficient information exists to determine that general controls will
provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this 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. Memorandum to the Cardiovascular Device Classification Panel from Richard E. Clark, M.D., minutes of the May 2, 1977 meeting.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 512, 701(a)), 52 Stat. 1065, 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 870 in Subpart E by adding new §870.4250 as follows:

§870.4250 Cardiopulmonary bypass arterial line blood filter.

(a) Identification. A cardiopulmonary bypass arterial line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (blood clots or pieces of foreign material flowing in the bloodstream which will obstruct normal blood flow). The device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize body reactions and disruption of normal blood flow. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's filtration efficiency, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. 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 the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation regarding classification of cardiopulmonary bypass cardiotomy suction line blood filters:

1. Identification: A cardiopulmonary bypass cardiotomy suction line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (a blood clot or a piece of foreign material flowing in the bloodstream which will obstruct circulation by blocking a vessel) out of the blood. This device is intended for use in the cardiotomy suction line.

2. Recommended classification: Class II (performance standard). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass cardiotomy suction line blood filter be classified into class II because the device is neither life-sustaining nor life-supporting, but is potentially hazardous to life or health if it fails to filter the blood effectively. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize body reactions and disruption of normal blood flow. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's filtration efficiency, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. 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 the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
device. In addition, the Panel found further evidence for their recommendation in the medical literature. Literature was supplied to the Panel by Dr. Richard dation in the medical literature. Little further evidence for their recommendation in the device. In addition, the Panel found problems arising during clinical perfusions in which the device is used are usually not life threatening. The blood filtered by this device is removed from the operative field by suction, and contains a large amount of fat and debris, and has a large blood gas interface (Ref. 1). Gaseous emboli present no problem in the use of this filter, nor do excessive erythrocytes, because only a small percentage of the total blood pumped passes through the cardiotomy filter system. The particle size range estimated to be of importance is probably greater than 20 to 25 microns (Ref. 2). Several referenced reports note certain advantages of filtering blood during infusions, including decrease in oxygen consumption with the use of filtered blood (Ref. 3). Infusion filters have also been found to keep the lungs free of emboli (Ref. 4). The incidence of pulmonary insufficiency in trauma patients was lower when filtered blood was used (Ref. 5). Studies have shown that blood microfilters accumulate twice as much debris as standard 170-micron infusion set filters (Ref. 6). Reports have also shown that these migrating thrombi, which would be filtered by this device, are associated with neuro-ophthalmic disturbances (Ref. 7). Studies (8) and other cerebral and pulmonary complications (Refs. 6, 9, 10, 11, and 12). While a filter with small pore sizes is a more effective filter, the pores tend to clog easily and thus reduce the filter's capacity. Although it is possible to design a filter with larger pores that could operate for a hour without obstruction, such a filter would miss many potentially harmful microaggregates (Refs. 10, 11, 12, and 13). Filters with large pores also tend to leak aggregates because of pressure extrusion of some particles occluding the pores of the filter (Refs. 10, 11, and 12). Filters currently on the market compromise either capacity or smaller pore size. In the Panel's opinion, for the limited volume of cardipulmonary bypass cardiotomy suction line blood filters handled by the cardiotomy line filter, sufficient filtration efficiency and capacity will be assured through performance standards.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and the inadequate design and cleanliness can lead to potentially de- vittilating or fatal thromboembolism. (b) Particle embolism: Inability of the device of filter properly particles from the blood can lead to potentially de- vittilating or fatal embolism.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass cardiotomy suction line blood filter 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 is necessary to provide assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to 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.


2. Memorandum to the Cardiovascular Device Classification Panel from Richard E. Clark, MD, in the addenda to the minutes of the May 2, 1977 meeting.


Therefore, under the Federal Drug, Food, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 350, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 807 in Subpart E by adding new § 870.4270 as follows:

§ 870.4270 Cardiopulmonary bypass car- diotomy suction line blood filter.

(a) Identification. A cardiopulmonary bypass cardiotomy suction line blood filter is a device used as part of a gas exchange (oxygenator) system to filter nonbiologic particles and emboli (a blood clot or a piece of foreign material flowing in the bloodstream, which will obstruct circulation by blocking a vessel) out of the blood. This device is intended for use in the cardiotomy suction line.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-A, 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 office above between the hours of 9 a.m. and 4 p.m., Monday through Friday.


Joseph P. Hall
Associate Commissioner for Regulatory Affairs.
PROPOSED RULES

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1517]

MEDICAL DEVICES

Classification of Cardiopulmonary Prebypass Filters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary prebypass filters into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation classifying the device be published in the Federal Register 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:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary prebypass filters:

1. Identification: A cardiopulmonary prebypass filter is a device used during priming of the oxygenator circuit to remove particulates or other debris from the circuit prior to initiating bypass. The device is not to be used to filter blood.

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 cardiopulmonary prebypass filter be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. If the device fails to filter particulates from the system during priming, those particles can be introduced into the body during the subsequent perfusion. Performance characteristics, including accuracy, reproductibility, and any limitations on the device's ability to filter particles, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Infusion of foreign particulates: Inadequate design of the filter can lead to unnecessary infusion of foreign particles into the patient which may lead to post bypass neural, renal, or pulmonary complications.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary prebypass filter 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 such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 25 Stat. 1655, 50 Stat. 540-546 (21 U.S.C. 356c, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new §870.4280 as follows:

§870.4280 Cardiopulmonary prebypass filter.

(a) Identification. A cardiopulmonary prebypass filter is a device used during priming of the oxygenator circuit to remove particulates or other debris from the circuit prior to initiating bypass. The device is not to be used to filter blood.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


Joseph P. Hile, Associate Commissioner for Regulatory Affairs.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
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:
Glenn A. Rahmoller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8737 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with regard to the classification of cardiopulmonary bypass adaptors, stopcocks, manifolds, and fittings:

1. Identification: Cardiopulmonary bypass adaptors, stopcocks, manifolds, and fittings are devices used in cardiovascular diagnostic, surgical, and therapeutic applications to interconnect tubing, catheters, or other devices.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that cardiopulmonary bypass adaptors, stopcocks, manifolds, and fittings be classified into class II because the devices are neither life supporting nor life sustaining but are potentially hazardous to health even when properly used. Because the devices are placed directly in contact with the bloodstream they should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the devices should meet a generally accepted satisfactory level of blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of these devices. 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 the potential hazards associated with the inherent properties of the devices and on their personal knowledge of, and experience with, the devices.

5. Risks to health:
   (a) Thromboembolism: inadequate blood compatibility of the materials used in these devices and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboembolism.
   (b) Blood damage: If the materials, surface finish, or cleanliness of these devices are inadequate, damage to the blood may result.
   (c) Blood or infusion fluid loss: Improper mechanical design of the devices can lead to blood or infusion fluid leakage.
   (d) Infection: Sterility of the device must be ensured to prevent infection.

PROPOSED RULES

PROPOSED CLASSIFICATION

The commissioner agrees with the panel's recommendation and proposes that cardiopulmonary bypass adaptors, stopcocks, manifolds, and fittings 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 such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 515, 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 870 in Subpart E by adding new § 870.4290 as follows:

§ 870.4290 Cardiopulmonary bypass adaptors, stopcocks, manifolds, and fittings.

(a) Identification. Cardiopulmonary bypass adaptors, stopcocks, manifolds, and fittings are devices used in cardiovascular diagnostic, surgical, and therapeutic applications to interconnect tubing, catheters, or other devices.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


J. Joseph P. Hill
Associate Commissioner for Regulatory Affairs

[FR Doc. 79-6559 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

(Docket No. 78N-1519)

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Gas Control Units

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass gas control units into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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.


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:
Glenn A. Rahmoller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8737 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification
of cardiopulmonary bypass gas control unit.

1. Identification: A cardiopulmonary bypass gas control unit is a device used to control and measure the flow of gas into the oxygenator. The device is calibrated for a specific gas.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that cardiopulmonary bypass gas control units be classified into class II because the device is neither life-sustaining nor life-supporting, but improper gas flow rates allowed by the device are potentially hazardous to life and health. Performance characteristics, including accuracy, reproducibility, and any limitations on the device’s flow control, should be maintained at a generally satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the 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 the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Inadequate gas transfer: Inaccuracy or instability of the flow control can lead to inadequate or excessive gas transfer.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel’s recommendation and is proposing that the cardiopulmonary bypass gas control unit 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 such assured classification.

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 U.S.C. 360c, 371(a)), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4300 as follows:

§ 870.4300 Cardiopulmonary bypass gas control unit.

(a) Identification. A cardiopulmonary bypass gas control unit is a device used to control and measure the flow of gas into the oxygenator. The device is calibrated for a specific gas.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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. The Commissioner proposes to amend the classification of this device because general controls alone would not provide sufficient control over the performance characteristics of this device. The Panel recommends that establishing a classification for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass coronary pressure gauge be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Performance characteristics, including accuracy, reproducibility, and any limitations on the device’s measurement of the pressure in the coronary artery should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. This device is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. The Panel believes that general controls alone would not provide sufficient control over the 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
PROPOSED RULES

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposal and related comments. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass pulsatile flow generators:

1. Identification: A cardiopulmonary bypass pulsatile flow generator is an electrically and pneumatically operated device used to create pulsatile blood flow. The device is placed in a cardiopulmonary bypass circuit downstream from the oxygenator.

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 cardiopulmonary bypass pulsatile flow generator be classified into class III because, although this device is neither life-supporting nor life-sustaining, it is potentially hazardous to life or health even when properly used, and because there are insufficient data to establish the safety and effectiveness of this device. This device is attached to the body through the blood and the extracorporeal oxygenator circuit and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Although the device releases an acceptable energy level into the bloodstream when functioning properly, unsafe energy levels may be released if the device malfunctions. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to provide pulsatile flow, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. In addition, the performance characteristics of the device are not well-defined and the data on them are insufficient to establish a performance standard. The Panel believes that premarket approval is necessary 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 the potential hazards associated

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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

Risks to health: (a) Inadequate or excessive blood supply to the coronary arteries: If the zero or calibration of the device is inaccurate or unstable, the device may generate false pressure readings. If false pressure readings are used in managing the patient, inadequate or excessive blood may be supplied to the coronary arteries.

(b) Cardiac arrhythmias or electrical shock: If the device is electrically powered, excessive electrical leakage current can disturb the normal electrophysiological characteristics of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass coronary pressure gauge 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 on the device to establish a standard to 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 870 in Subpart E by adding new § 870.4310 as follows:

§ 870.4310 Cardiopulmonary bypass coronary pressure gauge.

(a) Identification. A cardiopulmonary bypass coronary pressure gauge is a device used in cardiovascular bypass surgery to measure the pressure of the blood perfusing the coronary arteries.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6261 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

(Docket No. 78N-15211)

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Pulsatile Flow Generators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a regulation classifying cardiopulmonary bypass pulsatile flow generators into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular 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.


The Commissioner of Food and Drugs proposes that the final regulation based on this proposed regulation 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:

Glenn A. Rahmoeiler, Bureau of Medical Devices (HFZ-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8775 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

FEDERAL REGISTER, VOL. 44, NO. 43—FRIDAY, MARCH 9, 1979
with the inherent properties of the device and on their personal knowledge of, and experience with, the device. The Commissioner believes that data do not exist to demonstrate the safety and efficacy of the device and that clinical trials are currently the only method capable of establishing safety and efficacy.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Blood damage: If the materials, surface finish, cleanliness, or mechanical design of this device are inadequate, damage to the blood may result. (c) Thromboembolism: Inadequate blood compatibility of the materials used in this device, inadequate surface finish and cleanliness, or mechanical design may lead to potentially debilitating or fatal thromboembolism. (d) Gas embolism: Rupture of the pumping bladder or a leak in the pumping chamber can allow potentially debili-
tating or fatal emboli to escape into the bloodstream.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing to amend the cardiopulmonary bypass pulseatile flow generator be classified into class III (premarket approval). After reviewing the literature, FDA has found that pulseatile flow in oxygenator circuits is a major topic of debate. The hazards of pulseless flow at a rate less than 100 milliliters per kilogram per minute have been listed as metabolic acidosis, weight gain, edema, visceral pooling, capillary stasis, operarterial venous shunt, and decreased lymph flow (Ref. 1). However, at greater flow rates it is stated that none of these changes is apparent and no significant physiological differences occur. Increased renal production has also been shown to occur with pulseless flow (Refs. 2 and 3), and it has been hypothesized that reduced reticuloendothelial system phagocytic function (white blood cell defensive function) can occur due to prolonged pulseless flow (Ref. 4). On the other hand, pulseatile flow has been indicated in increased blood damage and a greater chance of rupture or leaks in the extracorporeal circuit (Refs. 2 and 5). The data to support either side of this controversy are not convincing. The Commissioner believes the device is purported or represented to be for use in establishment of pulseatile flow through the cardiopulmonary bypass circuit which may be of substantial importance in preventing impairment of human health. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this 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.

6. Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360a, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new §870.4320 as follows:

§870.4320 Cardiopulmonary bypass pulseatile flow generator.
(a) Identification. A cardiopulmonary bypass pulseatile flow generator is an electrically and pneumatically operated device used to create pulseatile blood flow. The device is placed in a cardiopulmonary bypass circuit downstream from the oxygenator.
(b) Classification. Class III (premarket approval).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments to the above address. 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 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6263 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

(Docket No. 79N-1522)

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass On-line Blood Gas Monitors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a public comment a proposed regulation classifying cardiopulmonary bypass on-line blood gas monitors into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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:

Glenn A. Rahmoslier, Bureau of Medical Devices (HIFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of FEDERAL REGISTER provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification
of cardiopulmonary bypass on-line blood gas monitors:

1. Identification: A cardiopulmonary bypass on-line blood gas monitor is a device used in conjunction with a blood gas sensor to measure the level of gases in the blood.

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 cardiopulmonary bypass on-line blood gas monitors be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is attached to the cardiopulmonary bypass circuit through a transducer and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical characteristics of this device. The Panel believes that a performance standard would 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to intravenous complications. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, the device may generate inaccurate diagnostic information. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

**PROPOSED CLASSIFICATION**

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass on-line blood gas 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 such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 80 Stat. 540-546 (21 U.S.C. 360e, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new §870.4330 as follows:

§870.4330 Cardiopulmonary bypass on-line blood gas monitor.
(a) Identification. A cardiopulmonary bypass on-line blood gas monitor is a device used in conjunction with a blood gas sensor to measure the level of gases in the blood.
(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5500 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. Written comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.


JOSEPH P. HILE
Associate Commissioner for Regulatory Affairs.

(FR Doc. 79-6264 Filed 3-8-79; 8:45 am)

[4110-03-M]

[21 CFR Part 870]
(Docket No. 78N-1523)

**MEDICAL DEVICES**

Classification of Cardiopulmonary Bypass Level sensing Monitors and/or Controls

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The food and Drug Administration (FDA) is issuing for public comment a proposed rule amending the cardiopulmonary bypass level sensing monitor and/or controls into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 1979. The Commissioner of Food and Drugs proposes that the final regulation based on this proposal becomes 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, 5500 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoller, Bureau of Medical Devices (HFE-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass level sensing monitors and/or controls:

1. Identification: A cardiopulmonary bypass level sensing monitor and/or control is a device used to monitor and/or control the level of blood in the blood reservoir and to sound an alarm when the level falls below a predetermined value.

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 cardiopulmonary bypass level sensing monitor and/or control be classified into class II because the device is neither life-supporting nor
PROPOSED RULES

life-sustaining, but loss of reservoir volume undetected and/or uncontrolled by the device is potentially hazardous to life and health. This device is attached by a cardiopulmonary bypass circuit through a transducer and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device’s sensing and measurement of the blood level in the reservoir, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the performance and electrical 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Introduction of air into the extracorporeal blood circuit: If the sensing circuit or alarm is inaccurate or unreliable, the level of blood in the reservoir could fall to zero and allow air to enter the extracorporeal blood circuit.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel’s recommendation and is proposing that the cardiopulmonary bypass level sensing monitor and/or control 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 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 870 in Subpart E by adding new §870.4340 as follows:

§870.4340 Cardiopulmonary bypass level sensing monitor and/or control.

(a) Identification. A cardiopulmonary bypass level sensing monitor and/or control is a device used to monitor and/or control the level of blood in the blood reservoir and to sound an alarm when the level falls below a predetermined value.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


Joseph P. Hile, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6385 Filed 3-8-79; 8:45 am] [4110-03-M] [21 CFR Part 870] (Docket No. 78N-1524)

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Oxygenators

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 cardiopulmonary bypass oxygenator into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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:

Glenn A. Rahmboeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass oxygenators:

1. Identification: A cardiopulmonary bypass oxygenator is a device used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during open-heart surgery.

2. Recommended classification: Class III (premarket approval). The Panel recommends that this approval of this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass oxygenator be classified into class III because this device is life-supporting and presents a potential unreasonable risk of illness or injury. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize foreign body reactions and disruption of normal blood flow. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to exchange gas, and to minimize blood damage and particulate generation, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
would not provide sufficient control over the performance characteristics of this device. The Panel members also believe that insufficient medical data exist concerning the performance and design characteristics of the device to establish a performance standard to provide reasonable assurance of the device's safety and effectiveness. Therefore, the Panel believes that this device needs to be subject to premarket approval.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device, their personal knowledge of, and experience with, the device, and the lack of sufficient scientific and medical data to enable the development of performance standards to assure the safety and effectiveness of the device.

5. Risks to health: (a) Blood damage: If the materials, surface finish, or cleanliness of this device are inadequate, damage to the blood may result. (b) Inadequate or excessive gas transfer: Improper design of the gas transfer mechanism can lead to this hazard. (c) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboembolism. (d) Gas embolism: Inadequate debubbling, filtering, or separation of the gas and blood phases can lead to potentially debilitating or fatal gas embolism.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass oxygenator be classified into class III (premarket approval). The Commissioner believes that the device is purposed or represented to be for a use (providing oxygen and carbon dioxide transfer for the blood during cardiopulmonary bypass operations) in support of or sustaining human health. The act requires the Commissioner to classify a life supporting or sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that sufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this 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. 366c, 371(a)(2)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new §870.4350 as follows:

§870.4350 Cardiopulmonary bypass oxygenator.

(a) Identification. A cardiopulmonary bypass oxygenator is a device used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during open-heart surgery.

(b) Classification. Class III (premarket approval).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, 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.


JOSEPH P. HILE
Associate Commissioner
Regulatory Affairs

[FR Doc. 79-6256 Filed 3-8-79; 8:45 am]

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendations regarding the classification of nonroller-type cardiopulmonary bypass blood pumps:

1. Identification: A nonroller-type cardiopulmonary bypass blood pump is a device that uses a method other than revolving rollers to pump the blood through the cardiopulmonary bypass circuit during bypass surgery.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the nonroller-type cardiodlmonary bypass blood pump be classified into class III because this device is life supporting and sustaining and is potentially hazardous to life or health even when properly used. This device is attached directly to the cardiopulmonary bypass circuit and is used in a clinical environment where excessive leakage current can be a serious hazard. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, or maintained. The Panel believes that general controls alone do not provide sufficient control over the performance characteristics of this device. The Panel also believes that a performance standard would not provide reasonable assurance of the safety and effectiveness of the device and, moreover, that there is not 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Panel reviewed the medical literature. At present, there are several types of blood pumps available. These types can be divided into two pulsatile blood pumps and nonpulsatile flow pumps. Pulsatile pumps are of a diaphragmatic, pneumatic, piston, bellows, or bar compression design (Ref. 1). There are three main issues concerning blood pumps that are addressed in the literature: (1) the advantages and disadvantages of pulsatile flow (Refs. 1 through 3 and 5 through 12), (2) the effect of occlusive versus nonocclusive roller pressure (Refs. 1 through 4), and (3) the effect on the patient of particulate, including any developed by the pump, from the extracorporeal circuit (Refs. 13 through 17). The controversy over pulsatile flow is the major topic of debate in the literature. Nose (Ref. 1) listed the hazards of pulseless flow of a rate less than 100 milliliters per kilogram per minute as metabolic acidosis, weight gain, edema, splanchic pooling, capillary stasis, opening of the arterial venous shunt, and decreased lymph flow. However, at greater flow rates it is stated that none of these changes are apparent and no significant physiological differences occur. Increased renal production has also been shown to occur with pulseless flow (Refs. 2 and 5), and usserow et al. (Ref. 6) have hypothesized that reduced reticuloendothelial system phagocytic function (white blood cell defensive function) can occur due to prolonged pulseless flow. Bartlett (Refs. 2 and 3) indicates that many of the problems of pulseless flow can be controlled and that, because of pulsatile flow through narrow caliber blood vessels, blood velocity increases causing increased hemolysis and a greater chance of rupture or leaks. Therefore, he believes a roller pump to be the equipment of choice. However, many authors (Refs. 5 through 12) disagree with this position and favor pulsatile flow. It does not appear that this conflict will be resolved easily or in the near future. From the literature reviewed, the Panel believes that sufficient data do not exist to establish adequate performance standards to assure the safety and effectiveness of nonpulsatile cardiopulmonary bypass pumps.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage can also cause electrical shock to a patient during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Blood damage: If the materials, surface finish, or geometry of these devices are inadequate, damage to the blood may result. Improper mechanical design of the device can also lead to this hazard. (c) Variability in stroke volume: The design of the pump head and the torque developed by the pump are characterized by those that can lead to variability in stroke volume. (d) Embolism: Improper design of the device may cause the generation of gaseous, particulate, or thrombotic embolisms, which may be debilitating or fatal.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that nonroller-type cardiopulmonary bypass blood pumps be classified into class III (premarket approval). The Commissioner believes the device is purposed or represented to be for a use (pumping the blood through the cardiopulmonary bypass circuit) in supporting or sustaining human health. The act requires the Commissioner to classify a "life-supporting or life-sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

References

The following information has been placed in the office of the Hearing Clerk (address above) any may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.


Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-516 (21 U.S.C. 360, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new §870.4360 as follows:

§870.4360 Nonroller-type cardiopulmonary bypass blood pump.

(a) Identification. A nonroller-type cardiopulmonary bypass blood pump is a device that uses a method other than revolving rollers to pump the
FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFZ-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8707 Georgia Ave., Silver Spring, MD 20201, 301-427-7559.

SUPPLEMENTARY INFORMATION:

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of roller-type cardiopulmonary bypass blood pumps:

1. Identification: A roller-type cardiopulmonary bypass blood pump is a device that uses a revolving roller mechanism to pump the blood through the cardiopulmonary bypass circuit during bypass surgery.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: Although this device is life-supporting, the Panel recommends that the cardiopulmonary bypass roller-type blood pump be classified into class II. This electrically powered device pumps the blood through the extracorporeal blood circuit, is directly attached to the cardiopulmonary bypass circuit, and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to pump the blood, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device, plus technical knowledge of, and experience with, the device. In addition, the Panel reviewed the medical literature concerning this device and found further support for their recommendation. At present, there are several blood pumps available. These can be divided into two categories, namely, pulsatile flow pumps and nonpulsatile flow pumps. The pulsatile pump is an example of a nonpulsatile type of pump. If the blood pump is used in cardiopulmonary bypass because it is reliable, durable, and easy to regulate and operate (Ref. 3). There are three main issues concerning blood pumps that are important to patients that have blood by-pass surgery. The advantages and disadvantages of pulsatile flow (Refs. 1 through 3, and 5 through 12), the effect of occlusive versus nonocclusive roller pump (Refs. 1 through 4), and the effect on the patient of particularities of the pump developed any developed by the blood pump, from the extracorporeal circuit (Refs. 13 through 17). Bartlett (Refs. 2 and 3) indicates that many of the problems of pulsatile flow can be reduced and that, because of pulsatile flow through the narrow cannula, less thrombus is formed. Therefore, Bartlett believes a pump to be the best choice. The literature indicates concern over blood damage caused during compression of the pump tubing by the rollers. Hemolysis was the main problem addressed in this regard. Nosé (Ref. 1) states that increased hemolysis increases directly with the number of rollers on the pump and the occlusive pressure applied by these rollers. This is supported by Bernstein and Gleason (Ref. 4). However, Bartlett (Ref. 2) indicates no difference in hemoysis between "almost" occlusive and completely occlusive pressure settings. Nosé (Ref. 1) and Bernstein and Gleason (Ref. 4) mention an occlusive pressure sufficient to support a diameter of water as being the proper adjustment. Bartlett (Ref. 3) recommended 150 centimeters of water as the proper adjustment. In general, occlusive settings are accepted because they allow accurate flow calibration, have the feature of positive displacement, and their output does not depend on the resistance of the extracorporeal circuit (Ref. 1). The risk of occlusion and the effectiveness of roller pumps is proved daily by the results of thousands of cardiopulmonary bypass operations. The Panel believes that sufficient technical and clinical information is available to establish performance standards for blood pumps used in cardiopulmonary bypass surgery.

5. Risks to health: (a) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of car-
POPROSED RULES

The Commissioner agrees with the Panel’s recommendation and is proposing that the roller-type cardiopulmonary bypass pump be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by the manufacturer 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 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.

18. Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 511, 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 870 in Subpart E by adding new § 870.4370 as follows:

§ 870.4370 Roller-type cardiopulmonary bypass pump.

(a) Identification. A roller-type cardiopulmonary bypass pump is a device which uses a revolving roller mechanism to pump the blood through the cardiopulmonary bypass circuit during bypass surgery.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HFA-303), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20207, 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 9 a.m. and 4 p.m., Monday through Friday.


Joseph P. Hile, Associate Commissioner
for Regulatory Affairs.

[FEDERAL REGISTER, VOL 44, NO. 48—FRIDAY, MARCH 9, 1979]
A proposal elsewhere in this issue of the Federal Register provides back-
ground information concerning the de-
velopment of the proposed regulation.
The Cardiovascular Device Classifica-
ton Panel, and FDA advisory commit-
te, made the following recommendation:
with respect to the classification of
cardiopulmonary bypass pump speed:

1. Identification: A cardiopulmonary
pump speed control is a device that in-
corporates an electrical system or a
mechanical system, or both, and is used
to control the speed of blood pumps
used in cardiopulmonary bypass surgery.

2. Recommended classification: Class
II (performance standards). The Panel
recommends that establishing a per-
formance standard for this device be a
medium priority.

3. Summary of reasons for recom-
mandation: The Panel recommends
that the cardiopulmonary bypass
pump speed control be classified into
Class II because this device is neither
life-supporting nor life-sustaining, but
is potentially hazardous to life or
health even when properly used. This
device is attached to the cardiopul-
monary bypass circuit through the
blood pump and is used in a clinical
environment where excessive leakage
current can be a serious hazard. Thus
the electrical characteristics of this
device, e.g., electrical leakage current,
need to meet certain requirements.
Performance characteristics, including
accuracy, reproducibility, and any
limitations on the device's control of
pump speed, should be maintained at
a generally accepted satisfactory level
and should be made known to the user
through special labeling. The device is
used with other devices in a system
that may be hazardous if not satisfac-
torily assembled, used, and main-
tained. The Panel believes that gener-
al controls alone would not provide
sufficient control over the perfor-
ance and electrical characteristics of
this device. The Panel believes that a
performance standard will provide rea-
sonable assurance of the safety and ef-
fективness of the device and that
there is sufficient information to es-
tablish a standard to provide such
assurance.

4. Summary of data on which the
recommendation is based: The Panel
members based their recommendation
on the potential hazards associated
with the inherent properties of the
device and on their personal knowl-
dge of, and experience with, the
device.

5. Risks to health: (a) Cardiac ar-
rhymias or electrical shock: Exces-
sive electrical leakage current can dis-
turb the normal electrophysiology of
the heart, leading to the onset of car-
diac arrhythmias. Electrical leakage
current can also cause electrical shock
to a physician during a catheterization
or surgical procedure, and this may
lead to iatrogenic complications. (b)
Inadequate or excessive flow: Inaccur-
acy or instability of the control
system can lead to improper flow
rates.

PROPOSED CLASSIFICATION

The Commissioner agrees with the
Panel's recommendation and is pro-
posing that the cardiopulmonary
bypass pump speed control be classi-
fied into class II (performance stan-
dards). The Commissioner believes that
a performance standard is necessary
for this device because general con-
trols by themselves are insufficient to
control the risks to health. A perfor-
mance standard would provide reason-
able assurance of the safety and effec-
tiveness of the device. The Commis-
sioner also believes that there is suffi-
cient information to establish a stan-
dard to provide such assurance.

Therefore, under the Federal Food,
Drug, and Cosmetic Act (secs. 513,
701(a), 52 Stat. 1055, 80 Stat. 540-546
(21 U.S.C. 360e, 371(a))) and under au-
tority delegated to him (21 CFR 5.1),
the Commissioner proposes to amend
Part 870 in Subpart E by adding new
§ 870.4380 as follows:

§ 870.4380 Cardiopulmonary bypass pump
speed control.

(a) Identification. A cardiopulmonary
bypass pump speed control is a device
that incorporates and electrical
system or a mechanical system, or
both, and is used to control the speed
of blood pumps used in cardiopul-
monary bypass surgery.

(b) Classification. Class II (per-
formance standards).

Interested persons may, on or before
May 8, 1979, submit to the Hearing
Clerk (HFA-305), Food 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 hear-
ing clerk docket number found in
brackets in the heading of this docu-
ment. Received comments may be seen
in the above office between the hours
of 9 a.m. and 4 p.m., Monday through
Friday.


JOSEPH P. HILE,
Associate Commissioner
for Regulatory Affairs.

[FR Doc. 79-6299 Filed 3-8-79; 8:45 am]
2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that cardiopulmonary bypass pump tubing be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. This device is part of the extracorporeal oxygenation circuit and is in direct contact with the blood. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Propensity to rupture: The material properties, stiffness, and electrolyte of the tubing are associated with the propensity to rupture. (b) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (c) Embolism: Pieces of the tubing which break or flake off may lead to potentially debilitating or fatal embolism.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass pump tubing 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 such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 80 Stat. 540-546 (21 U.S.C. 356c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4390 as follows:

§ 870.4390 Cardiopulmonary bypass pump tubing.
(a) Identification. Cardiopulmonary bypass pump tubing is polymeric tubing which is used in the blood pump head and which is cyclically compressed by the pump to cause the blood to flow through the cardiopulmonary bypass circuit.
(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6270 Filed 3-6-79; 8:45 am]

4110-03-M

[21 CFR Part 870]

[DOCKET No. 78N-1529]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Blood Reservoirs

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass blood reservoirs into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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.

DATE: Comments by May 8, 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:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass blood reservoirs:

Identification: A cardiopulmonary bypass blood reservoir is a device used in conjunction with short-term extracorporeal circulation devices to hold a reserve, supply of blood in the bypass circulation. (If a reservoir contains a defoamer or filter, it is classified into the same category as the defoamer or filter.)

[2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.]

3. Summary of reasons for recommendation: The Panel recommends that cardiopulmonary bypass blood reservoir be classified into class II because the device is neither life-supporting nor life-sustaining but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of this device and on the personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device or inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Blood damage: If the materials, surface finish, or cleanliness of this device are inadequate, damage to the blood may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel’s recommendation and is proposing that the cardiopulmonary bypass blood reservoir 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 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 870 in Subpart E by adding new §870.4400 as follows:

§870.4400 Cardiopulmonary bypass blood reservoir.

(a) Identification. A cardiopulmonary bypass blood reservoir is a device used in conjunction with short-term extracorporeal circulation devices to hold a reserve supply of blood in the bypass circulation. If a reservoir contains a deoxygenator or filter, it is classified into the same category as the deoxygenator or filter.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILLE, Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6271 Filed 3-6-79; 8:45 am]

PROPOSED RULES

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass In-Line Blood Gas Sensors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass in-line blood gas sensor into Class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the device be classified into Class II. The effect of classifying a device into class II is to provide 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 May 8, 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:

Glenn A. Rahmoller, Bureau of Medical Devices (HFR-450), Food and Drug Administration, Department of Health and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass in-line blood gas sensors:

1. Identification: A cardiopulmonary bypass in-line blood gas sensor is a transducer that measures the level of gases in the blood.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass in-line blood gas sensor be classified into Class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream it should be designed and constructed minimizes foreign body reactions and disruption of normal blood flow. This device is attached to the body through an extracorporeal blood circuit and is used in a clinical environment where leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to sense gas levels, should be maintained at a generally acceptable satisfactory level and should be made known to the user through special labeling. The device is used with other devices in a system that may be hazardous if not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of this device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Missdiagnosis: Inadequate design with regard to blood gas information can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. (b) Embolism: Breakage of the sensor can form potentially debilitating or fatal particle emboli. (c) Blood damage: If the materials, surface finish, or cleanliness of this
device are inadequate, damage to the blood may result. (d) Toxic reaction: Breakage of the sensor can release toxic chemicals from the sensor into the bloodstream and cause a toxic reaction.

**PROPOSED CLASSIFICATION**

The Commissioner agrees with the Panel’s recommendation and is proposing that the cardiopulmonary bypass in-line blood gas sensor 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 such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 50 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4410 as follows:

§ 870.4410 Cardiopulmonary bypass in-line blood gas sensor.

(a) Identification. A cardiopulmonary bypass in-line blood gas sensor is a transducer that measures the level of gases in the blood.

(b) Classification. Class II (performance standards).

**PROPOSED RULES**

| [4110–03–M] |
| [21 CFR Part 870] |
| (Docket No. 78N–1531) |

**MEDICAL DEVICES**

**Classification of Cardiopulmonary Bypass Cardiomyotomy Return Suckers**

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed Rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass cardiomyotomy return suckers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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:**


**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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass cardiomyotomy return suckers:

1. Identification: A cardiopulmonary bypass cardiomyotomy return sucker is a device that consists of tubing, a connector, and a probe or tip that is used to remove blood from the chest or heart during cardiopulmonary bypass surgery.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass cardiomyotomy return sucker be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Because the device is placed directly in contact with the bloodstream, it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Tissue and blood damage. If the materials, surface finish, or cleanliness of this device are inadequate, or if the probe tip is not designed properly, damage to the blood and tissue may result. (b) Damage to the heart: If the probe is too rough or too stiff damage to the heart may result.

**PROPOSED CLASSIFICATION**

The Commissioner agrees with the Panel’s recommendation and is proposing that the cardiopulmonary bypass cardiomyotomy return sucker 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 such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 50 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 870 in Subpart E by adding new § 870.4410 as follows:

---

**FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979**
§ 870.4420 Cardiopulmonary bypass cardiotomy return sucker.

(a) Identification. A cardiopulmonary bypass cardiotomy return sucker is a device that consists of tubing, a connector, and a probe or tip that is used to remove blood from the chest or heart during cardiopulmonary bypass surgery.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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 the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.


JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6273 Filed 3-8-79; 8:45 a.m.]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1532]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Intracardiac Suction Controls

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cardiopulmonary bypass intracardiac suction controls into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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.


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 COMMENT CONTACT:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Georgia Ave., Silver Spring, MD 20910, 301-427-7555.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass intracardiac suction controls:

1. Identification: A cardiopulmonary bypass intracardiac suction control is a device which provides the vacuum and control for a cardiotomy return sucker.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass intracardiac suction control be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life and health even when properly used. The device develops a vacuum through an electrically powered source to permit the suction of blood from the chest cavity during open heart surgery. This device is attached to the body through the blood and is used in a clinical environment where excessive leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. Electrical leakage current can also cause electrical shock to a physician during a catheterization or surgical procedure, and this may lead to iatrogenic complications.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel’s recommendation and is proposing that the cardiopulmonary bypass intracardiac suction control 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 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 870 in Subpart B by adding new § 870.4430 as follows:

§ 870.4430 Cardiopulmonary bypass intracardiac suction control.

(a) Identification. A cardiopulmonary bypass intracardiac suction control is a device which provides the vacuum and control for a cardiotomy return sucker.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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 the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

FEDERAL REGISTER, VOL 44, NO. 48—FRIDAY, MARCH 9, 1979
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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

(FR Doc. 79-6274 Filed 3-6-79; 8:45 am)

PROPOSED RULES

tee, made the following recommendation with respect to the classification of vascular clamps:

1. Identification: A vascular clamp is a surgical instrument used to occlude a blood vessel temporarily.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel believes that the vascular clamp be classified into class II because the device is neither life-supporting nor life-sustaining, but is potentially hazardous to life and health even when properly used. The materials used in the device should be generally acceptable for surgical application, and the mechanical design of the device should minimize tissue damage. Pressure applied to a blood vessel should be great enough to stop the flow of blood but not so great as to cause tissue damage. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Tissue damage which may lead to thrombus formation: Improper mechanical design, inadequate tissue compatibility of the materials used in this device, or inadequate surface finish, and cleanliness, may lead to tissue damage which can cause potentially debilitating or fatal thrombus formations.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the vascular 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 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 870 in Subpart E by adding new §870.4450 as follows:

§870.4450 Vascular clamp.

(a) Identification. A vascular clamp is a surgical instrument used to occlude a blood vessel temporarily.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

(FR Doc. 79-6275 Filed 3-8-79; 8:45 am)
A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of surgical vessel dilators:

1. Identification: A surgical vessel dilator is a device used to enlarge or calibrate a vessel.

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 surgical vessel dilator be classified into class II because the device is neither life-supporting nor life-sustaining, but is potentially hazardous to life and health even when properly used. Because the device is placed in direct contact with the bloodstream and the vessel walls it should be designed and constructed to minimize blood and tissue damage. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Damage to the vessel. If the materials, surface finish or cleanliness of the device are inadequate, damage to the vessel may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the surgical vessel dilator 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 such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 50 Stat. 540-549 (21 U.S.C. 360s, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4475 as follows:

§ 870.4475 Surgical vessel dilator.

(a) Identification. A surgical vessel dilator is a device used to enlarge or calibrate a vessel.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit 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 by 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.


JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6276 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

(Docket No. 78N-1535)

MEDICAL DEVICES

Classification of Cardiovascular Surgical 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 cardiovascular surgical instruments into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.
PROPOSED RULES


JOSEPH P. EIL, Associate Commissioner for Regulatory Affairs.

[FDR Doc. 79-6278 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870].

(Docket No. 78N-1536)

MEDICAL DEVICES

Classification of Intraluminal Artery Strippers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying intraluminal artery strippers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the intraluminal artery stripper be classified into class II because the device is neither life-supporting nor life-sustaining but is potentially hazardous to life and health even when properly used. The materials used in the device and the mechanical design of the device should meet a generally accepted satisfactory level for surgical applications and should minimize the possibility of vessel perforation. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Predisposition to perforation of the vessel: Improper mechanical design and surface finish can lead to vessel perforation.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that cardiovascular surgical instruments 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 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 870 in Subpart E by adding new § 870.4500 as follows:

§ 870.4500 Cardiovascular surgical instruments.

(a) Identification. Cardiovascular surgical instruments are surgical instruments that have special features for use in cardiovascular surgery. These devices include, e.g., forceps, retractors, and scissors.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HPA-305), Food and Drug Administration, Rm. 4-65, 5800 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.

FEDERAL REGISTER, VOL. 44, NO. 48—FRIDAY, MARCH 9, 1979
form an endarterectomy (removal of plaque deposits from arteriosclerotic arteries).

(b) **Classification.** Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HPA-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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

(FR Doc. 79-6278 Filed 3-8-79; 8:45 am)

[4110-03-M]

[21 CFR Part 870]

(Docket No. 78N-1537)

**MEDICAL DEVICES**

Classification of External Vein Strippers

AGENCY: Food and Drug Administration.

**ACTION: Proposed Rule.**

**SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying external vein strippers into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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 (HPA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.**

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoeuler, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Silver Spring, MD 20910, 301-427-7559.

**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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of external vein strippers:

1. Identification: An external vein stripper is an extravascular device used to remove a section of a vein.

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 external vein stripper be classified into class II because this device is neither life-supporting nor life-sustaining but is potentially hazardous to life and health even when properly used. Because this device is used in cardiovascular surgery and comes into direct contact with the body, materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Tissue damage: If the materials, surface finish, or cleanliness of this device are inadequate, damage to the tissue may result.

**Proposed Classification:**

The Commissioner agrees with the Panel's recommendation and is proposing that the external vein stripper 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 such assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-545 (21 U.S.C. 360c, 311(a))) and under authority delegated to him (21 CFR 5.1), the commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4885 as follows:

§ 870.4885 External vein stripper.

(a) **Identification.** An external vein stripper is an extravascular device used to remove a section of a vein.

(b) **Classification.** Class II (performance standards).

Interested persons may, on or before May 8, 1979 submit to the Hearing Clerk (HPA-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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

(FR Doc. 79-6278 Filed 3-8-79; 8:45 am)

[4110-03-M]

[21 CFR Part 870]

(Docket No. 78N-1538)

**MEDICAL DEVICES**

Classification of Patient Care Suction Apparatus

AGENCY: Food and Drug Administration.

**ACTION: Proposed rule.**

**SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying patient care suction apparatus into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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 (HPA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.**
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 May 8, 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:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendations with respect to the classification of patient care suction apparatus:

1. Identification: A patient care suction apparatus is a device used with an intrathoracic catheter to withdraw fluid from the chest during the recovery period following surgery.

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 patient care suction apparatus be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. The device is connected to the chest cavity via a catheter, providing a direct electrical pathway to the chest. Suction is developed electrically in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel’s recommendation and is proposing that the patient care suction apparatus 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 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. 356c, 571(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 by adding Subpart F and new §870.5050 as follows:

Subpart F—Cardiovascular Therapeutic Devices

§870.5050 Patient care suction apparatus.

(a) Identification. A patient care suction apparatus is a device which is used with an intrathoracic catheter to withdraw fluid from the chest during the recovery period following surgery.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.

PROPOSED RULES


JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6280 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1539]

MEDICAL DEVICES

Classification of Embolectomy Catheters

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule classifying embolectomy catheters into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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.

DATE: Comments by May 8, 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:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendations with respect to the classification of patient care suction apparatus:

1. Identification: An embolectomy catheter is a balloon-tipped catheter that is used to remove thromboemboli, i.e., blood clots which have migrated...
from blood vessels from one site in the vascular system to another.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the embolectomy catheter be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life and health when properly used. Because it is placed directly in contact with the bloodstream, the device should be designed and constructed to minimize hemodynamic disruption and any foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, with the degree of compatibility. In addition, the material used for the balloon should not be excessively permeable to gas and should resist bursting under pressure at an accepted standard limit. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal thromboemboli. (b) Embolism: Pieces of the catheter that break or flake off may form emboli which can be debilitating or fatal. (c) Gas embolism: A rupture or leak in the balloon can allow potentially debilitating or fatal gas emboli to escape into the bloodstream. (d) Damage to blood vessels: Overinflation of the balloon can lead to excess pressure on the blood vessels and cause damage to them.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the embolectomy 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 such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sects. 515, 701(a), 52 USCA 1655, 50 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 870 in Subpart F by adding new § 870.5150 as follows:

§ 870.5150 Embolectomy catheter.

(a) Identification. An embolectomy catheter is a balloon-tipped catheter that is used to remove thromboemboli, i.e., blood clots which migrate from blood vessels from one site to another in the vascular tree.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5800 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.


JOSEPH P. HILE
Associate Commissioner for Regulatory Affairs

[FR Doc. 79-3281 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1540]

MEDICAL DEVICES

Classification of Septostomy 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 septostomy catheters into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Devices 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.

DATE: Comments by May 8, 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, 5800 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Rahmoller, Bureau of Medical Devices (HFA-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8717 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of septostomy catheters:

1. Identification: A septostomy catheter is a special balloon catheter that is used to create or enlarge the atrial septal defect found in the heart of infants.

2. Recommended classifications: 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 septostomy catheter be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life and health even when properly used. Because the device is placed directly in contact with the bloodstream it should be designed and constructed to minimize disruption of normal blood flow and foreign body reactions. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility, including requirements for adequate surface finish and cleanliness which may affect the degree of compatibility. In addition, the balloon should resist bursting under pressure at an acceptable limit. The Panel believes that general controls alone would not provide sufficient control
over the 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 the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness may lead to potentially detrimental or fatal thromboembolism. (b) Embolism: Pieces of the catheter that break or flake off may form embolus which can be debilitating or fatal.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the septostomy catheters 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 such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 513, 501(a), 52 Stat. 1055, 90 Stat, 540-546 (21 U.S.C. 380c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend 21 CFR Part 870 in Subpart F by adding new § 870.5175 as follows:

§870.5175 Septostomy catheter.

(a) Identification. A septostomy catheter is a special balloon catheter that is used to create or enlarge the atrial septal defect found in the heart of infants.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILL
Associate Commissionerfor Respiratory Affairs.

[FR Doc. 79-6282 Filed 3-6-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

(Docket No. 78N-1541)

MEDICAL DEVICES

Classification of External Cardiac Compressors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying external cardiac compressors into class III (premarket approval). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel and the Anesthesiology Device Classification Panel that the device be classified into class III, and the recommendation of the General Hospital and Personal Use Device Classification Panel, that manually operated external cardiac compressors be classified into class III and that pneumatically and electrically powered external cardiac compressors be classified into class II.


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:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFK-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8157 Georgia Ave., Silver Spring, Md. 20910, 301-427-7829.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register proposes a ground information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, the Anesthesiology Device Classification Panel, and the General Hospital and Personal Use Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of external cardiac compressors:

1. Identification: An external cardiac compressor is an external device that is electrically, pneumatically, or manually powered and is used to compress the chest periodically in the region of the heart to provide blood flow during cardiac arrest.

2. Recommended classification: The Cardiovascular Device Classification Panel and the Anesthesiology Device Classification Panel recommend that external cardiac compressors be classified into class III (premarket approval) and that premarket approval of this device be a medium priority. The General Hospital and Personal Use Device Classification Panel recommends that manually operated external cardiac compressors be classified into class III and that pneumatically and electrically powered external cardiac compressors be classified into class II.

3. Summary of reasons for recommendations: The Cardiovascular Device Classification Panel and the Anesthesiology Device Classification Panel recommend that external cardiac compressors be classified into class III because this device is life-supporting and is potentially hazardous to life or health even when properly used. This device is attached directly to the body and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's compression rate and applied force, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The surface area of the plunger and the use of the device on infants and children are subjects which should be considered in the design and labeling of the device. The Panels believe that general controls alone would not provide sufficient control over the performance characteristics of this device. The Panels also believe that a performance standard will not provide reasonable assurance of the safety and effectiveness of the device and that there is not sufficient information to establish a standard to provide such assurance.
The General Hospital and Personal Use Device Classification Panel agrees with the Class III recommendation for manual external cardiac compressors, but believes that, for pneumatically and electrically powered external cardiac compressors, a performance standard would 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 recommendations are based: The Panel members based their recommendations on the potential hazards associated with the inherent properties of the device. Seven doctors' personal knowledge of, and experience with, the device. In addition, the Panels found further support for their recommendations in the medical literature. This device has the advantage of efficiency and ease of use (Refs. 1 through 4). An external cardiac compressor does offer several advantages to the trained operator. The automatic compressor frees the operator and allows the performance of other duties (Refs. 3 and 4). Little, et al. (Ref. 3) claim that external cardiac compressors operate well during patient transport and control sternal deflection more precisely than does manual chest compression (CPR). However, safe and effective use of this device requires extensive operator training, and there is a hazard associated with the required setup time during which cardiac compression is halted (Refs. 3 and 4). Sledband (Ref. 6) and other hazards are associated with the use of the device. The device can cause fractures of the ribs and sternum (Refs. 5, 6, 8, and 9), lung (Refs. 5, 6, 8, and 9); and possible bone marrow emboli (Ref. 8). However, these injuries can also result from manual CPR and are relatively minor compared to the serious nature of cardiopulmonary arrest. The literature offers conflicting evidence regarding the efficacy of the external cardiac compressor as compared to manual CPR (Refs. 5, 7, 9, and 10). However, the device is not designed to replace manual CPR. The literature seems to recommend it for certain situations such as long-term applications and patient transport. Although some preliminary standards for the external cardiac compressor have been researched, addressing such parameters as compression rate, force, systolic/diastolic time interval, and degree of sternal deflection (Refs. 1 and 11), the Panels believe those efforts are inadequate to provide reasonable assurance of the safety and effectiveness of the device.

5. Risks to health: (a) Tissue damage, bone breakage, or inadequate blood flow: Damage to the heart, other organs or tissues, or inadequate blood flow can result from poor mechanical design, improper surface area of the plunger, improper vertical excursion of the plunger, improper force applied by the plunger, or improper energy transmission by the device. (b) Cardiac arrhythmias or electrical shock: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias.

PROPOSED CLASSIFICATION

The Commissioner agrees with the recommendations of the Cardiovascular Device Classification Panel and the Anesthesiology Device Classification Panel, and is proposing that the external cardiac compressor be classified into class III (premarket approval). The Commissioner believes the device is purposed or represented to be for a use (for mechanically pumping the heart during cardiopulmonary resuscitation) in supporting or sustaining human health. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify a life-supporting or life-sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

REFERENCES

The following information has been placed in the office of the Hearing Clerk (office above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.


Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 50 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 870 in Subpart P by adding new § 870.5200 as follows:

§ 870.5200 External cardiac compressor.

(a) Identification. An external cardiac compressor is an external device that is electrically, pneumatically, or manually powered and is used to compress the chest periodically in the region of the heart to provide blood flow during cardiac arrest.

(b) Classification. Class III (premarket approval).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.
proposing that the external counter-pulsating device be classified into class III (premarket approval). The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 840-846 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart F by adding new § 870.5225 as follows:

§ 870.5225 External counter-pulsating device.
(a) Identification. An external counter-pulsating device is a noninvasive device used to assist the heart by applying positive or negative pressure to one or more of the body's limbs in synchrony with the heart cycle.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the external counter-pulsating device be classified into class III because this electrically or pneumatically powered device is life-supporting and is potentially hazardous to life or health even when properly used. This device surrounds the limbs to which it is attached, is in direct contact with the skin, and is used in a clinical environment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's cardiac synchronizaton and pressure application, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The device is used with other equipment, and the device and other equipment may be used by personnel who are not satisfactorily assembled, used, and maintained. The Panel believes that general controls alone would not provide sufficient control over the electrical characteristics of this device. The Panel also believes that there is not sufficient information to establish a performance standard to provide assurance of the safety and effectiveness of the device and, therefore, that premarket approval is necessary for this device.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Trauma to the limb: Improper mechanical design can cause trauma to the limb to which the device is applied. (c) Ineffective cardiac assistance: Improper timing or a failure to synchronize with the appropriate phase of the cardiac cycle can lead to ineffective cardiac assistance by the device.

The Commissioner agrees with the Panel recommendation and is proposing that the external counter-pulsating device be classified into class III (premarket approval). The Commissioner believes that the device is potentially hazardous, even if properly used, and that premarket approval is necessary to provide reasonable assurance of the device's safety and effectiveness.

AGENCY: Food and Drug Administration.

FEDERAL REGISTER, VOL 44, NO. 48—FRIDAY, MARCH 9, 1979
ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying DC-defibrillators (including paddles) into class III (premarket approval). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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 office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5800 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendations regarding the classification of DC-defibrillators (including paddles):

1. Identification: A DC-defibrillator (including paddles) is a device used to produce an electrical shock for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart or to terminate other cardiac arrhythmias. The device may either synchronize the shock with the proper phase of the electrocardiogram or may operate asynchronously. The device delivers the electrical shock through paddles placed either directly across the heart or on the surface of the body.

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 the DC-defibrillator (including paddles) be classified into class III because the device is life sustaining and presents a potential unreasonable risk of illness or injury. If the device fails to perform adequately, unnecessary heart damage may occur. Based upon the information available to it, the Panel has reviewed and revised its recommendation many times over the past several years. On July 30, 1976, the Panel recommended that all defibrillators be classified into class II. The debate about the classification of defibrillators continued and, after reviewing significant additional data, the Panel recommended on October 7, 1977, to classify all damped sinusoidal defibrillators and trapezoidal defibrillators with delivered energies of 400 joules or less into class II and to classify all other defibrillators into class III. On April 4, 1977, after additional information was supplied to the Panel, the Panel recommended that all defibrillators be classified into class II. The debate about the classification of defibrillators continued and, after reviewing significant additional data, the Panel recommended that all defibrillators be classified into class II and that all other defibrillators be classified into class III. On April 4, 1977, after additional information was supplied to the Panel, the Panel recommended that all defibrillators be classified into class II and that all other defibrillators be classified into class III. On April 4, 1977, after additional information was supplied to the Panel, the Panel recommended that all defibrillators be classified into class II and that all other defibrillators be classified into class III. On April 4, 1977, after additional information was supplied to the Panel, the Panel recommended that all defibrillators be classified into class II and that all other defibrillators be classified into class III. On April 4, 1977, after additional information was supplied to the Panel, the Panel recommended that all defibrillators be classified into class II and that all other defibrillators be classified into class III. On April 4, 1977, after additional information was supplied to the Panel, the Panel recommended that all defibrillators be classified into class II and that all other defibrillators be classified into class III. On April 4, 1977, after additional information was supplied to the Panel, the Panel recommended that all defibrillators be classified into class II and that all other defibrillators be classified into class III.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with the inherent properties of the device and on the Panel members' personal knowledge, experience with the device. In addition, the Panel sought information from the medical and scientific community, the industry, and the medical literature.

A summary elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendations regarding the classification of DC-defibrillators (including paddles):

1. Identification: A DC-defibrillator (including paddles) is a device used to produce an electrical shock for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart or to terminate other cardiac arrhythmias. The device may either synchronize the shock with the proper phase of the electrocardiogram or may operate asynchronously. The device delivers the electrical shock through paddles placed either directly across the heart or on the surface of the body.

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 the DC-defibrillator (including paddles) be classified into class III because the device is life sustaining and presents a potential unreasonable risk of illness or injury. If the device fails to perform adequately, unnecessary heart damage may occur. Based upon the information available to it, the Panel has reviewed and revised its recommendation many times over the past several years. On July 30, 1976, the Panel recommended that all defibrillators be classified into class II. The debate about the classification of defibrillators continued and, after reviewing significant additional data, the Panel recommended on October 7, 1977, to classify all damped sinusoidal defibrillators and trapezoidal defibrillators with delivered energies of 400 joules or less into class II and to classify all other defibrillators into class III. On April 4, 1977, after additional information was supplied to the Panel, the Panel recommended that all defibrillators be classified into class II. The debate about the classification of defibrillators continued and, after reviewing significant additional data, the Panel recommended that all defibrillators be classified into class II and that all other defibrillators be classified into class III. On April 4, 1977, after additional information was supplied to the Panel, the Panel recommended that all defibrillators be classified into class II and that all other defibrillators be classified into class III. On April 4, 1977, after additional information was supplied to the Panel, the Panel recommended that all defibrillators be classified into class II and that all other defibrillators be classified into class III. On April 4, 1977, after additional information was supplied to the Panel, the Panel recommended that all defibrillators be classified into class II and that all other defibrillators be classified into class III. On April 4, 1977, after additional information was supplied to the Panel, the Panel recommended that all defibrillators be classified into class II and that all other defibrillators be classified into class III. On April 4, 1977, after additional information was supplied to the Panel, the Panel recommended that all defibrillators be classified into class II and that all other defibrillators be classified into class III.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the potential hazards associated with the inherent properties of the device and on the Panel members' personal knowledge, experience with the device. In addition, the Panel sought information from the medical and scientific community, the industry, and the medical literature.

The summary minutes (Refs. 1 through 10) of these meetings contain the data and discussions on which the Panel based its recommendation. The characteristics of the electrical shock used to defibrillate the heart include energy, charge, duration, average current, peak current, current density, voltage, power, and waveform. In addition to these characteristics, paddle size and paddle position can affect defibrillation effectiveness.

Many factors other than device-related properties can alter the defibrillation threshold of a patient, including the use of drugs such as lidocaine, the presence of a myocardial infarction, and endogenously liberated substances such as adrenaline. Much of the data about classification of defibrillators focused upon the amount of energy required to defibrillate a patient, espes...
cially a patient weighing over 100 kilo-
grams.

There are two theories regarding the energy required for defibrillation. The first theory is a dose concept for defi-
brillation energy—body weight in-
creases the amount of energy required
for defibrillation increases. Data in
support of the first theory were pre-
sented by Geddes (Refs. 1 and 4),
Grayzel (Ref. 9), Gordon (Ref. 9),
Larsen (Ref. 9), Gallagher (Ref. 9),
Babbs (Ref. 9), and the Health Indus-
tries Manufacturers Association (Ref.
8) represented by Gallagher and
Larsen.

A paper by Tacker, et al. (Ref. 11),
which retrospectively studied defibril-
lation in 111 patients, presented an
energy threshold curve relating
energy to bodyweight and was cited,
among other articles (Refs. 12 through
15), as indicating the need for higher
energy defibrillation.

The second theory is that a dose
concept based upon bodyweight is not
valid and that higher energy defibril-
lation places the patient at a greater
risk of heart damage without increas-
ing the probability of successful defi-
brillation. Lown (Ref. 8) presented his
data on human cardioversion from
ventricular tachycardia and atrial fi-
brillation indicating that weight had
no bearing upon the energy required
to accomplish cardioversion.

Pantridge (Ref. 8) reviewed a study
he had performed, where 100-percent
successful defibrillation occurred at
a stored energy of 400 joules. Crampton
(Ref. 8) reported a prospective study
in which he achieved 96-percent suc-
cessful defibrillation in 46 episodes
involving patents weighing 91 to 225
kilograms with an average energy dose
of 1.8 joules/kilogram. The average
dose was 3.1 joules/kilogram in
Crampton's study of 233 episodes in-
volving patients of all weights. In con-
junction with the energy-dose issue,
the Panel also discussed the amount
of energy required to cause heart
damage.

Geddes (Ref. 8) indicated that, in
dogs, 300 joules/kilogram will perma-
nently stop the heart and that damage
occurs at 15 times the defibrillation
threhold.

Kerber (Ref. 9) reviewed his own
study which showed no change in the
myocardial contractility in dogs with
shocks of 40- to 460-joules- delivered
energy. Kerber also studied the level of
CPK isoenzyme in the blood of 15
patients and suggested that 2 of those
patients may have had some myocardial
damage due to a 400-joule-delivered
energy shock.

Lown (Ref. 8) indicated that, in his
studies on dogs, 30 to 75 joules were
required to defibrillate, and 400 joules
produced significant lesions on the
heart. Pantridge (Ref. 8) indicated
that, due to multiple shocks in 25-kilo-
gram dogs, the damage from 10 shocks
of 400 joules is 7 times the damage
from 20 shocks of 200 joules and 30
times the damage of 40 shocks of 100
joules.

However, Grayzel (Ref. 9), in refer-
ing to a study by Ewy (Ref. 16), indi-
cated that no discernible difference
was found between the damage due to
3 shocks of 1,000 joules and that due
to 10 shocks of 300 joules when ap-
plicated to 25-kilogram dogs.

Babbs (Ref. 9) presented therapeutic
effect curves for defibrillation of
healthy dogs that showed a 50-percent
effective dose of 1.5 joules/kilogram.
Babbs' data also show that 1 to 2 per-
cent damage is expected from shocks
with 90-percent effectiveness and that
16-percent damage is expected from
shocks with 99-percent effectiveness.
Dr. Babbs defined damage as any de-
tectable degree of myocardial necrosis
by either gross or pathological exami-
nation. Another subject of debate in
the classification of defibrillators was
the electrical waveform used to defi-
brillate. There are now two types of
waveform designs for defibrillation: the
damped sinusoidal and the truncated
exponential (trapezoidal). Geddes
(Ref. 1) noted that defibrillation is
possible with many waveforms pro-
vided the current and duration param-
ers are chosen properly.

Tacker (Ref. 1) indicated that suc-
cessful defibrillation cannot be expect-
ed from an untruncated exponential
waveform and that a long, low-ampli-
tude tail may actually cause the heart
to refibrillate after the initial portion
of the waveform has defibrillated the
heart. Larsen (Ref. 3) gave a presenta-
tion demonstrating that the waveform
can be controlled and described in en-
gineering terms to small tolerances. In
referring to work performed by Tacker
(Ref. 17), Geddes (Ref. 4) stated that,
for trapezoidal waveforms, as the tilt
increases the current and energy re-
quired increases. It increases such that
when the tilt reaches 95 per-
cent the energy required with a trape-
zoidal waveform is approximately
equal to that required with a damped
sinusoidal waveform.

Geddes and Tacker (Ref. 3) present-
ed references showing the effective-
ness of various specific marketed defi-
brillator waveforms. Other issues in-
volving defibrillator design discussed
in much less detail by the Panel were
peak and average current, duration,
paddle size and position, current densi-
ty, and charge. As regards peak cur-
cent, Gallagher (Ref. 6) indicated that
60 to 70 amperes is the peak current
range of currently marketed damped
sinusoidal waveform defibrillators.

Schuder (Ref. 1) stated that there is
a minimum current amplitude required
for defibrillation, but that the per-
centage of arrhythmias that occur fol-
lowing successful defibrillation in-
creases rapidly as the current ampli-
tude increases above a certain level.
Geddes (Ref. 6) believes that average
current rather than peak current may
provide a more accurate comparison of
waveforms.

Gordon (Ref. 9) said that, based on
his enzyme studies, a steep rise time
and high peak current are more dam-
aging than other waveform character-
stics. With respect to duration,
Geddes (Ref. 6) indicated that cur-
rently marketed defibrillators have a
duration of 4 to 12 milliseconds.

Schuder (Ref. 1) stated that duration
greater than 8 milliseconds can suc-
cessfully defibrillate but that more con-
sideration must then be placed upon
waveform and energy.

Tacker (Ref. 1) indicated that the
relative importance of duration, volt-
tages, and currents for different wave-
forms is largely unknown. Ewy et al.
(Refs. 18 through 21) and Geddes et
al. (Ref. 22) extensively studied paddle
size and position. They found no dif-
ference in defibrillation success be-
tween transverse or paddle paddle posi-
tions so long as the left
cheest paddle was placed over the apex
of the heart. Geddes (Ref. 6) stated
that paddle position data were collect-
ed from animal studies and that there
are no data related to paddle position
on humans. Specific data on current
density and charge were not presented
to the Panel, although these proper-
ties are intimately related to paddle
size and waveform, among other prop-
erties.

The Panel recognized the work in
progress to standardize defibrillators,
including the efforts of American
Heart Association (Refs. 23 through
25) and the Utah Biomedical Test Lab-
oratories (Ref. 26).

5. Risks to Health: (a) Electrical
shock to operator: Improper electrical
design of the device can lead to vari-
ious electrical shock to the operator.
(b) Inability to defibrillate or persis-
tence of the arrhythmia: Inability to
defibrillate or persistence of the ar-
rhythmia may occur because of exces-
sive energy, excessive current, insuffi-
cient energy, insufficient current, a
difference between the indicated level
of energy and the delivered level of
energy, as delivered into a 50-ohm
load, or excessive leakage current. (c)
Inability to defibrillate: Inability to
defibrillate may occur when certain
drugs that can raise the defibrillation
threshold are used. (d) Inability to de-
ffibrillate due to paddle design: Inabil-
ity to defibrillate may result from in-
appropriate paddle size or inappropri-
ate paddle location on the subject.
PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the DC-defibrillator be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (e.g., restoring a fibrillating heart to normal rhythm and functions) in supporting or sustaining human life. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify a life-supporting or life-sustaining 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, because of the contradictory data presented and available, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard assurance of the device. At the Panel's request, the Commissioner is also announcing his intention to schedule a Panel meeting prior to the final classification of defibrillators at which interested parties are invited to present relevant scientific data regarding the safety and effectiveness of DC-defibrillators.

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.


Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(x)), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 571(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart F by adding new § 870.5300 as follows:

§ 870.5300 DC-defibrillators (including paddles).

(a) Identification. A DC-defibrillator (including paddles) is a device used to produce an electrical shock for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart or to terminate other cardiac arrhythmias. The device may either synchronize the shock with the proper phase of the electrocardiogram or may operate asynchronously. The device delivers the electrical shock through paddles placed either directly across the heart or on the surface of the body.

(b) Classification. Class III (premarket approval).

Interested persons may, on or before May 3, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5000 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.


JOSPEH P. HILL,  
Associated Commissioner for Regulatory Affairs.

[FR Doc. 79-6393 Filed 3-6-79; 8:45 am]  
[110-03-M]  
[Docket No. 78N-1544]  
MEDICAL DEVICES  
Classification of Defibrillator 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 defibrillator testers into
class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

SUPPLEMENTARY INFORMATION:

- PANEL RECOMMENDATION

A proposal elsewhere in this issue of the Federal Register provided background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of defibrillator testers:

1. Identification: A defibrillator tester is a device that is connected to the output of the defibrillator and is used to measure the energy delivered by the defibrillator into a standard resistive load. Some testers also provide waveform information.

2. Recommended classification: Class II (performance standards). The Panel recommends that this performance standard for the device be of high priority.

3. Summary of reasons for recommendation: The Panel recommends that the defibrillator tester be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life or health even when properly used. Failure of the device to accurately measure defibrillator output can lead to excessive or insufficient energy delivered to a patient during defibrillation. Performance characteristics, including accuracy and reproducibility, and any limitations on the device's ability to measure defibrillator output should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that a performance standard would not provide sufficient control over the performance characteristics of this device. The Panel believes that a performance standard would 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 recommends that the potential hazards associated with the inherent properties of the device and on their personal knowledge, and experience with, the device.

5. Risks to health: (a) Misdiagnosis: Inadequate design with regard to indication of defibrillator output can lead to generation of inaccurate defibrillator output data. In inaccurate defibrillator output data are used in managing the patient, the physician may prescribe a course of treatment which places the patient at risk unnecessarily.

(b) Electrical shock to operator: Improper electrical isolation can lead to electrical shock to the operator.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the defibrillator 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 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 such assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 50 Stat. 540-546 (21 U.S.C. 350c, 371(a)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart F by adding new §870.5325 as follows:

§870.5325 Defibrillator tester.

(a) Identification. A defibrillator tester is a device that is connected to the output of a defibrillator and is used to measure the energy delivered by the defibrillator into a standard resistive load. Some testers also provide waveform information.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.
A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of external transcutaneous cardiac pacemakers (noninvasive):

1. Identification: An external transcutaneous cardiac pacemaker (noninvasive) is a device used to supply a periodic electrical pulse intended to pace the heart. The device is usually applied to the surface of the chest through electrodes such as defibrillator paddles.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval of this device be a medium priority.

3. Summaries of reasons for recommendation: The Panel recommends that the external transcutaneous cardiac pacemaker (noninvasive) be classified into class III because this device is life-supporting and presents a potential unreasonable risk of illness, injury or death. This device is most frequently used in emergency care situations where the introduction of a cardiac lead is impractical or impossible. The Panel is concerned that there is not enough information on energy levels and electrode configurations needed for reliable pacing. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of this device. Although some electrical safety aspects can be controlled by standards, the Panel believes there is insufficient scientific and medical data for this life-supporting product to establish a standard that can assure safety and efficacy. Therefore, the Panel believes that premarket approval is necessary.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Myocardial or tissue damage: Excessive energy or poor electrode design and placement can cause tissue damage or myocardial damage. (b) Failure to pace: The pacemaker will not pace the heart if inadequate energy levels are used, or if a poor electrode design or configuration is employed.

PROPOSED RULES

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the external transcutaneous cardiac pacemaker (noninvasive) be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (maintaining heart function by electrical stimulation) in supporting or sustaining human health. The Federal Food, Drug, and Cosmetic Act requires the Commissioner to classify a life-supporting or life-sustaining device into class III unless the Commissioner determines that premarket approval is not necessary to provide reasonable assurance of the device's safety and effectiveness. In this case, the Commissioner has determined that premarket approval is necessary. The Commissioner believes that insufficient information exists to determine that general controls will provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540546 (21 U.S.C. 300c, 371(a)) and under authority delegated to him (21 CFR §1.), the Commissioner proposes to amend Part 870 in Subpart P by adding new §870.5550 as follows:

§870.5550 External transcutaneous cardiac pacemaker (noninvasive).

(a) Identification. An external transcutaneous cardiac pacemaker (noninvasive) is a device used to supply a periodic electrical pulse intended to pace the heart. The device is usually applied to the surface of the chest through electrodes such as defibrillator paddles.

(b) Classification. Class III (premarket approval).

Interested persons may, on or before May 8, 1979, submit to the Hearing Clerk (FFA-305), Food and Drug Administration, Rm. 4-65, 5000 Fishers Lane, Rockville, MD 20857, 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.


JOSEPH P. HILE, Associate Commissioner for Regulatory Affairs.

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1549]

MEDICAL DEVICES

Classification of Compressible Limb Sleeves

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying compressible limb sleeves into class II (performance standards).

The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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, 5000 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Glenn A. Rahmeoller, Bureau of Medical Devices (HFE-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of compressible limb sleeves:

1. Identification: A compressible limb sleeve is a device that is used to prevent pooling of blood in a limb by...
Inflating periodically a sleeve around the limb.

2. Recommended classification: Class II (performance standards). The Panel recommends that a compressible limb sleeve be classified into class II because this device is neither life-supporting nor life-sustaining, but is potentially hazardous to life and health when primarily used. The device applies external pressure to the extremities of the body and applies periodic pressure to the limb by pneumatic action. Malfunction of the device can result in unsafe excess pressure. The methods used to control the potential hazards associated with the inherent properties of the device and on the personal knowledge of, and experience with, the device.

3. Summary of reasons for recommendation: The Panel recommends that the compressible limb sleeve be classified into class II (performance standards). The Commissioner believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device and on the personal knowledge of, and experience with, the device.

5. Risks to health: (a) Tissue trauma: Overinflation of the sleeve, associated with excess local pressure, can lead to tissue trauma. (b) Tissue damage: Tissue compatibility to the sleeve material is related to allergic and other similar or related skin reactions.

PROPOSED RULES

Part 870 in Subpart F by adding new § 870.5800 as follows:

§ 870.5800 Compressible limb sleeve.

(a) Identification. A compressible limb sleeve is a device that is used to prevent pooling of blood in a limb by inflating periodically a sleeve around the limb.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


Joseph P. Hile,
Associate Commissioner for Regulatory Affairs.
(FR Doc. 79-6288 Filed 3-8-79; 8:45 am)

[4110-03-M]

[21 CFR Part 870]

Docket No. 78N-1547)

MEDICAL DEVICES

Classification of Thermal Regulating 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 thermal regulating systems into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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.


The Commissioner of Food and Drugs proposes that the final regulation be issued within the 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:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFA-460), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

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 Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of thermal regulating systems:

1. Identification: A thermal regulating system is an external system consisting of a device that is placed in contact with the patient and a temperature controller for the device. The system is used to regulate a patient's temperature.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the thermal regulating system be classified into class II because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life and health even when properly used. The device is used to warm or cool a patient. Malfunction of the device is potentially hazardous to life and health. Performance characteristics, including accuracy and reproducibility, and any limitations on the device's thermal properties should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. Thus the electrical characteristics of the device, e.g., electrical leakage current, need to meet certain requirements. The Panel believes that general controls alone would not provide sufficient control over the 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 the potential hazards associated with the inherent properties of the device.
device and on their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias. Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Tissue damage: Inaccuracy of temperature control can lead to burns or tissue damage related to hypothermia. (c) Mechanical tissue damage: Excessive pressure can cause the device to harden to the point of causing pressure necrosis, especially during hypothermia. (d) Chemical tissue damage: The integrity of the fluid chambers of the device can be violated by excessive pressure-causing fluids such as ethylene glycol contacting the skin and causing chemical tissue damage.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the thermal regulating 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 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. 380c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart F by adding new § 870.5900 as follows:

§ 870.5900 Thermal regulating system.

(a) Identification. A thermal regulating system is an external system consisting of a device that is placed in contact with the patient and a temperature controller for the device. The system is used to regulate patient temperature.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILDE Associate Commissioner for Regulatory Affairs.

(FR Doc. 79-6289 Filed 3-8-79; 846 am)

[4110-03-M]

[21 CFR Part 870]

(Docket No. 78N-1548)

MEDICAL DEVICES

Classification of Automatic Rotating Tourniquets

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automatic rotating tourniquets into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular 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 May 8, 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:

Glenn A. Rahmoeller, Bureau of Medical Devices (HFP-450), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7559.

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 Cardiovascular Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of automatic rotating tourniquets:

1. Identification: An automatic rotating tourniquet is a device that prevents blood flow in one limb at a time, which temporarily reduces the total blood volume, thereby reducing the normal workload of the heart.

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 automatic rotating tourniquet not be classified into class I (performance standards) because this electrically powered device is neither life-supporting nor life-sustaining, but is potentially hazardous to life and health even when properly used. The device is placed around the patient's limbs. It can be either mechanically or electrically operated. Excessive or prolonged pressure applied by the device can lead to tissue damage by reducing blood flow to distal areas of the body. This device is attached directly to the surface of the body and is used in a clinical environment where excessive leakage current can be a serious hazard. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's mechanical design should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. The Panel believes that general controls alone would not provide incident control over the 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 the potential hazards associated with the inherent properties of the device and their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Cardiac arrhythmias: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Tissue damage: If the mechanical design of the device causes excessive or prolonged pressure on a limb, tissue damage due to the pressure or lack of blood flow can result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the automatic rotating tourniquet 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 870 in Subpart F by adding new §870.5925 as follows:

§870.5925 Automatic rotating tourniquet.

(a) Identification. An automatic rotating tourniquet is a device that prevents blood flow in one limb at a time, which temporarily reduces the total blood volume, thereby reducing the normal workload of the heart.

(b) Classification. Class II (performance standards).

Interested persons may, on or before May 8, 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.


JOSEPH P. HILE,
Associate Commissioner
for Regulatory Affairs.

[FR Doc. 79-6290 Filed 3-8-79; 8:45 am]