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federal register

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FRIDAY, MARCH 9, 1979

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

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

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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.)**

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

[3410-02-M]

Title 7—Agriculture

CHAPTER IX—AGRICULTURAL MARKETING SERVICE (MARKETING AGREEMENTS AND ORDERS; FRUITS, VEGETABLES, NUTS), DEPARTMENT OF AGRICULTURE

[Lemon Reg. 189]

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:

Charles R. Brader, (202) 447-6393.

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. 601-674), 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.

(Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674.)

CHARLES R. BRADER,
Acting Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 79-7482 Filed 3-8-79; 12:00 pm]

[3410-37-M]

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 provisions of Pub. L. 92-210 have resulted in a 5.5 percent pay increase for Federal employees for FY 1979, 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:

David K. Hallett, Chief, Meat Grading Branch, Meat Quality Division, Food Safety and Quality Service, U.S. Department of Agriculture, First Floor Mezzanine, Annex Building, Washington, D.C. 20250, Area Code (202) 447-2210.

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.

(Sec. 203, 205, 60 Stat. 1087, 1090, 7 U.S.C. 1622, 1624)

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. 553, it is found upon good cause that notice and other public procedure with respect to these amendments are 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.

Done at Washington, D.C. on: March 2, 1979.

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

[FR Doc. 79-6916 Filed 3-8-79; 8:45 am]

[3410-37-M]

SUBCHAPTER E—EXPORT AND DOMESTIC CONSUMPTION PROGRAMS

PART 2880—FRESH IRISH POTATOES

Subpart—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:

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.

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 principally 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. A potato diversion program accounting for a sufficient tonnage will stabilize potato prices which have been depressed owing to an existing nationwide surplus. U.S. potato production in 1978 (360.4 million cwt.) exceeds the previous record high set in 1976. Trade reports show that current field run prices for Red River Valley potatoes fall within one-half to two-thirds of production costs.

An Impact Analysis Statement for a Round White and Red potato diversion program has been prepared and provides specific detail of the need for the diversion action, the scope of the action proposed, the cost to the Government and the likely effect on producer prices.

Due to the low returns from potato sales, many producers of Round White and Red potatoes are on the brink of economic disaster. It is the judgment of the USDA that the surplus of Round White and Red potatoes in the Red River Valley of North Dakota and Minnesota ranges from 1 to 1½ million hundredweights and that action is needed to divert surplus potatoes to enhance potato prices. This action is consistent with the original guidelines of USDA to divert 12 million hundredweights of potatoes from the 1978 fall crop.

Options considered for disposing of the potatoes consisted of Government aided and commercial export sales, donations to school lunches, animal feed, conversion to alcohol, starch, and fertilizer, and natural dehydration for animal feed. Due to large potato crops in most parts of the world where potatoes are consumed, export sales opportunities are limited this season. However, the Department is considering encouraging the export of dehydrated potatoes and conversion of potatoes into alcohol. This Department has also made heavier than usual donations of potato products to schools and elderly feeding program this season. However, this has had a limited impact on the heavy domestic supply of potatoes.

No starch facilities are available for diversion of potatoes in the Red River Valley. Livestock feeding either for immediate use or spreading on pastures for feeding later in the Spring are the most expedient means of diverting potatoes. Accordingly, in order to provide an incentive to producers to divert their potatoes to use as livestock feed, payments are being offered to eligible producers in the Red River Valley production area to encourage such diversions. These payments are being offered over a period of 30 days, beginning March 12, 1979. The diversion payments will compensate potato producers for low prices obtained from sales of potatoes for livestock feed.

Feeding potatoes to livestock can be expected to be carried out under variable conditions under this program. In this respect the feeding requirements of the program attempt to encompass all generally used methods. It is understood that some feeding arrangements will be temporary and unsophisticated and therefore less efficient in limiting waste than some others.

In computing the permitted rates of spreading potatoes on pasture land where livestock are grazing, consideration was given to the waste that will occur through the animals trampling the potatoes spread on the ground. Similar consideration will be given by USDA when determining whether adequate pasturing by livestock has occurred under the freeze-thaw method of feeding. The definition of adequate pasturing in the regulation contains more details.

Diverters who are indebted to USDA or to any other agency of the United States are subject to the creditor

agency making a claim against any amount due under the program. However, the diverter has the right to contest the justness of the indebtedness involved either by administrative appeal or legal action.

The payment will be $2.00 per hundredweight 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 relieve the commerical potato markets from the price-depressing impact which persistently exists when potato supplies are in surplus. Accordingly, Dr. Donald L. Houston, Acting Administrator, FSQS, has determined that an emergency situation exists requiring immediate program action without a 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 12661, 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, Washington, D.C. 20250. In order to be sure of consideration, comments must be received by March 21, 1979. The program 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 Secretariat 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.

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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 participation.
2880.57 Performance bond.
2880.58 Period of diversion.
2880.59 Definition of diversion.
2880.60 Diversion specifications.
2880.61 Inspection and certificate of diversion.
2880.62 Methods of utilization.
2880.63 Claim for payment.
2880.64 Compliance with program provisions.
2880.65 Inspection of premises.
2880.66 Records and accounts.
2880.67 Set-off.
2880.68 Joint payment or assignment.
2880.69 Officials not to benefit.
2880.70 Amendment and termination.

AUTHORITY: §§ 2880.50 to 2880.70 issued under sec. 32, 49 Stat. 774, as amended (7 U.S.C. 612c).

§ 2880.50 General statement.

In order to encourage the domestic consumption of fresh Round White and Red potatoes by diverting them from normal channels of trade and commerce, the Secretary of Agriculture, pursuant to the authority conferred by section 32 of Public Law 320, 74th Congress, as amended, offers to make payment for the diversion for use as livestock feed of 1978 crop Round White and Red potatoes, subject to the terms and conditions set forth in this subpart. Information relating to this program and forms prescribed for use hereunder may be obtained from the following:

Fruit and Vegetable Quality Division, Food Safety and Quality 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, Fruit and Vegetable Quality Division, Food Safety and Quality Service, and in the field will be carried out by the Agricultural Stabilization 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 Agriculture, hereinafter referred to as USDA, to approve applications for participation. The State and County Committees or their authorized representatives do not have authority to modify or waive any 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 defined in § 2880.60 will be two dollars per hundredweight for potatoes diverted from the inception of the program through a period of 30 days. No payment will be made for any fractional 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, partnership, association, or corporation producing 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 performance bond as provided in § 2880.57, (c) whose application is approved, (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 "Application for Participation in Fresh Irish Potato Livestock Feed Diversion Program". 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 applications 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 applicant is hereinafter referred to as "the diverter".

§ 2880.57 Performance bond.

In order to protect the Government's interest, each applicant shall submit with his first application for participation a performance bond as further assurance that the potatoes di-

verted pursuant to this program will be used exclusively for feeding to livestock by methods prescribed in § 2880.62. The bond shall be executed on Form ASCS-119, "Performance Bond", by the principal and two individual sureties, all of whom shall agree to indemnify USDA for any losses, claims, or payments made by USDA with respect to any quantity of such potatoes not used for livestock feed. USDA may disapprove any bond if for any reason any surety does not in the opinion of USDA afford USDA full protection and security.

§ 2880.58 Period of diversion.

The potatoes in connection with which payments are to be made must be diverted (a) after the date of approval of the diverter's application, (b) within the time period specified in the approved application, and (c) in any event on or before the termination date of the program.

§ 2880.59 Definition of diversion.

Diversion of potatoes for use as livestock feed as used herein means the initial processing of potatoes for feeding to livestock by cutting, chopping, ensiling, slicing, gouging, crushing, cooking or spreading for alternate freezing and thawing to the degree that the general appearance of the lot as a whole has been damaged to such an extent that, in the opinion of the inspector, the potatoes are readily and obviously identifiable as having been initially processed and rendered unsuitable to enter into normal channels of trade and commerce as potatoes.

§ 2880.60 Diversion specifications.

Round White and Red potatoes in connection with which payments will be made, will be the potatoes in each lot which meet the requirements of "Specification A", which potatoes are hereby defined as meaning "Cellar Run" potatoes [1] which are equal to or better than the quality requirements of U.S. No. 2 Processing Grade (7 CFR Sec. 51.3411), except that they must have a minimum diameter of 1½ inches and no tolerance will be allowed for defects or undersize. Also, fry color, glucose content, and specific gravity determination are hereby waived under this grade determination. Potatoes which by clipping ends or second growth could be made to meet the quality requirements of U.S. No. 2 Processing Grade need not be so clipped to be classed as Specification A, but the weight of the portions which customarily would be clipped off shall be deducted in determining the weight of those potatoes in the lot which do meet the requirements of Specification A.

[1] "Cellar Run" potatoes are hereby defined as storage potatoes which have not been sorted.

§ 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 be 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 volume measurements as 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 barns 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 alternate 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 edible 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, tramplings, 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-

ject 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 and any 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 diverting, storing and using potatoes 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-66 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 Reports 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]

[3410-34-M]

Title 9—Animals and Animal Products

CHAPTER I—ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

SUBCHAPTER C—INTERSTATE TRANSPORTATION OF ANIMALS (INCLUDING POULTRY) AND ANIMAL PRODUCTS

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

Areas Quarantined

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 exotic Newcastle disease it is necessary to quarantine additional portions of such counties.

EFFECTIVE DATE: March 5, 1979.

FOR FURTHER INFORMATION CONTACT:

Dr. M. A. Mixson, USDA, APHIS, VS, Federal Building, Room 748, Hyattsville, Maryland 20782, 301-436-8073.

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., 12531 Harbor Boulevard, Garden Grove, Orange County.

(vi) The premises of For The Birds, Inc., 6605 Clava Street, Bell Gardens, Los Angeles County.

(vii) The premises of Barry's Burl, Exotic Birds, 6141 Clava Street, Bell Gardens, Los Angeles County.

* * * * *

(Secs. 4-7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791-792, as amended; secs. 1-4, 33 Stat. 1264, 1265, as amended; secs. 3 and 11, 76 Stat. 130, 132 (21 U.S.C. 111-113, 115, 117, 120, 123-126, 134b, 134f); 37 FR 28464, 28477; 38 FR 19141.)

The amendment imposes certain restrictions necessary to prevent the interstate spread of exotic Newcastle disease, a communicable disease of poultry, from the quarantined areas, and, therefore, must be made effective immediately to accomplish its purpose in the public interest. It does not appear that public participation in this rulemaking proceeding would make additional relevant information available to the Department.

Accordingly, under the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to the amendment are impracticable and contrary to the public interest, and good cause is found for making the amendment effective before April 9, 1979.

Done at Washington, D.C., this 5th day of March 1979.

NOTE.—This final rulemaking is being published under emergency procedures as authorized by E.O. 12044 and Secretary's Memorandum 1955. It has been determined by M. A. Mixson, Acting Assistant Deputy Administrator, Animal Health Programs, APHIS, VS, USDA, that the possibility of the spread of exotic Newcastle disease into other States or Territories of the United States from the quarantined areas is severe enough to constitute an emergency which warrants the publication of this quarantine without waiting for public comment. This amendment, as well as the complete regulation, will be scheduled for review under provisions of E.O. 12044 and Secretary's Memorandum 1955. The review will include preparation of an Impact Analysis Statement which will be available from Program Services Staff, Room 870, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782. 301-436-8695.

PIERRE A. CHALOUX,
Deputy Administrator,
Veterinary Services.

[FR Doc. 79-7192 Filed 3-8-79; 8:45 am]

[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 or 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 cooperator'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 cooperator.

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 (1)(a) and A(1)(b) 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.*

A. *The Cooperator Agrees*

1. a. To deposit with the Service upon execution of this agreement the amount of —— (equal to the established fee multiplied by the number of cattle for which an import permit is to be issued to the cooperator) to cover the cost to the Department to qualify animals in the foreign country for entrance into the Harry S. Truman Animal Import Center and the quarantine period at that facility and to qualify the cattle for importation into the United States, or;

b. To deposit with the Service upon execution of this agreement a payment bond in the amount of —— (equal to the established fee multiplied by the number of cattle for which an import permit is to be issued to the Cooperator). Payment will be due one month prior to the day the cattle are scheduled to be released from quarantine. The bond shall be in effect from the date of the issuance of the import permit to the date the cattle are released from quarantine or otherwise disposed of. This time is estimated to be for not less than 8 months. Forfeiture for the entire amount of the bond shall occur if payment is not received from the Cooperator by the due date.

It is necessary to publish these regulations as a final rule, to become effective immediately, in order to allow the importers of cattle to (1) secure the necessary financing; (2) enter into a cooperative agreement with the Department; and (3) make the necessary arrangements for the required preentry quarantine procedures. This is necessary in order to insure that the space available in HSTAIC is as fully utilized as possible.

Therefore, for such good cause the Department finds that notice and other public procedure regarding these amendments are 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.

NOTE.—This final rulemaking is being published under emergency procedures as authorized by E.O. 12044, and Secretary's Memorandum No. 1955. It has been determined by Dr. G. V. Peacock, Director, National Program Planning Staffs, Veterinary Services, Animal and Plant Health Inspection Service, that the emergency nature of this rule, as indicated above, warrants the publication of this rule without waiting for public comment. This amendment, as well as the complete regulation, will be scheduled for review under provisions of E.O. 12044 and Secretary's Memorandum No. 1955. An Impact Analysis Statement has been prepared and is available from Program Services Staff, Room 870, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-8695.

Done at Washington, D.C., this 5th day of March 1979.

PIERRE A. CHALOUX,
Deputy Administrator,
Veterinary Services.

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

[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. Requests to speak must be made by March 16, 1979. If your are selected to be heard, you will be so notified before 4:30 p.m., e.s.t., March 19, 1979, and will be required to submit one hundred copies of your statement to: Public Hearing Management, Standby Activation Order No. 1, Economic Regulatory Administration, Room 2313, 2000 M Street, N.W., Washington, D.C. 20461, before 4:30 p.m., e.s.t., March 19, 1979.

HEARING LOCATION: The hearing location is changed from Room 2105, 2000 M Street, N.W., Washington, D.C. to Room 3000A, Federal Building, 12th and Pennsylvania Avenue, N.W., Washington, D.C. 20461.

FOR FURTHER INFORMATION CONTACT:

Robert G. Gillette (Comment Procedures), Economic Regulatory Administration, 2000 M Street, N.W., Room 2214B, Washington, D.C. 20461 (202) 254-5201.

William Webb (Office of Public Information), Economic Regulatory Administration, 2000 M Street, N.W., Room B-110, Washington, D.C. 20461 (202) 634-2170.

Gerald P. Emmer (Regulations and Emergency Planning), Economic Regulatory Administration, 2000 M Street, N.W., Room 2304, Washington, D.C. 20461 (202) 254-7200.

Michael Paige or Joel M. Yudson (Office of General Counsel), Department of Energy, 1000 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. 79-7233 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 new section 22(h) of the Federal Reserve Act, recently enacted by Congress as section 104 of the Financial Institutions Regulatory and Interest Rate Control Act of 1978 ("FIRA") (Pub. L. 95-630). The requirements of section 22(h) 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.

The amendments to the regulation were adopted after review of the extensive public comment on the proposals. The amendments will become effective on March 10, 1979, to meet 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 comments 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 (202-452-2620), 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 893, January 3, 1979). Section 22(h) governs loans by a member bank to any of its executive officers, directors or principal shareholders and to their related interests. An executive officer, director or principal shareholder of the member bank is defined to include any person that has the same relationship with (1) a bank holding company of which the member bank is a subsidiary or (2) any other subsidiary of that bank holding company.[1] A principal shareholder means an individual or company that controls more than 10 per cent [2] of any class of voting shares of the bank or company. (Shares held by a member of an individual's immediate family are considered held by the individual in determining principal shareholder status). The limitations of section 22(h) (except for the overdraft prohibition) also apply to a related interest of any of these persons. A related interest is a company that is controlled by, or a political or campaign committee that is controlled by or that benefits, a person.

Section 22(h) has four limitations. The statue generally:

(1) Establishes a lending limit of 10 percent of a member bank's capital and surplus (subject to certain exceptions) [3] 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; [4]

(2) Prohibits the payment by a member bank of an overdraft of an executive officer or director on an account at the bank; [5]

(3) 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 (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, when all loans to the person and the person's related interests are aggregated, be approved in advance by a majority of the entire board of directors of the bank, with the interested party abstaining from voting.

The Board has received well over 200 written comments concerning the proposed regulation and has modified the regulation after considering the concerns expressed by the comments. The Board and the Comptroller of the Currency are aware of the complexities of the new statute and the brief period of time between publication of amended Regulation O and the effective date of the statute. The agencies will consider these factors in connection with any enforcement action for a violation occurring during the first 60 days that the regulation is in effect. The agencies have adopted this policy in recognition of the fact that some may inadvertently violate the regulation before they have developed procedures for compliance with it.

DISCUSSION OF ISSUES

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.

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).

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

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[1] In certain circumstances, as discussed below, executive officers of other subsidiaries of the member bank's parent bank holding company are not considered to be executive officers of the member bank.

[2] If the member bank is located in a city, town or village with a population of less than 30,000, this figure is 18 percent for the purpose of the 10 percent lending limit established by section 22(h). If such a member bank is a subsidiary of a bank holding company, a person will not be a principal shareholder of the bank holding company unless the person controls more than 18 percent of any class of voting securities of the bank holding company.

[3] These exceptions are set forth in section 5200 of the Revised Statutes, 12 U.S.C. 84. The exceptions generally provide higher or no limits for certain types of secured obligations. For example, obligations fully secured by direct obligations of, or fully guaranteed as to principal and interest by, the United States are not subject to any limitation under section 5200 of the Revised Statutes. 12 CFR 7.1580. A copy of that statute has been included as an appendix to the regulation. See also 12 CFR Part 7, Subpart A, for a discussion of these exceptions.

[4] The 10 percent lending limit does not apply to member bank loans to a director of (a) the member bank, (b) the member bank's parent bank holding company, or (c) any other subsidiary of the parent bank holding company, unless the director is also an executive officer or principal shareholder.

[5] The prohibition against payment by a member bank of an overdraft does not apply to an overdraft of a principal shareholder of (a) the member bank, (b) its parent bank holding company, or (c) any other subsidiary of the parent bank holding company, unless the principal shareholder is also an executive officer or director. The overdraft prohibition also does not apply to related interests.

promptly repaid. The regulation requires the member bank to charge the director or officer the same fee charged any other customer of 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 consistent with 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 a nonbank subsidiary of that holding company.[6] 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 would be 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 amendment of the 20 per cent lending limit of section 23A. The Board finds no evidence of any Congressional intent to effect such an amendment or significant modification of section 23A. Indeed, a Congressional intent that the two statutes be interpreted consistently is evident from the requirement in section 22(h) that the term extension of credit shall have the same meaning as in section 23A. Accordingly, the regulation excludes from the lending limit of section 22(h) an extension of credit by a member bank to its parent 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 the other subsidiaries of the foreign bank.

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 and to all related interests of these persons are subject to the 10 per cent lending limit (and other applicable restrictions) of section 22(h).

The Board has also excluded from coverage as a member bank 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 should be placed on foreign banks regarding loans to their affiliates. It should be noted that the Board maintains residual supervisory authority over all U.S. operations of foreign banks.

4. *Preferential Lending.* Under the statute, a member bank's loans to bank officials and their related interests must be made on "substantially the same terms" as "comparable transactions with other persons." The proposed regulation issued for comment reflected the Board's view that "other persons" meant persons not associated with the bank. A number of the comments (mainly from State nonmember banks) inquired whether, under the proposed Regulation O issued for comment, executive officers may obtain preferential interest rates under bank employee benefit plans. The issue has arisen because State nonmember banks are not subject to the prohibition of section 22(g) of the Federal Reserve Act against lending by a member bank to its executive officers at preferential rates.[7]

The Board has decided that the preferential lending rules should be uniform for all insured banks. Since the Board finds little basis to change its long-held view that preferential lending by a member bank to its executive officers is not permitted by section 22(g) 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 FIRA, Congress has prohibited such preferential lending by banks that maintain a correspondent account relationship to each other's executive officers, directors, or principal shareholders.

5. *Executive officer.* The Board has continued in Regulation O its previous defintion 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(h), an "officer" of a 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 member bank's holding company affiliates 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 of which the member bank is a subsidiary. The regulation also includes, as executive officers of the member bank, all executive officers of all other subsidiaries of the member bank's parent 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 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* subsidiaries would be 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).

[6] Because insured banks are excluded from the definition of "company" in section 22(h), loans by a member bank to any of its insured bank affiliates are not subject to the restrictions of section 22(h) (including the 10 per cent lending limit).

[7] Under Regulation O, the Board has allowed executive officers of member banks to participate in bank credit card, check credit and similar open end credit plans as long as the terms of such indebtedness were not more favorable than those offered to the general public. The Board has also required other indebtedness of executive officers to a member bank to be on terms no more favorable than those available to persons not associated with the bank. See footnote 8, below.

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 cover credit 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 of the kind intended to be restricted by section 23A. (12 CFR 250.240). The Board reasoned that the 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 requirements) and that 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(l) of the regulation specifies that 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 authority to participate, in major policymaking functions of the member bank, that individual is considered to be an executive officer of the member bank under the definition of executive officer in amended Regulation O, whether or not the person holds any official position with the member bank. Such a person and all his related interests would then be subject to all the restrictions of section 22(h). The Board's rules concerning member bank lending with respect to its own subsidiaries have been adopted on the basis of the Board's experience in the supervision of such relationships and in the light of the purposes of the Act.

7. *Control of a bank or company.* A number of comments questioned whether an individual would, by reason of a position as an executive officer or director of a bank or company, be considered to control the bank or company or to exercise a controlling influence over its management or policies. The Board has amended the regulation to clarify that an individual will not be presumed 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 per cent of the shares of the bank or company; or

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

Provision has been made in the regulation for a person to rebut these presumptions.

8. *Immediate family.* Under the regulation, shares owned or controlled by a member of an individual's immediate family are considered to be owned or controlled by the individual for the purpose of determining whether the individual is a principal shareholder. The Board has limited the definition of immediate family to an individual's spouse, minor children, and the individual's children (including adults) living in the same household.

9. *Time to bring outstanding loans into compliance with the lending limit.* The proposed regulation issued for comment provided two different schedules for bringing loans outstanding on the effective date of section 22(h) (March 10, 1979) into compliance with the 10 per cent lending limit. The Board proposed one schedule for loans made before November 10, 1978 (the date section 22(h) was enacted), and another schedule for loans made between November 10, 1978, and March 10, 1979.

Many of the comments stated that these periods were too short (especially in the case of State banks not before subject to the general 10 per cent limit of section 5200 of the Revised Statutes) and that the effect of the compliance deadlines would be particularly harsh in the case of term loans, such as residential mortgage loans, that are payable on a fixed schedule.

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 also revised the proposed regulation to eliminate the separate compliance schedule for loans made between the enactment date and effective date of section 22(h)—that is, between November 10, 1978, and March 10, 1979. Loans made during this interim period (except for term loans with fixed maturities) must now be brought into compliance within the same time period as loans made before November 10, 1978, that is, by March 10, 1980. The Board expects that no extensions of time beyond March 10, 1980, to bring these loans into compliance will be granted.

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 official or to a related interest of such a person 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 an addition to the bank's capital structure by the appropriate Federal bank-

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 by section 22(h) and should not be construed as reflecting any position of the Board on whether 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).[8] 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 Statutes.

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 made before 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 insured 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 has not been made applicable by 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.[9] The regulation excludes certain indebtedness necessary to protect the bank against loss 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 regulation. The regulation also makes clear that a participation with out recourse is considered to be an extension of credit by the participating 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 full 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:

[8] Section 22(g) of the Federal Reserve Act limits member bank loans to each of its executive officers to $30,000 for home mortgage credit, $10,000 to educate the executive officer's children, and $5,000 for other purposes. Effective March 10, 1979, section 110 of Title I of FIRA doubles these amounts.

[9] To avoid double counting of extensions of credit to a bank official and the related interests of the bank official, an endorsement or guarantee by a bank official of an extension of credit to a related interest of the bank official (or vice-versa) will be considered a single extension of credit in the amount of the direct obligation of the related interest for the purposes of the 10 per cent lending limit of section 22(h).

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

Sec.
215.1 Authority, purpose, and scope.
215.2 Definitions.
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215.6 Exentions of Credit Outstanding on March 10, 1979.
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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.

§ 215.2 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(h)) 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.

(4) A person may rebut a 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.

(c) "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.

(d) "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 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 considered 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.

(e) "Immediate family" means the spouse of an individual, the individual's minor children, and any of the individual's children (including adults) residing in the individual's home.

(f) The "lending limit" for a member bank is an amount equal to the limit on loans to a single borrower established by section 5200 of the Revised Statutes, 12 U.S.C. 84. This amount is 10 percent of the bank's capital stock and unimpaired surplus or any higher amount permitted by section 5200 of the Revised Statutes for the types of obligations listed therein as exceptions to the 10 percent limit. A member bank's capital stock and unimpaired surplus equals the sum of (1) the "total equity capital" of the member bank reported on its most recent consolidated report of condition filed under 12 U.S.C. 1817(a)(3), (2) any subordinated notes and debentures approved as an addition to the member bank's capital structure by the appropriate Federal banking agency, and (3) any valuation reserves created by charges to the member bank's income.

(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(s)) and regardless of 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

[1] The 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 determination 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 individual participates, or is authorized to participate, in major policymaking functions of the bank or company.

excess of funds on deposit in the account.

(i) "Person" means an individual or a company.

(j) "Principal shareholder" means an individual or a company (other than an insured bank) that directly or indirectly, or 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 18 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)) of which the member bank is a subsidiary and (2) a principal shareholder of any other 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.

(l) "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) Issuance of a standby letter of credit (or other similar arragement regardless of name or description) or an ineligible acceptance, as those terms are defined in § 208.8(d) of this chapter;

(4) An acquistion 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 by the bank for 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 proceeding 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;

(4)(i) 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 (ii) 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, an extension 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 considered to be an extension of credit by the participating bank, not by the originating bank.

(f) 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, 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 grant a line of 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 and lines of credit by the member bank to that person and to all related interests of that 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 extension of credit. 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 the voting, 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 [2] 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 12 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 [3] 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 written, 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,[4] and no executive officer of a member bank shall borrow from or otherwise become indebted to the bank, except in the amounts, for the purposes, and upon the conditions specified in paragraphs (c) and (d) of this section.

(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 a first lien on 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 § 215.4(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) above, shall be reduced in amount by March 10, 1980, to be in compliance with the lending limit in § 215.4(c). Any renewal or extension of such an extension of credit on or after March 10, 1979, shall be made only on terms that will bring the extension of credit into compliance with the lending limit of § 215.4(c) by March 10, 1980. However, any extension of credit made before March 10, 1979, that bears a specific maturity date of March 10, 1980, or later, shall be repaid in accordance with its repayment schedule in existence on or before March 10, 1979.

(b) If a member bank is unable to bring all extensions of credit outstanding on March 10, 1979, into compliance as required by paragraph (a) of this section, the member bank shall promptly report that fact to 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 [5] 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 § 215.5(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.

§ 215.9 Reports by Member Banks.

Each member bank shall include with (but not as part of) each report of condition (and copy thereof) filed pursuant to 12 U.S.C. 1817(a)(3) a report of all extensions of credit made by the member bank to its executive officers [6] since the date of the bank's previous report of condition.

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[2] 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(j) above, in the case of a member bank located in a city, town or village with a population of less than 30,000.

[3] 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. 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.

[4] Sections 215.5, 215.8 and 215.9 of Regulation O implement section 22(g) of the Federal Reserve Act and do not apply to nonmember 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.

[5] See note 4 above.

[6] 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 part is subject to a civil penalty of not more than $1,000 per day for each day during which the violation continues.

Effective date: March 10, 1979.

Board of Governors of the Federal Reserve System, March 5, 1979.

THEODORE E. ALLISON,
Secretary of the Board.

APPENDIX.—SECTION 5200 OF THE REVISED STATUTES

The total obligations to any national banking association of any person, copartnership, association, or corporation shall at no time exceed 10 per centum of the amount of the capital stock of such association actually paid in and unimpaired and 10 per centum of its unimpaired surplus fund. The term "obligations" shall mean 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 guarantor who obtains a loan from or discounts paper with or sells paper under his guaranty to such association and shall include in the case of obligations of a copartnership or association the obligations of the several members thereof and shall include in the case of obligations of a corporation all obligations of all subsidiaries thereof in which such corporation owns or controls a majority interest. Such limitation of 10 per centum shall be subject to the following exceptions:

(1) Obligations in the form of drafts or bills of exchange drawn in good faith against actually existing values shall not be subject under this section to any limitation based upon such capital and surplus.

(2) Obligations arising out of the discount of commercial or business paper actually owned by the person, copartnership, association, or corporation negotiating the same shall not be subject under this section to any limitation based upon such capital and surplus.

(3) Obligations drawn in good faith against actually existing values and secured by goods or commodities in process of shipment shall not be subject under this section to any limitation based upon such capital and surplus.

(4) Obligations as indorser or guarantor of notes, other than commercial or business paper excepted under (2) hereof, having a maturity of not more than six months, and owned by the person, corporation, association, or copartnership indorsing and negotiating 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.

(5) Obligations in the form of banker's acceptances of other banks of the kind described in sections 372 and 373 of this title shall not be subject under this section to any limitation based upon such capital and surplus.

(6) Obligations of any person, copartnership, association or corporation, in the form of notes or drafts secured by shipping documents, warehouse receipts, or other such documents transferring or securing title covering readily marketable nonperishable staples when such property is fully covered by insurance, if it is customary to insure such staples 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 when the market value of such staples securing such obligation is not at any time less than 115 per centum of the face amount of such obligation, and to an additional increase of limitation of 5 per centum of such capital and surplus in addition to such 25 per centum of such capital and surplus when the market value of such staples securing such additional obligation is not at any time less than 120 per centum of the face amount of such additional obligation, and to a further additional increase of limitation of 5 per centum of such capital and surplus in addition to such 30 per centum of such capital and surplus when the market value of such staples securing such additional obligation is not at any time less than 125 per centum of the face amount of such additional obligation, and to a further additional increase of limitation of 5 per centum of such capital and surplus when the market value of such staples securing such additional obligation is not at any time less than 130 per centum of the face amount of such additional obligation, and to a further additional increase of limitation of 5 per centum of such capital and surplus in addition to such 40 per centum of such capital and surplus when the market value of such staples securing such additional obligation is not at any time less than 135 per centum of the face amount of such additional obligation, and to a further additional increase of limitation of 5 per centum of such capital and surplus in addition to such 45 per centum of such capital and surplus when the market value of such staples securing such additional obligation is not at any time less than 140 per centum of the face amount of such additional obligation, but this exception shall not apply to obligations of any one person, copartnership, association, or corporation arising from the same transactions and/or secured by the identical staples for more than ten months. Obligations of any person, copartnership, association, or corporation in the form of notes or drafts secured by shipping documents, warehouse receipts, or other such documents transferring or securing title covering refrigerated or frozen readily marketable staples when such property is fully covered by insurance, 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 when the market value of such staples securing such obligation is not at any time less than 115 per centum of the face amount of such additional obligation but this exception shall not apply to obligations of any one person, copartnership, association, or corporation arising from the same transactions and/or secured by the identical staples for more than six months.

(7) Obligations of any person, copartnership, association, or corporation in the form of notes or drafts secured by shipping documents or instruments transferring or securing title covering livestock or giving a lien on livestock when the market value of the livestock securing the obligation is not at any time less than 115 per centum of the face amount of the notes covered by such documents 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. Obligations arising out of the discount by dealers in dairy cattle of paper given in payment for dairy cattle, which bear a full recourse endorsement or unconditional guarantee of the seller and are secured by the cattle being sold, 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.

(8) Obligations of any person, copartnership, association, or corporation secured by not less than a like amount of bonds or notes of the United States issued since April 24, 1917, or certificates of indebtedness of the United States, treasury bills of the United States or obligations fully guaranteed both as to principal and interest by the United States, shall (except to the extent permitted by rules and regulations prescribed by the Comptroller of the Currency, with the approval of the Secretary of the Treasury) 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.

(9) Obligations representing loans to any national banking association or to any banking institution organized under the laws of any State, or to any receiver, conservator, or superintendent of banks, or to any other agent, in charge of the business and property of any such association or banking institution, when such loans are approved by the Comptroller of the Currency, shall not be subject under this section to any limitation based upon such capital and surplus.

(10) Obligations shall not be subject under this section to any limitation based upon such capital and surplus to the extent that such obligations are secured or covered by guaranties, of by commitments or agreements to take over or to purchase, made by any Federal reserve bank or by the United States or any department, bureau, board, commission, or establishment of the United States, including any corporation wholly owned directly or indirectly by the United States: *Provided*, That such guaranties, agreements, or commitments are unconditional and must be performed by payment of cash or its equivalent within sixty days after demand. The Comptroller of the Currency is hereby authorized to define the terms herein used if and when he may deem it necessary.

(11) Obligations 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 borrow 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 with interest to maturity, 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 Tenant 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 carriers 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: *Provided, however,* That if the bank's files or the knowledge of its officers of the financial condition of each maker of such obligations is reasonably adequate, and upon certification by an officer of the bank designated for that purpose by the board of directors of the bank, that the responsibility of each maker of such obligations has been evaluated and the bank is relying primarily upon each such maker for the payment of such obligations, the limitations of this section as to the obligations of each such maker shall be the sole applicable loan limitation: *Provided further,* That such certification shall be in writing and shall be retained as part of the records of such bank.

(14) Obligations of the Student Loan Marketing Association shall not be subject to any limitation based upon such capital and surplus.

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[6210-01-M]

[Reg. S, Docket No. R-0209]

PART 219—BANK SERVICE ARRANGEMENTS

PART 250—MISCELLANEOUS INTERPRETATIONS

Rescission of Regulation S; Amendment of Interpretation Regulations

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Revocation and amendment of interpretations.

SUMMARY: As part of its Regulatory Improvement Project, involving a substantive review of all Federal Reserve regulations, the Board has reviewed Regulation S, "Bank Service Arrangements" (12 CFR Part 219), which implements the Bank Service Corporation Act (12 U.S.C. 1861-65). That regulation specifies the manner of assuring the Board that the performance of bank services for State member banks will be subject to regulation and examination by the Board whenever the services are performed by anyone other than the bank itself. On the basis of its review and in the light of a recent amendment of the Act (Pub. L. 95-630, 92 Stat. 3677), that becomes effective on March 10, 1979, the Board has decided to: (1) Rescind Regulation S as no longer necessary; (2) revise and update its interpretations of the Act; and (3) send to State member banks through the Reserve Banks an announcement and explanation of the new provisions. The Board's actions are intended for simplification and clarification, 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:

Carl V. Howard, Attorney, Legal Division, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 (202/452-3786).

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 would 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 308 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 or guard services, is not 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* (48 Fed. Res. Bull. 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 these 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 Janury 15, 1979 (44 F.R. 3957) 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

Sec.
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.

Summary. The performance of bank services for State member banks is subject to the Board's regulation and examination, regardless of the nature of the bank servicer, including servicers that are national banks; State nonmember insured banks; non-profit, no-stock credit card servicing organizations; and servicing subsidiaries of bank holding companies.

Text. (a) Since the enactment of the Bank Service Corporation Act (the "Act") (12 U.S.C. 1861-65), the Board has on several occasions considered whether performance of "bank services" (as that term is defined in section 1(b) of the Act) for State member banks is subject to regulation and examination by the Board under section 5 of the Act if (1) the bank servicer is not a "bank service corporation" (as that term is defined in the Act), or (2) the bank servicer is a bank itself. In each instance, based on the reasoning set forth below, the Board expressed the view that section 5 of the Act applied to any organization that performed bank services for State member banks, including national banks; another State member bank; State nonmember insured banks; servicing subsidiaries of bank holding companies; and non-profit, no stock credit card servicing organizations.

(b) The Senate Committee on Banking and Currency stated with regard to section 5 of the Act, as enacted in 1962, that the Federal supervisory agencies "must be able to examine all of the banks' records, and they must be able to exercise proper supervision over all the banks' activities, whether performed by the banks' employees on their premises or by anyone else on or off the banks' premises. This examination and this supervision cannot be frustrated by a transfer of the banks' records to some other organization or by having some other organization carry out all or part of the banks' functions." (S. Rep. No. 2105, 87th Cong. 3 (1962)). Similarly, the Committee on Banking and Currency of the House of Representatives stated that "it would obviously be unwise to permit banks to avoid the examination and supervision of vital banking functions by the simple expedient of farming out such functions." (H.R. Rep. No. 2062, 87th Cong. 3 (1962)).

(c) Section 5 of the Act is not limited by its terms to "bank service corporations" as defined in the Act; nor, in the Board's opinion based on the legislative history of the Act, should such a limitation be implied. The Board concludes that the performance of bank services for State member banks by organizations that are not bank service corporations is also subject to Board regulation and examination.

(d) If the bank servicer is a national bank or a State nonmember insured bank, its performance of bank services for State member banks is subject to Board regulation and examination, despite the fact that the servicer is subject primarily to regulation and examination by one of the other Federal banking agencies. By the same token, the performance of bank services by a State member bank for a national bank or State nonmember insured bank is subject to regulation and examination by the Comptroller of the Currency or the Federal Deposit Insurance Corporation, respectively. The purpose of section 5 of the Act is to make certain that the appropriate Federal banking agency will be able effectively to exercise its responsibilities with respect to a bank subject primarily to its supervision.

(e) It is important to note that the scope of the Board's regulation and examination under section 5 of the Act does not extent to all affairs of the bank servicer, but only to the "bank services" performed for a State member bank and only to the same extent as if the services were being performed by the State member bank itself on its own premises.

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

Summary. (a) The authority of State member banks under the Bank Service Corporation Act to invest in bank service corporations is limited to investments in corporations that perform "bank services" solely.

(b) A State member bank is required by the Act to notify the Board only of the performance of "bank services" for it.

(c) "Bank services" will not usually be regarded as including legal, advisory, and administrative services, such as transportation or guard services.

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 centum 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 1(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 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."

* 12 CFR 219.101 is a cross reference to 12 CFR 225.115. The revocation of the former is not intended to result in the revocation of the latter.

(d) 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."

(e) 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 is broad and must be vigorously exercised. At the same time sound discretion 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 of such accounts. Banks 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 bank supervisory 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 (1962)).

(f) On the basis of the Act's definition of "bank 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. For example, 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 definition of "bank services" in section 1(b), or a service similar to one of those services, 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 this Act, unless such services are legitimately incidental to the provision of "bank services" by that corporation.

(h) 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 or 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.

Text. (a) 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) 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(c) of the Act.

(d) However, the Board concluded 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.

Board of Governors of the Federal Reserve System, March 5, 1979.

THEODORE E. ALLISON,
Secretary of the Board.

[FR Doc. 79-7307 Filed 3-8-79; 8:45 am]

[6210-01-M]

[Reg. Z; Docket No. R-0208]

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(i)(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. 95-630) was enacted. Section 1501 of that law (92 Stat. 3713) extended the prohibition against surcharges to February 27, 1981. Section 226.4(i)(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:

Dolores S. Smith, Section Chief, Division of Consumer Affairs, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, 202-452-2412.

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(i)(4), to read as follows:

§ 226.4 Determination of finance charge.

* * * * *

(i) * * *

(4) No creditor in any sales transaction may impose a surcharge. This

paragraph shall cease to be effective on February 27, 1981.

* * * * *

By order of the Board of Governors, March 5, 1979.

THEODORE E. ALLISON,
Secretary of the Board.

[FR Doc. 79-7154 Filed 3-8-79; 8:45 am]

[6320-01-M]

Title 14—Aeronautics and Space

CHAPTER II—CIVIL AERONAUTICS BOARD

SUBCHAPTER D—SPECIAL REGULATION

[Regulation SPR-156; Amdt. No. 2; Docket 29165]

PART 380—PUBLIC CHARTERS

Consumer Protections For Charter Participants; Simplified Prospectus Filing Procedures

Adopted by the Civil Aeronautics Board at its office in Washington, D.C. March 2, 1979.

AGENCY: Civil Aeronautics Board.

ACTION: Final Rule.

SUMMARY: The CAB is requiring that charter participants be given refunds when there are major changes in the charter packages they have purchased. In addition, there are new disclosure requirements for charter advertising and specific requirements for the contracts between charter operators and participants. The CAB is also simplifying the procedures under which operators must file prospectuses before marketing charters. This rule is designed to help to insure the participants fair treatment by the operators or, if necessary, from a court.

DATES: Adopted: March 2, 1979. Effective: the amendment of § 380.20 and the revocation of § 380.43 are effective March 2, 1979. Sections 380.31 and 380.32 (operator-participant contract requirements), § 380.33 (major changes), § 380.33a (operator's option plan), and § 380.12 (notifications) 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. Section 380.30 applies 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 amendments of §§ 380.2, 380.18, 380.23, 380.25, 380.28, 380.34, and 380.40 are effective May 1, 1979.

FOR FURTHER INFORMATION CONTACT:

Mark Schwimmer, Office of the General Counsel, Civil Aeronautics Board, 1825 Connecticut Avenue, Washington, D.C. 20428, (202) 673-5442.

SUPPLEMENTARY INFORMATION:

By a notice of proposed rulemaking, SPDR-50B, 43 FR 39807, 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 SPDR-50, 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 both requiring operator-participant contracts to contain certain terms and making the refunds a direct regulatory obligation. SPDR-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 filing Public Charter prospectuses were also proposed. Finally, SPDR-50B invited comments on the possibility of requiring operators to obtain permits before marketing charters.

Thirty-three comments and reply comments were filed by consumer protection 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 * * *." 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. SPDR-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 charters are not intended to limit the Board's authority to adopt regulations for the protection of consumers. (H. Rept. No. 95-1779, October 12, 1978, p. 68)

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 we have made a reasonable allocation between operators and participants of the burden of uncertainty that is inherent in charter transportation. The FTC stated that the rule could go a long way toward protecting consumers from major problems that they may experience on charter tours without harming the charter industry. Both the Board and the FTC have examined the travel industry, and each has found that substantial problems exist between consumers and charter tour operators. These problems have existed for a long time, and for us now to pass them on to another agency would serve only to further delay their solution.

Some commenters argued for a postponement or transfer of this rulemaking on the ground that it should include non-charter tours within its coverage. Even if it is advisable to have consumer protection rules for tours operated on scheduled air transportation, we could not do so now. Such action is beyond the scope of this rulemaking. The different legal relationships between passengers and scheduled tour 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 on operators' ability to engage in the kinds of unfair practices that we are prohibiting here.

The National Air Carrier Association (NACA) asserted 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 nonpublic ex parte participation in the development of the rule. The APA's separation of functions requirements, 5 U.S.C. 554(d), apply 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 recover 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 arbiter.

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 decreased competition and increased prices. 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, would be unobjectionable. 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 sell air transportation. 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 substitutions 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, and prices were 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 cancellations, 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 available to charter consumers. The changes that would be de-

fined as major are so fundamental that, in our tentative judgment, few consumers would freely contract away their right to object to them. Those few must be balanced against the larger number who would not be reached by even the most stringent disclosure requirements that could be devised.

The comments have not persuaded us to abandon this general approach, particularly since many of the changes in 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 filings." 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 filings 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 second option, which is more liberal than the first.) ACAP and Donald L. Pevsner preferred the first option, fearing that the more stringent disclosure accompanying the second would not be effective.

We are reluctant to flatly prohibit charter operators from naming alternative cities. As long as prospective participants can be adequately informed of the risks involved, there is no need to prohibit contracts 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 the 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 commit themselves to a particular 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, to be known as "operator's 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 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 rest of Part 380, the Board may seek civil penalties from those who violate this rule. Like the other notification requirements, the 10-day notice of that selection is a regulatory obligation in addition to a contractual obligation for the charter operator. Once 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 in each should be considered 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 allocation of the total tour time among various cities being visited is important to participants, this type of change imposes less of a hardship on passengers than changes in departure and return dates.

The FTC also recommended that "city" be defined in terms of government-established Standard Metropolitan Statistical Areas and Standard Consolidated Statistical Areas. Such a definition would unnecessarily complicate the rule. If ambiguities or deception arise in the designation of cities, they can be addressed in future rulemaking proceedings.

One commenter asked whether a changed origin city would be considered a major change if the operator provided transportation to the new city. If that transportation is not by air, the change would be major. If it is by air, there would not really be a change in the origin city. There might be, however, a violation of contractual obligations if the operator originally undertook to provide nonstop or single-plane service.

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 home and away cities, respectively. 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

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 64905, December 29, 1977, Docket 31229.) 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 actual dates at least 10 days 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 also invited comments on 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 dispose of the issue, 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 sure 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 charter 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 sale of 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 period of inflation and dollar 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 flexibility 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 for defining 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 charter operators. Since a stricter rule was not proposed, the rule adopted today incorporates the 10 percent limit. Operators should note, however, that even price increases that are within the 10 percent limit could, if they are not based on cost increases, be considered as unfair or deceptive practices in violation of section 411 of the Act. We plan to issue a further notice of proposed rule making on price increases in the near future.

Operators should also note that there is no prohibition against charging different prices to different participants on the same charter. Thus the operator can respond to an increase in the direct air carrier's charter price by increasing the price to participants who have not yet signed up while preserving it for those who already have. The fact that contracts with direct carriers, hotels, and other suppliers of services to the charter operator are made many months in advance with great price uncertainty is therefore not significant.

Remedies for Major Changes

The proposed remedy scheme for major changes was as follows: If an operator knew of a major change before departure, it would have to notify each participant within 7 days but in any event before departure. Notifications would be considered made when they were received. After receiving the notice, the participant would have 7 days to cancel (unless departure was sooner) and would get a full refund within 7 days after that. If the operator did not learn of the major change until after departure, the participant could still reject the change, but would only be entitled to a partial refund equal to that portion of his payments allocable to the component of the charter being changed. These procedures would be both incorporated in the operator-participant contract and made regulatory obligations for the charter operator.

The proposed rule also would require operator-participant contracts to state that the rights and remedies set forth in them are in addition to any others that the participant may have under applicable law. The proposal stated, however, that operators could specify that acceptance of a refund would constitute a waiver of those other remedies.

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 should be required to accept it and 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 difference in the cost of hotels to the operator is not likely to satisfy a participant who is unhappy with the substitute. Moreover, 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 that the period be lengthened, 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 must 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 the same reason, there is no requirement that refunds be received in any event before scheduled departure. (The proposed rule included such a requirement for refunds upon operator cancellations, but not for other types of refunds.)

American Express suggested that charter operators' notification duties be considered satisfied by giving notice to travel agents rather than to participants, since agents are often reluctant to disclose the addresses of their clients. This suggestion is not being 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 the required time. Similarly, if the agent does not disclose participants' addresses to the operator, the operator must ensure that the agent transmits the addresses to the depository bank (if any).

The proposal would require contracts to state that the participant's contract rights and remedies are in addition to others available under applicable law. Proposed § 380.33(c) would require an operator, upon notifying participants of major changes and their rights to refunds, to also notify them, if such is the case, that acceptance of a refund will cut off any other remedies. Some commenters argued that these provisions are inconsistent. 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(t) 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 addressed in a further notice of proposed rulemaking.

Solicitation Materials

The proposed definition of "solicitation material" was broad, and included all advertising, brochures, and any other 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 ordered or seen. The words "on behalf of", however, adequately limit the coverage of the rule to distributions for which the operator can fairly be held responsible.

ACAP 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 hotels. 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&P 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, ACAP, 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 upon discovering conditions 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 will need to obtain the signature before sending the money on 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 that 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 bold-face type at least 50 percent larger than the rest. The 7-point 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 § 380.32 of the final rule, they are (a), the charter operator's name and ad-

dress, (f), a statement about payments to the escrow account, (h), a statement about the charter operator's cancellation rights, (l), a statement that the participant's cancellation rights are limited, and (r) and (s), statements about participants' refund rights when there are major changes. Statements in 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 de-tachable booking or reservation form. That practice can continue.

Since the contract is important to consumers after signing, in addition to when they are making their purchasing decisions, we are adding a requirement that the form be designed so as to enable participants to retain a copy of its general terms and conditions. Specific information that is supplied by participants, such as choices of dates, cities, or other options, need not be retainable. Contracts with detachable booking forms would thus satisfy this requirement.

Miscellaneous Consumer Protection Provisions

The current Public Charter rule specifies that when a charter operator cancels a charter, it shall notify participants in writing within 15 days after the cancellation and in any event by the 10th day before scheduled departure. If the cancellation occurs less than 10 days before departure, the notification need not be in writing 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 suggested 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. The 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 bond-and-escrow option for 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 optional-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 Charters, 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 is 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 must supplement an escrow 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 the filing of actual charter contracts 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. Rentention of the contract filing requirement merely for this purpose is unnecessary, however, since the Board has ample authority to obtain information from carriers about their pricing 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 those contracts. 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 guarantee that the operator has in fact made arrangements for the necessary air transportation and protection of participants' funds. The proposed 10-day period reflects the staff time estimated to be necessary for review. If, after experience with simplified prospectuses, it appears that less time is needed, we will shrink further the review period. Charter operators should also note that the Board's staff can, under delegated authority, waive the 10-day ban when justified by an emergency or other circumstances.

ASTA, 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

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, so that 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 sent 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 § 380.20, 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.
380.33 Major changes in itinerary or price; refunds.
380.33a Operator's option plan.

* * * * *

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 so 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 get 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.

* * * * *

6. In § 380.23, the list of sections in paragraph (b) is amended to read:

§ 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 § 380.28.

(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 accommodations and 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 schedule 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 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. 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 flight schedule 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 also 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), (l), (r), and (s) of § 380.32 shall be printed so as to contrast with the rest of the contract, by the use of boldfaced 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-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 depository 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 may not cancel the charter less than 10 days before the scheduled departure date, except for circumstances that make it physically impossible to perform the charter trip;

(i) That if the charter is canceled 10 or more days before the scheduled departure date, the operator will notify the participant in writing within 7 days after the cancellation, but in any event at least 10 days before the scheduled departure;

(j) That if the charter is canceled less than 10 days before departure (i.e. for circumstances that make it physically impossible to perform the charter trip), the operator will get the message to the participant as soon as possible;

(k) That if the charter is canceled, a full refund will be made to the participant within 14 days after the cancellation;

(l) That the right to refunds if the participant changes plans is limited;

(m) The right to refunds if the participant changes plans, including that any participant who wishes to cancel will receive a full refund (less any applicable administrative fee, not to exceed $25) upon providing a substitute participant to the charter operator or its sales agent, or upon being substituted for by a participant found by the charter operator;

(n) The procedure for obtaining the refunds described in paragraph (m) of this section, including that they will be made within 14 days after the cancellation or substitution;

(o) The meaning of "major change", as set forth in § 380.33(a);

(p) That if the charter operator knows of a major change 10 or more days before scheduled departure, the operator will notify the participant of the change within 7 days after first knowing of it, but in any event at least 10 days before scheduled departure;

(q) That if the operator first knows of a major change less than 10 days before scheduled departure, the operator will get the message to the participant as soon as possible;

(r) That within 7 days after receiving a pre-departure notification of a major change 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;

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

(t) 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;

(u) 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;

(v) 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 all liability under the bond to that participant;

(w) 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;

(x) That the charter operator is the principal and is responsible to the participants for all services and accommo-

dations offered in connection with the charter. However, the contract may expressly provide that the charter operator, unless he is negligent, is not responsible for personal injury or property damage caused by any direct air carrier, hotel, or other supplier of services in connection with the charter.

12. A new § 380.33 is added, to read:

§ 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 (or, 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; and

(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 (k), (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 ¼ 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(e).

(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 foreign charter operators: A direct air carrier shall not perform air transportation in connection with such a charter unless it has made a reasonable effort to verify that all provisions of this part have been complied with and that the charter operator's authority under this part has not been suspended by the Board.

(b) For foreign-originating Public Charters organized by foreign charter operators: 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]

16. Section 380.43, *Record retention*, is revoked and reserved.

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

APPENDIX B, C, AND D—CAB FORMS 380-B, 380-C, AND 380-D

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 Divisions, Civil Aeronautics Board, Washington, D.C. 20428.

(Secs. 101(3), 204, 401, 402, 404, 407, 411, 416, and 1102 of the Federal Aviation Act of 1958, as amended, 72 Stat. 737, 743, 754, 757, 760, 766, 769, 771, 791; 49 U.S.C. 1301, 1324, 1371, 1372, 1374, 1377, 1381, 1386, and 1502.)

By the Civil Aeronautics Board:

PHYLLIS 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 _____ (charter operator's surety) [and to _____ (depository bank)].[1]

[1] Omit the bracketed portion if no depository bank is used.

CHARTER OPERATOR

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. ————, in the amount of $————, on ———— (date). This bond covers proposed 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).

(Check one)

☐There are no outstanding claims against this bond.

☐There are outstanding claims against this bond in the amount of $————. We have executed a rider to the bond on ———— (date) increasing the bond by this amount.[2]

CHARTER OPERATOR

By:

.....
(Signature and date)

.....
(Title)

.....
(Address)

SURETY COMPANY

By:

.....
(Signature and date)

.....
(Title)

.....
(Address)

APPENDIX D

STATEMENT OF CHARTER OPERATOR, DIRECT AIR CARRIER AND DEPOSITORY BANK

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

CHARTER OPERATOR

By:

.....
(Signature and date)

.....
(Title)

.....
(Address)

DIRECT AIR CARRIER

By:

.....
(Signature and date)

.....
(Title)

.....
(Address)

DEPOSITORY BANK

By:

.....
(Signature and date)

.....
(Title)

.....
(Address)

[FR Doc. 79-7115 Filed 3-8-79; 8:45 am]

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

[3510-13-M]

Title 15—Commerce and Foreign Trade

SUBTITLE A—OFFICE OF THE SECRETARY OF COMMERCE

PART 7a—NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM: GENERAL

PART 7b—NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM: FEDERAL GOVERNMENT

Optional Procedures; Final Rule

AGENCY: Assistant Secretary of Commerce for Science and Technology.

ACTION: Final rule; announcing optional procedures for use by Federal agencies in utilizing the National Voluntary Laboratory Accreditation Program.

SUMMARY: Procedures for accrediting laboratories under the National Voluntary Laboratory Accreditation Program (NVLAP) were established on February 25, 1976 (15 CFR Part 7; 41 FR 8163-8168). On October 25, 1978 (43 FR 49812-49818), the Department of Commerce (hereafter referred to as Department) proposed to redesignate the existing NVLAP procedures as 15 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 also 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:

Dr. Howard I. Forman, Deputy Assistant Secretary for Product Standards, Room 3876, U.S. Department of Commerce, Washington, D.C. 20230, 202-377-3221.

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 15 CFR Part 7, will now 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 specfic 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 are 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 Secretary 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 Received in Response to Proposed Optional Laboratory Accreditation Procedures Designed for Federal Agency Needs." This report and a copy of the comments are part of the public record and are available for inspection and copying in the Department's Central Reference and Records Inspection Facility, Room 5317, 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 issued 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 associaton 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 a new 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 adapting 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 or otherwise controlled by another 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 of need requirement 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(b)(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(c)) that the request for a NVLAP program under these optional procedures will be published by the Department in the FEDERAL REGISTER, along 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 requesting the program.

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 requestors 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 interests objected to the possibility of eliminating the establishment of a National Laboratory Accreditation Criteria Committee and the involvement of the private sector in establishing accreditation criteria. In this regard, the actual 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 an informal 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 a 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 specifies particular facilities, 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 accepted 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 are 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 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 materials 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 a LAP 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 periods of certain aspects of evaluation of the laboratories 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 a 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 product areas served by NVLAP, 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 provisions of NVLAP in regulated product areas is clearly the responsibility of the Federal regulatory agency. Since Part 7b is entirely optional for use at the discretion of requesting Federal agencies, the prerogatives of such agencies will not be affected.

Another Federal agency suggested that the Department should plan to request its own agency funding for all product areas covered by NVLAP since the final benefits of NVLAP would be a national laboratory family leading to a more dependable national system and better international recognition of accredited United States' laboratories. But NVLAP was designed as a service program for industry and ultimately consumers in areas where there appeared to be significant needs. The program is intended to be financially self-sustaining after an initial period of development. Funding by the Department, even for that initial period of development, is limited. Only product areas with the highest priority can be included under current funding levels. The provision allowing other agencies to provide funding gives a requesting Federal agency an oportunity to have a program initiated in a product area of great interest to it but which may not be of as great a priority to the Department as are other product areas awaiting action in the program.

Another respondent suggested that, in eliminating the provisions for finding a need and assembling a Criteria Committee to recommend accreditation criteria, and in offering the program to Federal regulatory agencies thereby establishing accreditation programs by rule, it would be euphemistic to refer to such programs as voluntary. Many alternatives were considered before it was decided to use National Voluntary Laboratory Accreditation Program (NVLAP) in the title of these optional procedures. It is true that the nature of voluntary participation may change if the program is used by Federal agencies, particularly regulatory agencies. However, since accreditation would be granted under procedures compatible with existing NVLAP procedures, the Department decided that in this case NVLAP really identified the method for accreditation, and use of another acronym or name may cause confusion by denying that close relationship. Moreover, even though Federal agencies may, on their own authority, decide to establish an accreditation program under which products subject to their regulatory control must be tested by accredited laboratories, the laboratories can elect to participate or not as they see fit. An election not to participate, although reducing the opportunity to serve certain market areas, is nevertheless a voluntary act.

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.

A Federal agency suggested that all Federal construction agencies should participate in establishing uniform accreditation procedures for laboratories testing construction materials and that the procedures should delineate the areas in which a laboratory has demonstrated testing competence. The proposed optional procedures do not provide for separate laboratory accreditation procedures for each agency but they do allow an agency to request a program expressly for its needs. Because of the Department's control of the criteria, uniform accreditation procedures are expected. The test methods for which a laboratory has demonstrated competence will be delineated, and that information will be announced in the FEDERAL REGISTER in the month the decision is made and will be contained in quarterly reports available to all interested parties.

In addition to the above areas of interest and concern, six respondents simply acknowledged the procedures and expressed no objection to them.

Regulatory Analysis. President Carter's Executive Order 12044, "Improving Government Regulations," directs that a regulatory analysis be prepared for each significant regulation determined to have 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 requesting agency.

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, these 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.

Issued: February 28, 1979.

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 8163-8168) is hereby redesignated Title 15 CFR Part 7a—National Voluntary Laboratory

Accreditation Program: General. Each section thereunder shall be denominated as 7a followed by the appropriate section number.

15 CFR Part 7b National Voluntary Laboratory Accreditation Program: Federal Government. Part 7b is added to Title 15 CFR to read as follows:

Sec.
7b.1 Purpose.
7b.2 Description and goal of program.
7b.3 Definitions.
7b.4 Request to establish a laboratory accreditation program (LAP).
7b.5 Establishment of criteria with which to accredit laboratories.
7b.6 Establishment and functions of a National Laboratory Accreditation Criteria Committee.
7b.7 Development and recommendation of criteria for accrediting testing laboratories.
7b.8 Publication of proposed criteria.
7b.9 Coordination with Federal agencies.
7b.10 Establishment of fees and charges.
7b.11 Participation of testing laboratories.
7b.12 Reference to accredited status.
7b.13 Revocation or termination of accreditation of a testing laboratory.
7b.14 Cessation of accreditations.
7b.15 Refund of fees and charges.
7b.16 Amendment or revision of criteria.
7b.17 User information and reports.
7b.18 Support function.

AUTHORITY: Sec. 2, 31 Stat. 1449, as amended; sec. 1, 64 Stat. 371 (15 U.S.C. 272); Reorganization Plan No. 3 of 1946, Part VI.

§ 7b.1 Purpose.

The purpose of this part is to establish procedures for the operation of a National Voluntary Laboratory Accreditation Program (NVLAP) serving Federal agencies which have specific regulatory or public service programs.

§ 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 interest 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 accrediting 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 evolution 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 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 the 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.

(b) Such a request shall be in writing and will include the following:

(1) Identification of the product;

(2) Text of applicable rules or product standards;

(3) Text of test methods, if not included in the applicable rule or standard identified in paragraph (b)(2) of this section;

(4) A statement of the need identified under paragraph (a) of this section for accrediting testing laboratories that serve the product identified in paragraph (b)(1) of this section, a description of the procedures followed (if any) in making the determination, and a citation of the specific authority relied upon in making the determination of need;

(5) Recommended general and specific criteria compatible with similar criteria established under either NVLAP Part 7a procedures or these Part 7b procedures to be used in accreditation of test laboratories, or a request for the establishment of a National Laboratory Accreditation Criteria Committee to develop and recommend such criteria to the Secretary;

(6) A statement regarding the degree to which the agency is willing to support any necessary developmental aspects of the program with funding and personnel; and

(7) A designation of one or more representatives of the agency with whom the Secretary may consult in administering the requested LAP.

(c) Such request when received will be published by the Department in the FEDERAL REGISTER giving the name, address, and telephone number of the responsible official of the requesting Federal agency who may be contacted with respect to the need for such program. Comments as to the need shall be made directly to the requesting agency with a copy to the Department of Commerce for information.

(d) If, on the basis of the information provided or because of the lack of funding and personnel from the requesting agency, the Secretary is unable to justify the establishment of a NVLAP under these Part 7b procedures, the Secretary will decline to act further on the request. The Secretary shall in that event notify the requesting agency in writing within ten (10) working days after making a decision and shall state the reasons for so declining.

§ 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 issued by the Secretary under these procedures. The general criteria will deal with those qualities which

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 chose 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.

(2) 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.

(b) The general and specific criteria developed under this section for accrediting testing laboratories will be based upon criteria found in existing rules or standards where such existing criteria are deemed appropriate. Where appropriate existing criteria cannot be found, the requesting Federal agency, in those cases where it has elected to recommend general and specific criteria to the Secretary, or the Criteria Committee, will, at the request of the Secretary, undertake to develop and recommend such appropriate general and specific criteria as may be needed.

(c) The criteria shall contain instructions for making application for accreditation by testing laboratories serving the product involved and shall require that each testing laboratory that desires to participate in this program must agree to conditions that include but are not limited to the following:

(1) Be examined and audited initially and on a continuing basis;

(2) Pay accreditation fees and charges; and

(3) Avoid reference by itself and forbid others utilizing the services of an accredited testing laboratory from referencing its accredited status under NVLAP in consumer media and in product advertising or on product labels, containers and packaging or the contents therein or in any other way which might convey the concept of product certification by the Department of Commerce.

(d) The criteria shall contain a statement that compliance by testing laboratories with the general and specific criteria and other conditions established by the Secretary, and which laboratories are accredited by the Secretary under these procedures, shall in no way relieve such laboratories from the necessity of also observing and being in compliance with any existing Federal, State, and local statutes, ordinances, and regulations that may be applicable to the operation of such laboratories, including consumer protection and antitrust laws.

(e) In carrying out the activities authorized by this section:

(1) 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;

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

(3) No action will be taken under this program to modify a product standard, a test method standard, or a comparable administrative rule where such a standard or rule is in existence; and

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

§ 7b.8 Publication of proposed criteria.

(a) Upon its development of the general and specific criteria for accrediting testing laboratories under § 7b.7, 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. The Secretary, after consideration of such recommendations (see § 7b.5(c)), will publish in the FEDERAL REGISTER a notice giving the complete text of the proposed general and specific criteria, and inviting any interested persons to submit written comments on such proposed criteria within ninety (90) days after such publication in the FEDERAL REGISTER, unless another time limit is provided by the Secretary.

(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

5317, Department of Commerce Building, 14th Street between E Street and Constitution Avenue NW., Washington, D.C. 20230, and will be available for public inspection and copying at that location.

(c) The Secretary upon receipt of all written and oral comments will ask the requesting Federal agency, in those cases where it has recommended general and specific criteria to the Secretary, or the Criteria Committee, to conduct and return to the Secretary in writing, within a time period specified by the Secretary, its evaluation and recommendations with respect to such comments. After considering such evaluation and recommendations, and after consultation with the requesting Federal agency, the Secretary will publish in the FEDERAL REGISTER a notice:

(1) Announcing the final general and specific criteria that testing laboratories must meet in order to be accredited and the date when such final criteria shall go into effect which shall not be less than thirty (30) days after the date of publication of such notice;

(2) Stating that the proposed general and specific criteria will be further developed before final publication; or

(3) Withdrawing the proposed general and specific criteria from further consideration.

§ 7b.9 Coordination with Federal agencies.

As a means of assuring effective and meaningful cooperation, input, and participation by those Federal agencies (other than the requesting agency) that have an interest in and may be impacted by the laboratory accreditation program carried out under these procedures, the Secretary shall undertake to communicate and consult with appropriate officials within those agencies. The coordination efforts will include opportunities for representatives designated by those agencies to serve on each Criteria Committee established by the Secretary 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 amended (15 U.S.C. 278b), or any similar financial arrangement for this program, shall establish fees and charges for examining, accrediting, and auditing testing laboratories. The fees and charges established by the Secretary, which may be revised when the Secretary deems it appropriate to do so, shall be in amounts calculated to enable the self-sufficiency of this program. A separate notice will be published in the FEDERAL REGISTER simultaneously 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 establish. 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 referred to in § 7b.8(c)(1), the Secretary shall also simultaneously publish a separate notice in the FEDERAL REGISTER setting forth the final schedule of fees that will be charged testing laboratories that serve a specific product. The effective date of such final schedule 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 (b) of this section shall be published in subsequent FEDERAL 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 laboratories.

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

(b) After receipt and evaluation of the testing laboratory's application and information contained therein, the secretary shall, upon the acceptance thereof, notify the applicant testing laboratory and the National Bureau of Standards in writing of the specific applicable examination requirements 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 application, and such testing laboratory may reapply under § 7b.13(d) after correcting 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 requests a hearing within that thirty (30) day period the Secretary's rejection 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 accordance with the administrative rules, standards, and test methods identified must meet the general and specific criteria 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 paragraph (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 personnel used by the contractor or by the National Bureau of Standards possess the professional and technical qualifications as may be set out in the specific 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 following the date on which the report is received. If the determination is not made within such time limit, the Secretary shall notify the applicant testing laboratory in writing of the reasons for the delay. Upon making such determination, the Secretary will notify the testing laboratory in writing of its accreditation status. If the Secretary proposes to deny accreditation 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 proposal to deny accreditation, the testing 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

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 letterheads and in professional, technical and trade publications: "Accredited by the Department of Commerce, National Laboratory Accreditation Program for (appropriate wording as authorized by the Secretary's notification under § 7b.11(e))."

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

(a) If the Secretary finds that a testing laboratory which has previously been accredited violated the terms of its accreditation or the provisions of these Part 7b procedures, after consultation with such testing laboratory, the Secretary shall notify that testing laboratory of the proposed revocation of its accreditation.

(b) Upon receipt of a notice from the Secretary of the proposed revocation, which notice shall set forth the reasons for such proposed revocation, the accredited testing 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 revocation shall become final through the issuance of a written decision to the testing laboratory in the event that such testing laboratory does not appeal the proposed revocation within that thirty (30) day period. In the event, however, that the accredited testing laboratory requests a hearing within that thirty (30) day period, the Secretary's proposed revocation shall be stayed until the hearing is held pursuant to 5 U.S.C. 556.

(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 by the Secretary 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 testing laboratory's accreditation. The Secretary shall notify the testing laboratory that its accreditation has been terminated pursuant to its request.

(d) A testing laboratory whose application has been rejected or whose accreditation has been denied, revoked or terminated or which has withdrawn its application prior to being accredited may reapply for and be accredited if it meets the applicable general and specific criteria promulgated by the Secretary under § 7b.8(c)(1) and agrees also to meet the conditions set out under § 7b.7(c) and the provisions of § 7b.12.

§ 7b.14 Cessation of accreditations.

(a) The Secretary shall cease the accreditation of testing laboratories that serve a specific product if requested to do so by the Federal agency which requested the program if such agency makes a determination that the program is no longer needed. Such request, however, may not be made if the program has been in existence for less than one year after publication of the final accreditation criteria. The determination that the program is no longer needed shall be submitted to the Secretary in writing and shall set forth the requesting agency's reasons for causing the Secretary to cease accreditation through this NVLAP. Termination of the program will occur 60 days after the Secretary has published in the FEDERAL REGISTER a notice of such determination. If the program is being used for a purpose in addition to the purpose specified by the requesting Federal agency, the accreditation program may be continued in its own right under the original or other optional NVLAP procedures.

(b) If the Secretary ceases the accreditation of testing laboratories that serve a specific product as provided in this section, accreditation issued to all those testing laboratories serving the same specific product before termination of the program has occurred shall continue for the remainder of the period for which accreditation has been granted.

§ 7b.15 Refund of fees and charges.

(a) If a testing laboratory withdraws its application for accreditation after it has submitted the required examination fees and provides written notice to the Secretary of such withdrawal prior to the issuance of an accreditation of the denial thereof, the testing laboratory will be refunded such fees except for the application fee, if any, and for any other costs that have been incurred relative to its application.

(b) If a testing laboratory terminates its participation and responsibilities under this Part 7b program at any time after it has been accredited or after it has been notified by the Secretary that it is not being accredited, no part of the fees and charges paid by the testing laboratory will be refunded.

(c) If the accreditation of a testing laboratory is revoked by the Secretary under § 7b.13, no part of the fees and charges paid by the testing laboratory will be refunded.

(d) If the Secretary ceases the accreditation of testing laboratories that serve a specific product under § 7b.14 and withdraws the 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 to maintain its accredited status 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 accreditation exists, the Secretary will 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 related 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. 79-7043 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-resistent 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-resistent 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:

Sandra Eberle, Directorate for Compliance and Enforcement, Consumer Product Safety Commission, Washington, D.C. 20207, phone (301) 492-6400.

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", 15 U.S.C. 1471-1476) 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.

On July 11, 1974, the Consumer Product Safety Commission received a petition (PP 75-2) from the Ortho Pharmaceutical Corporation (Ortho), Raritan, New Jersey, requesting an exemption from the special packaging requirements for "Vermox"[R] (mebendazole) in tablet form in packages containing not more than 600 mg. of the drug. Vermox[R] 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. After the denial of the petition, Ortho reported that a New Drug Application (NDA 17-481) had been approved on June 28, 1974. On June 23, 1975, 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 effect by interference with glucose uptake in susceptible worms while having no effect on human glucose metabolism. Currently, Vermox[R] is supplied in child-resistant blister strips 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 product, stating 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 this 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[R]: "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[R] 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 four cases, 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. However, the Commission considers the small number of reported ingestions and the fact that none of them was serious to be significant, even without age and dosage information. In addition, 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 calculated in the three species 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 mebendazole.

Studies submitted by the petitioner indicate that mebendazole has been evaluated in 4,657 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 gastrointestinal 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 noncomplying package is requested." Although 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 injury or serious illness.

After the comments responding to the proposal were received, the Commission again requested the opinions of the members of the Technical Advisory Committee on Poison Prevention Packaging since a number of new members of the Committee were not members at the time of the consultation before the proposal. Nine members of the Committee responded, and six of these were in favor of the exemption while three were opposed. Copies of the members' responses may be obtained from the Office of the Secretary, 1111 18th Street, NW., Washington, D.C. 20207.

Based on an overall review of toxicity information and human experience data as reported in the literature, the data submitted by the petitioner, and the opinions of the members of the Technical Advisory Committee, the Commission finds that mebendazole in tablet form in packages containing not more then 600 mg. of the drug, and containing no other substance subject to the requirements for special packaging under 16 CFR 1700.14(a)(10), does not pose a risk of serious personal illness or injury to children.

Because this rule grants an exemption, the requirement of the Administrative 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 exemption is therefore effective immediately.

Accordingly, pursuant to the provisions of the Poison Prevention Packaging 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 Product Safety Act (Pub. L. 92-572; sec. 30(a); 86 Stat. 1231; 15 U.S.C. 2079(a)), the Commission amends Subchapter E, Chapter II, of Title 16 of the Code of Federal Regulations by adding to § 1700.14 a new paragraph (a)(10)(xiii) reading as follows (the introductory portion of paragraph (a)(10), although unchanged, is included 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 600 mg. of the drug, and containing no other substance subject to the provisions of this section.

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

(Secs. 2, 3, 5, Pub. L. 91-601, 84 Stat. 1670-1672; 15 U.S.C. 1471, 1472, 1474)

Dated: March 5, 1979.

SADYE DUNN,
Secretary, Consumer Product Safety Commission.

[FR Doc. 79-7140 Filed 3-8-79; 8:45 am]

[4110-03-M]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

[Docket No. 78G-0488]

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

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

AGENCY: Food and Drug Administration.

ACTION: Correction.

SUMMARY: In FR Doc. 79-3805 appearing 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"; and (2) on page 6707 in the left column, the third line from the top of the page is changed by inserting the word "substitute" between the words "butter" and "from."

EFFECTIVE DATE: March 9, 1979.

FOR FURTHER INFORMATION CONTACT:

Corbin I. Miles, Bureau of Foods (HFF-335), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-472-4750.

Dated: March 2, 1979.

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

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

[4110-03-M]

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

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

Diethylcarbamazine Citrate Tablets

AGENCY: Food and Drug Administration.

ACTION: Final rule.

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 ascarids in dogs and cats 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 209, 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 (e)(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.

(*c*) As an aid in treatment of ascarid infections in dogs (*Toxocara canis* and cats (Toxocara Canis and *Toxascaris leonina.*)

* * * * *

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

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: March 2, 1979.

TERENCE HARVEY,
Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 79-7028 Filed 3-8-79; 8:45 am]

[4110-03-M]

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 (102-673V) 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 reevaluation 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 Dichlorophene and toluene capsules.

* * * * *

(c)(1) *Sponsor.* Nos. 000010, 000081, 000298, 000856, 010290, 011519, 011536, 011614, 015563, 017135, and 023851 in § 510.600(c) of this chapter.

* * * * *

(d)(1) *Sponsor.* Nos. 000124, 000859, and 011716 in § 510.600(c) of this chapter.

* * * * *

Effective date. This regulation becomes effective (*insert date of publication in the* FEDERAL REGISTER).

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: February 28, 1979.

LESTER CRAWFORD,
Director, Bureau of Veterinary Medicine.

[FR Doc. 79-7029 Filed 3-8-79; 8:45 am]

[4110-03-M]

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

PART 522—IMPLANTATION OR INJECTABLE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Diatrizoates

AGENCY: Food and Drug Administration.

ACTION: Final rule.

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

EFFECTIVE DATE: March 9, 1979.

FOR FURTHER INFORMATION CONTACT:
John A. Richards, Federal Register Writer (HFC-11), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2994.

SUPPLEMENTARY INFORMATION: Sections 520.1362 and 522.1362 of the animal drug regulations (21 CFR 520.1362 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, 1975 (40 FR 13802).

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 meglumine and diatrizoate sodium." The change in name necessitates the following nonsubstantive changes to the regulations:

(1) Section 520.1362 *Meglumine diatrizoate and sodium diatrizoate oral solution* is redesignated as § 520.563, and its heading and the names of the component drugs in paragraph (a) *Specifications* are revised, to correspond to the numbering scheme of the regulations and to the USP nomenclature.

(2) Section 522.564 *Sodium diatrizoate and meglumine diatrizoate injection* is deleted and its substance is incorporated into new § 522.563. In the new section, the names of the component drugs in the headings and in paragraph (a) *Specifications* are revised to correspond to the USP nomenclature. Also, additional specifications from § 522.1362 are incorporated into the new section.

(3) Section 522.1362 *Meglumine diatrizoate and sodium diatrizoate injection* is deleted, and its specifications, contained in paragraph (a), are incorporated, with appropriate name changes, into new § 522.563(a). Pargraphs (b) and (c) of § 522.1362, which are identical to § 522.564 (b) and (c) are incorporated unchanged into § 522.563.

To accomplish these changes expeditiously, FDA is reissuing the sections in full in this document.

Because the changes are editorial and nonsubstantive in nature, the Commissioner of Food and Drugs finds that notice and public procedure are unnecessary, and that good cause exists for making this regulation effective immediately upon publication in the FEDERAL REGISTER.

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 66 percent diatrizoate meglumine and 10 percent diatrizoate sodium.

(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 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 use in dogs and cats for visualization in excretion urography, including renal angiography, uretography, cystography, and urethrography; aortography; angiocardiography, peripheral arteriography, and venography; selective coronary arteriography; cerebral angiography; lymphography; arthrography; discography; and sialography. It is also useful as an aid in delineating peritoneal hernias and fistulous tracts.

(2) For excretion urography administer 0.5 to 1.0 milliliter per pound of body weight to a maximum of 30 milliliters intravenously. For cystography remove urine, administer 5 to 25 milliliters directly into the bladder via catheter. For urethrography administer 1.0 to 5 milliliters via catheter into the urethra to provide desired contracts delineation. For angiocardiography (including aortography) rapidly inject 5 to 10 milliliters directly into the heart via catherer or intraventricular puncture. For cerebral angiography rapid injection of 3 to 10 milliliters via carotid artery. For peripheral arteriography and/or venography and selective coronary arteriography rapidly inject 3 to 10 milliliters intravascularly into the vascular bed to be delineated. For lymphography slowly inject 1.0 to 10 milliliters directly into the lymph vessel to be delineated. For arthrography slowly inject 1.0 to 5 milliliters directly into the joint to be delineated. For discography slowly inject 0.5 to 1.0 milliliter directly into the disc to be delineated. For sialography slowly inject 0.5 to 1.0 milliliter into the duct to be delineated. For delineation of fistulous tracts slowly inject quantity necessary to fill the tract. For delineation of peritoneal hernias inject 0.5 to 1.0 milliliter per pound of body weight directly into the peritoneal cavity.

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

§§ 522.564, 522.1362 [Deleted]

b. By deleting §§ 522.564 *Sodium diatrizoate and meglumine diatrizoate injection* and 522.1362 *Meglumine diatrizoate and sodium diatrizoate injection.*

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

(Secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b, 371(a)).)

Dated: March 5, 1979.

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

[FR Doc. 79-7142 Filed 3-8-79; 8:45 am]

[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 Piperi-

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 piperidine 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:

Alfred A. Russell, Chief, Regulatory Support Division, Drug Enforcement Administration, telephone 202-633-1570.

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 Piperidine Reporting—of Pub. L. 96-633 "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:

* * * * *

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 "piperidine" includes its salts and acyl derivitives;

(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 piperidine, unless exempted in accordance with § 1310.04(c) shall report:

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

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

(c) All thefts or significant losses of piperidine.

§ 130.03 Content of reports.

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

(a) For an individual purchaser:

(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 piperidine;

(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 piperidine.

(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 piperidine;

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

(4) The quantity and form of piperidine;

(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 piperidine.

§ 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:

Supplier-Importer:
Name _____
Business phone _____
Address _____
City _____ State ___ Zip _____
Name of person authorizing shipment ___
Title _____
Purchaser:
Name _____
Business phone _____
Address _____
City _____ State ___ Zip _____
Age (if individual purchaser) _____
Name of Person Requesting Shipment ___
Title _____
Shipping address (if other than purchaser):
Street _____
City _____ State ___ Zip _____
Identification:
Purchase Order No. _____
Drivers License No. _____
Credit Card No. _____
Other _____
Method of Shipment:
Company Truck _____
Common Carrier _____
Customer pick up _____
Other _____
Quantity and Form _____
Date of Shipment _____
Intended use of piperidine: _____

_____

Loss or Theft:
Date _____ Quantity ___ In Transit ___
Theft from premises _____

(c) Notwithstanding the provisions of sub-paragraph (a) hereof, and § 1310.06, beginning on June 30, 1979 and on each December 31 and June 30

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 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 3-8-79; 8:45 am]

[4910-22-M]

Title 23—Highways

CHAPTER I—FEDERAL HIGHWAY ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

SUBCHAPTER H—RIGHT-OF-WAY AND ENVIRONMENT

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:

(16 U.S.C. 470f, 662(a), 1301; 23 U.S.C. 128, 138, 315; 42 U.S.C. 4332(2)(C) and (D), 7401; 49 U.S.C. 1653(f); 40 CFR 1500; and 49 CFR 1.48(b).)

Issued on: March 1, 1979.

LORENZO CASANOVA,
Chief Counsel.

[FR Doc. 79-7155 Filed 3-8-79; 8:45 am]

[4210-01-M]

Title 24—Housing and Urban Development

CHAPTER X—FEDERAL INSURANCE ADMINISTRATION

SUBCHAPTER B—NATIONAL FLOOD INSURANCE PROGRAM

[Docket No. 5199]

PART 1915—IDENTIFICATION AND MAPPING OF SPECIAL FLOOD HAZARD AREAS

Communities With Minimal Flood Hazard Areas

AGENCY: Federal Insurance Administration, HUD.

ACTION: Final rule.

SUMMARY: The Federal Insurance Administrator, after consultation with local officials of the communities listed below, has determined, based upon analysis of existing conditions in the communities, that these communities' Special Flood Hazard Areas are small in size, with minimal flooding problems. Because existing conditions indicate that the area is unlikely to be developed in the forseeable future, there is no immediate need to use the existing detailed study methodology to determine the base flood elevations for the Special Flood Hazard Areas.

Therefore, the Administrator is converting the communities listed below to the Regular Program of the National Flood Insurance Program (NFIP) without determining base flood elevations.

EFFECTIVE DATE: The date of this notice.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard W. Krimm, Assistant Administrator, Office of Flood Insurance, (202) 755-5581 or Toll Free Line 800-424-8872, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410.

SUPPLEMENTARY INFORMATION: In these communities, the full limits of flood insurance coverage are available at actuarial, non-subsidized rates. The rates will vary according to the zone designation of the particular area of the community.

Flood insurance for contents, as well as structures, is available. The maximum coverage available under the Regular Program is significantly greater than that available under the Emergency Program.

Flood insurance coverage for property located in the communities listed can be purchased from any licensed

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:

§ 1915.9 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
Ohio, Hamilton, City of Wyoming
Pennsylvania, Lycoming, Township of Mill Creek
Pennsylvania, York, Borough of New Freedom
Louisiana, St. Helena Parish, Village of Montpelier

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 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. 2080, this rule has been granted waiver of Congressional review requirements in order to permit it to take effect on the date indicated.

Issued: February 23, 1979.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

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

[4210-01-M]

[Docket No. FI-4721]

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 City of Hilliard, Franklin 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 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:

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 Hilliard, Franklin County, Ohio.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), 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:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Clover Groff Ditch.	South corporate limits	937
	Just downstream of Scioto Darby Creek Road.	940
Hayden Run	East corporate limit	909
	640 feet upstream of Avery Road.	910
	1,400 feet upstream of Avery Road.	912
Tudor Ditch	100 feet upstream of east corporate limit.	870
	50 feet upstream of Parkway Lane.	875
	940 feet upstream of Parkway Lane.	880
	Just downstream of ConRail.	889
Hamilton Ditch	East corporate limit	869
	100 feet downstream of Lyman Drive.	876
	800 feet upstream of Lyman Drive.	884
	Just downstream of ConRail.	898
	Just upstream of ConRail.	902
	Just downstream of Leap Road.	903
	Just upstream of Leap Road.	907
	1,670 feet upstream of Leap Road.	912

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 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. 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]

[4210-01-M]

[Docket No. FI-4639]

PART 1917—APPEALS FROM PROPOSED FLOOD ELEVATION DETERMINATIONS

Final Flood Elevation Determination for the Village of Jefferson, Ashtabula 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 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 Village of Jefferson, Ashtabula County, Ohio.

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. 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 Village of Jefferson, Ashtabula 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. 4001-4128, 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:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Cemetery Creek	At Poplar Street	866
	200 feet upstream of Poplar Street.	868
	600 feet upstream of Poplar Street.	870
	250 feet downstream of Elm Street.	872
	250 feet upstream of Elm Street.	874
	Just downstream of Chestnut Street.	882
	Just upstream of Chestnut Street.	884
	500 feet upstream of Chestnut Street.	885

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 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, 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 25, 1979.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 79-6791 Filed 3-8-79; 8:45 am]

[4210-01-M]

[Docket No. FI-4640]

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.

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 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. 4001-4128, 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:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Lake Erie	Entire City of Mentor-on-the-Lake.	576

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 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. 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. 79-6792 Filed 3-8-79; 8:45 am]

[4210-01-M]

[Docket No. FI-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-

dence 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 Village of Waite Hill, Lake County, Ohio.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the final elevations for the Village of Waite Hill are available for review at the Village Hall, Eagle Road, Waite Hill, Ohio.

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 Village of Waite Hill, 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. 4001-4128, 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:

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 Bound I-90.	620
	0.64 miles downstream of Markell Road.	628
	0.34 miles downstream of Markell Road.	631
	Upstream corporate limit.	638

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 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. 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. 79-6793 Filed 3-8-79; 8:45 am]

[4210-01-M]

[Docket No. FI-3744]

PART 1917—APPEALS FROM PROPOSED FLOOD ELEVATION DETERMINATION

Final Flood Elevation Determination for the City of Duncan, Stephens County, Oklahoma

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 Duncan, Stephens County, Oklahoma.

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 Duncan, Stephens County, Oklahoma.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the final elevations for the City of Duncan, Stephens County, Oklahoma, are available for review at the City Engineer's Office, Eighth and Willow Streets, Duncan, Oklahoma.

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 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 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,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:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Claridy Creek	Just upstream of Seminole Street.	1063
	Just downstream of Bois D'Arc.	1080
	Just downstream of Oak Avenue.	1102
	Just upstream of Elk Avenue.	1130
Cow Creek	Just upstream of State Highway 7 culvert.	1071
Holiday Inn Fork	Just downstream of Elk Avenue.	1140
Willow Creek	Just downstream of Fair Park Boulevard.	1085
	Just upstream of Main Street.	1107
	Just downstream of Plato Road.	1182
Tributary B	Just upstream of Beech Street.	1100
Tributary D	Just upstream of Park Avenue.	1100
Tributary E	Approximately 100 feet downstream of Pecan Avenue.	1115
Tributary F	Just downstream of State Highway 7.	1090

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 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 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.

[FR Doc. 79-6794 Filed 3-8-79; 8:45 am]

[4210-01-M]

[Docket No. FI-4566]

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 Drain, Oregon.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the final elevations for the City of Drain, are available for review at City Hall, City Administrator's Office, Drain, Oregon.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 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 Drain, 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 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:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Elk Creek	Fir Street—20 feet*	287
	Cedar Street—100 feet*	291
	Footbridge—100 feet*	294
	Southern Pacific Railroad—100 feet*.	296
Pass Creek	Southern Pacific Railroad—20 feet*.	293
	B Street—100 feet*	296

*Upstream of centerline.

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 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. 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 25, 1979.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 79-6795 Filed 3-8-79; 8:45 am]

[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, 647 1st 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, 202-755-5581 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 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 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:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Cow Creek	Downstream corporate limits.	669
	Main Street—20 feet upstream of centerline.	672

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33

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. 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 25, 1979.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 79-6796 Filed 3-8-79; 8:45 am]

[4210-01-M]

[Docket No. FI-4242]

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 City of Chester, Delaware County, Pennsylvania

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the final elevations for the City of Chester, 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:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Ridley Creek	Corporate limits upstream.	41
	Chester Park Dam upstream.	32
	Chester Park Dam downstream.	31
	East 25th Street upstream.	23
	Interstate Route 95 upstream.	14
	4th Street upstream	12
Chester Creek	Corporate limits upstream.	28
	Chessie System upstream.	26
	9th Street upstream	24
	2nd Street upstream	13

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 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, 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 5, 1979.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 79-6797 Filed 3-8-79; 8:45 am]

[4210-01-M]

[Docket No. FI-4596]

PART 1917—APPEALS FROM PROPOSED FLOOD ELEVATION DETERMINATION

Final Flood Elevation Determination for the Township of Cleveland, Columbia 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 Township of Cleveland, Columbia 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, Columbia County, Pennsylvania.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the final elevations for the Township of Cleveland, Columbia County, Pennsylvania, are available for review at the Cleveland Township Municipal Building, Fisherdale, 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 Township of Cleveland, Columbia 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:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Roaring Creek	Covered Bridge No. 10 (Upstream).	621
	Bridge No. 11 (Upstream).	645
	Bridge No. 12 (Upstream).	692
South Branch Roaring Creek.	Confluence with Mugser Run.	613
	Bridge No. 31 (Upstream).	647
	Bridge No. 32 (Upstream).	661
Mugser Run	Confluence with South Branch Roaring Creek.	613
	Township Route 316 (Upstream).	632
	Johnson Covered Bridge (Upstream).	663

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 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. 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. 79-6798 Filed 3-8-79; 8:45 am]

[4210-01-M]

[Docket No. FI-4571]

PART 1917—APPEALS FROM PROPOSED FLOOD ELEVATION DETERMINATIONS

Final Flood Elevation Determination for the Borough of Everson, Fayette 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 Borough of Everson, Fayette 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 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 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 Borough of Everson, Fayette 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:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Jacobs Creek	2,500 feet downstream of State Route 110.	1,027
	State Route 110	1,028
	ConRail	1,029
	Brown Street	1,029
	Upstream Corporate Limits.	1,031

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 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. 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 31, 1979.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 79-6799 Filed 3-8-79; 8:45 am]

[4210-01-M]

[Docket No. FI-4598]

PART 1917—APPEALS FROM PROPOSED FLOOD ELEVATION DETERMINATIONS

Final Flood Elevation Determination for the Township of Franklin, 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 Franklin, 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 Franklin, 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 Franklin, Columbia County, Pa., are available for review at the residence of Mr. Richard Fetterman, R.D. 2, Catawissa, 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 800-424-8872.

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. 4001-4128, 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:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Susquehanna River.	Confluence with Roaring Creek.	467
	Upstream Corporate Limits.	473
Roaring Creek	ConRail	467
	Old Concrete Dam (Upstream).	481
	Covered Bridge No. 6 (Upstream).	552
	Bridge No. 7 (Upstream 100').	567
	State Route 487 (Upstream 100').	596
	Upstream Corporate Limits.	620
South Branch Roaring Creek.	Bridge No. 24 (Upstream).	573
	Bridge No. 25 (Upstream).	600
	Legislative Route 49091 (Upstream).	612

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 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, 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. 79-6800 Filed 3-8-79; 8:45 am]

[4210-01-M]

[Docket No. FI-4615]

PART 1917—APPEALS FROM PROPOSED FLOOD ELEVATION DETERMINATIONS

Final Flood Elevation Determination for the Township of Hemlock, 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 Hemlock, 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 Hemlock, 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 Hemlock, Columbia County, Pa., are available for review at the residence of Mr. Herman Ikeler, Chairman of Hemlock, R.D. 2, Bloomsburg, 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 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the final determinations of flood elevations for the Township of Hemlock, 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:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Fishing Creek	State Route 44 (Upstream).	478
	Railroad Street (Upstream).	485
	Interstate Route 80 (Upstream).	497
Hemlock Creek	Legislative Route 19100 (Upstream).	478
	State Route 42 (Upstream).	492
	Interstate Route 80 (Upstream).	543
Little Fishing Creek.	Legislative Route 239 (Upstream)..	
	Dam	519
		501
	Township Road 519 (Upstream).	549
	Upstream Corporate Limits.	552

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 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. 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. 79-6801 Filed 3-8-79; 8:45 am]

[4210-01-M]

[Docket No. FI-4616]

PART 1917—APPEALS FROM PROPOSED FLOOD ELEVATION DETERMINATIONS

Final Flood Elevation Determination for the Borough of Herndon, 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 Borough of Herndon, Northumberland County, Pa. These base (100-year) flood eleva-

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 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 Borough of Herndon, Northumberland 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:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Susquehanna River.	Downstream Corporate Limits.	422
	Pine Street (extended)...	423
	Confluence of Mahanoy Creek.	426

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 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, 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. 79-6802 Filed 3-8-79; 8:45 am]

[4210-01-M]

[Docket No. FI-4617]

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 RCV Elementary School, Route 42, Numidia, 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 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the final determinations of flood elevations for 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:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Roaring Creek	State Route 42 (Upstream).	726
	LR 19086 (Upstream).....	758
	LR 19005 (Upstream).....	786
	Covered Bridge No. 17 (Upstream).	798
	Covered Bridge No. 19 (Upstream).	850
	LR 19009 (Upstream).....	878
	Confluence of Tributary No. 16 to Roaring Creek.	916
Mill Creek	Confluence with Roaring Creek.	853

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 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, 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. 79-6803 Filed 3-8-79; 8:45 am]

[4210-01-M]

[Docket No. FI-4618]

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).

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

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the final elevations for the Township of Lower Augusta, Northumberland County, Pa., are available for review at the Lower Augusta Township Building, Hollowing Run Road, Lower Augusta, 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 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the final determinations of flood elevations for the Township of Lower Augusta, Northumberland 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:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Susquehanna River.	Downstream Corporate Limits.	429
	Confluence of Boile Run	431
	ConRail	438
Boile Run	Confluence of Susquehanna River.	431
	State Route 147	431
	Legislative Route 49023	451
	Snyder Road	466
	Butler Road	478
	Footbridge (960 feet upstream of Butler Road).	488
	Wooden Bridge (1,340 feet upstream of Butler Road).	493
	Legislative Route 49023 (3,750 feet upstream of Butler Road).	519
	Township Route 390	559
	Township Route 394	579
	Legislative Route 49023 (2,000 upstream of Township Route 394).	601
	Unnamed Road (1,100 feet upstream of Legislative Route 49023).	616
	Legislative Route 49023 (4,440 feet upstream of Township Route 394).	633
	Petterman Road	657
	Township Route 396	692
	Legislative Route 49023 (1,920 feet upstream of Township Route 396).	722

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 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. 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. 79-6804 Filed 3-8-79; 8:45 am]

[4210-01-M]

[Docket No. FI-4574]

PART 1917—APPEALS FROM PROPOSED FLOOD ELEVATION DETERMINATIONS

Final Flood Elevation Determination for the Municipality of Monroeville, Allegheny 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 Municipality of Monroeville, Allegheny 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 Municipality of Monroeville, Allegheny County, Pa.

ADDRESS: Maps and other information showing the detailed outlines of the flood-prone areas and the final elevations for the Municipality of Monroeville, Allegheny County, Pa., are available for review at the Monroeville Municipal Building, 2700 Monroeville Boulevard, Monroeville, 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 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the final determinations of flood elevations for the Municipality of Monroeville, Allegheny 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:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Turtle Creek	Confluence with Abers Creek.	844
	Upstream Corporate Limits.	791
	Dam at Westinghouse (upstream).	780
	Dam at Westinghouse (downstream).	778
	Confluence of Brush Creek.	777
	Mosside Boulevard (upstream).	768
	Wall Borough Bridge (upstream).	750
West Thompson Run.	Union Railroad	948
	Thompson Run Road (upstream).	885
	Frey Road (upstream)	884
	Confluence with Leak Run.	866
	South McCully Drive (upstream).	859
	Private drive 2,450 feet downstream from South McCully Drive (upstream).	840
	U.S. Route 22 (upstream).	828
	Private drive 1,750 feet downstream from U.S. Route 22 (upstream).	809
	Newton Road (upstream).	808
	Buena Vista Drive (upstream).	788
	Downstream Corporate Limits.	787
Leak Run	Private road 1,950 feet upstream from Evergreen Drive (upstream).	1,003
	Private road 850 feet upstream from Evergreen Drive (upstream).	987
	Evergreen Drive (upstream).	970
	Old William Penn Highway (upstream).	959
	Confluence with West Thompson Run.	866
Unnamed stream along Mosside Boulevard.	Private drive 830 feet upstream from State Route 130.	799
	State Route 130 (upstream).	785
Dirty Camp Run	Park Bridge (upstream)	848
	Downstream Corporate Limits.	836
Abers Creek	Upstream Corporate Limits.	937
	Municipal road (upstream).	923
	Golden Mile Highway (upstream).	895
	Old Abers Creek Road (upstream).	890
	U.S. Route 22 (upstream).	886
	Confluence of East Thompson Run.	878
	Upstream Abers Creek Road (upstream).	859
	Downstream Abers Creek Road (upstream).	852
	Confluence of Turtle Creek.	844
East Thompson Run.	Upstream U.S. Route 22 (upstream).	965
	Downstream U.S. Route 22 (upstream).	928
Piersons Run	Old Abers Creek Road	935
	Confluence of Abers Creek.	935

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 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. 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 31, 1979.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 79-6805 Filed 3-8-79; 8:45 am]

[4210-01-M]

[Docket No. FI-4619]

PART 1917—APPEALS FROM PROPOSED FLOOD ELEVATION DETERMINATIONS

Final Flood Elevation Determination for the Township of Montour, 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 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, 202-755-5581 or toll-free line 800-424-8872.

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

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Susquehanna River.	State Route 42 (Upstream).	474
	Confluence with Fishing Creek.	476
Fishing Creek	Covered Bridge No. 65	477
	ConRail	477
	State Route 42 (Upstream).	478
Hemlock Creek	Legislative Route 19100 (Upstream).	478
	Legislative Route 19119 (Upstream).	497

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 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. 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. 79-6806 Filed 3-8-79; 8:45 am]

[4210-01-M]

[Docket No. FI-4620]

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 Township of Orange, 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 Orange, Columbia County, Pennsylvania, 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 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the final determinations of flood elevations for the Township of Orange, 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:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Fishing Creek	Confluence with Stony Brook.	538
	Confluence with Deer Lick Run.	558
	Legislative Route 19031 (Upstream).	564
	State Route 487 (Downstream).	583
	State Route 487 (Upstream).	588
	Upstream Corporate Limits.	612
Green Creek	Confluence with Fishing Creek.	569
	Legislative Route 19030 (Upstream).	580
	Covered Bridge No. 12 (Upstream).	597
	Upstream Corporate Limits.	606

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 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. 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. 79-6807 Filed 3-8-79; 8:45 am]

[4210-01-M]

[Docket No. FI-4576]

PART 1917—APPEALS FROM PROPOSED FLOOD ELEVATION DETERMINATIONS

Final Flood Elevation Determination for the Borough of Orangeville, 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 Borough of Orangeville, 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.

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 Orangeville Borough Building, Mills Street, 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 800-424-8872.

SUPPLEMENTARY INFORMATION: The Federal Insurance Administrator gives notice of the final determinations of flood elevations for the Borough of Orangeville, 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:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Fishing Creek	Downstream Corporate Limits.	572
	Upstream Corporate Limits.	577

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 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, 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. 79-6808 Filed 3-8-79; 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 rules recognize that residency can be established by substantial recurrent contacts with an identifiable homesite 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.

FOR FURTHER INFORMATION CONTACT:

Paul M. Tessler, CFR Liaison Officer, Navajo and Hopi Indian Relocation Commission, 2717 N. Steves Boulevard, Bldg. A, Flagstaff, Arizona 86001, Telephone (602) 779-3311 Extension 1376, FTS: 261-1376.

The principal author is William G. Lavell, Field Solicitor, Valley Bank Center, Suite 2080, 201 N. Central Avenue, Phoenix, Arizona 85073.

SUPPLEMENTARY INFORMATION: On December 20, 1978, there was published in the FEDERAL REGISTER (43 FR 59400) a notice of proposed Revision of Regulations concerning Eligibility for Relocation Benefits. Interested persons were given until February 22, 1979, to submit comments regarding the Proposed Rule.

DISCUSSION OF COMMENTS

A number of comments have been received from interested parties and considered by the Commission. After due consideration, the following suggestions have been incorporated in the final rule:

Section 700.5(y)(B)(i) is expanded to provide for those persons who have been temporarily away due to the search for employment.

Section (y)(1)(B)(v) was added to the proposed rule in its final form in order to provide for persons who have been temporarily away due to the unavailability of housing in the area. The Order of Compliance, issued by the United States District Court for the District of Arizona, in *Hamilton* v. *McDonald*, on October 14, 1972, prohibited new construction on the former Joint Use Area except under limited circumstances. Provision is made for those who have been temporarily away due to this "new construction freeze."

Section 700.5(y)(1)(B)(vi) was added to the proposed rule in its final form in order to provide for those persons who have been temporarily away due to incarceration.

Sections 700.5(y)(2) (x), (y), and (z) have been added to the Proposed Rule in its final form to reflect comment received. The consideration of court records, records of birth, and the Joint Use Area Roseter is consistent with the Commission's criteria in establishing whether or not there have been substantial recurring contacts.

In adopting the proposed rule in its final form, the Commission has substituted the term "recurring" for "continuous" in the phrase "substantial continuous contacts with an identifiable homesite." This was done to avoid the necessity of such contacts being "uninterrupted" or "unbroken."

Accordingly, § 700.5 is amended in its final form by redesignating paragraph (y) as (z) and adding a new paragraph (y) to read as follows:

§ 700.5 Definitions.

* * * * *

(y) Resident (or Residency)

(1) Residency is established by fulfilling either of the following criteria:

(i) Current occupancy

(ii) Maintenance of substantial recurring contacts with an identifiable homesite although the individual is temporarily away for any of the following reasons:

(A) Employment, and seeking employment

(B) Education or job training

(C) Medical

(D) Military (active duty in the military service)

(E) Unavailability of Housing

(F) Incarceration

(2)(i) Any one or more of the following criteria may be considered in establishing whether or not there have been substantial recurring contacts:

(A) Ownership of livestock

(B) Ownership of improvements

(C) Grazing permits

(D) Livestock sales receipts

(E) Homesite leases

(F) Public Health Records

(G) Medical and Hospital records, including those of Medicinemen

(H) Trading Post records

(I) School records

(J) Military records

(K) Employment records

(L) Mailing address records

(M) Banking records

(N) Drivers License records

(O) Voting Records (Tribal and County)

(P) Home ownership or rental off the Disputed Area

(Q) B.I.A. Census Data

(R) Certification from Chapter Officials

(S) Certification of Residency

(T) Certification by Relocatee

(U) Information obtained by Certification Field Investigation

(V) Social Security Administration

(W) Marital records

(X) Court Records

(Y) Records of Birth

(Z) Joint Use Area Roster

(aa) Any other relevant data

Section 700.11 is amended in its final form by revising paragraph (b) to read as follows:

§ 700.11 Relocation standards.

* * * * *

(b) Eligibility Requirements. (1) To be eligible as a displaced person for benefits provided for under the Act, and these regulations, a person must meet one of the following conditions:

(A) The person must be a resident in the area partitioned to the tribe of which he is not a member; or,

(B) The person was a resident in the Joint Use Area but moved from there between December 22, 1974, and August 30, 1978; or,

(C) The person was a resident of an area which was partitioned to a tribe of which he is not a member but moved therefrom after August 30, 1978.

(2) Moves described in paragraphs (1) (b) and (1) (c) are presumed to have been made pursuant to the Act.

(3). Eligibility for certain benefits is further restricted by Sections 14(c) and 15(c) of the Act (25 U.S.C. 640-d-13) and 14(c) as reflected in Sections 700.10 (d) and (e) 2 of these regulations.

HAWLEY ATKINSON,
Chairman, Navajo and Hopi Indian Relocation Commission.

[FR Doc. 79-7125 Filed 3-8-79; 8:45 am]

[1505-01-M]

Title 28—Judicial Administration

CHAPTER III—FEDERAL PRISON INDUSTRIES, DEPARTMENT OF JUSTICE

PART 301—INMATE ACCIDENT COMPENSATION

Final Rules

Correction

In FR Doc. 79-6303, appearing at page 11759 in the issue for Friday, March 2, 1979, on page 11760 the signature should read David C. Jelinek, Acting Commissioner.

[6732-01-M]

Title 29—Labor

CHAPTER XII—FEDERAL MEDIATION AND CONCILIATION SERVICE

PART 1404—ARBITRATION SERVICES

Revision

AGENCY: Federal Mediation and Conciliation Service.

ACTION: Promulgation of Final Regulations.

SUMMARY: Federal Mediation and Conciliation Service (FMCS) revises Part 1404 of Title 29, CFR, governing FMCS services in the arbitration of labor disputes. This notice contains the text of the regulations. The changes are designed primarily to clarify the current regulations, to strengthen the prohibitions against the listing of advocates on the Roster of Arbitrators, and to spell out certain concepts of due process in connection with the removal of arbitrators from the Roster. The regulations also establish in the Arbitrator Review Board a mechanism for advising the Director of the Service as to the Admission or removal of arbitrators, functions for which the Director has ultimate responsibility.

EFFECTIVE DATE: April 15, 1979.

FOR FURTHER INFORMATION CONTACT:

David Vaughn, Associate General Counsel, Federal Mediation and Conciliation Service, Washington, D.C. 20427, (202) 653-5305, FTS 653-5305.

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, (202) 653-5305, FTS 653-5305.

Adopted by the Federal Mediation and Conciliation Service at its office in Washington, D.C., on the 28th 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

Sec.
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

1404.10 Procedures for Requesting Arbitration Panels.
1404.11 Arbitrability.
1404.12 Nominations of Arbitrators.
1404.13 Selection and Appointment of Arbitrators.
1404.14 Conduct of Hearings.
1404.15 Decision and Award.

Sec.

1404.16 Fees and charges of arbitrators.
1404.17 Reports and biographical sketches.

AUTHORITY: Sec. 202, 61 Stat. 153, as amended; 29 U.S.C. 172, and interpret or apply sec. 3, 80 Stat. 250, sec. 203, 61 Stat. 153; 5 U.S.C. 552, 29 U.S.C. 173.

Subpart A—Arbitration Policy; Administration of Roster

§ 1404.1 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 submitted to arbitration or fact-finding.

§ 1404.2 Policy.

The labor policy of the United States is designed to promote the settlement of issues between employers and represented employees through the processes of collective bargaining and voluntary arbitration. This policy encourages the use of voluntary arbitration to resolve disputes over the interpretation or application of collective bargaining agreements. Voluntary arbitration and fact-finding in disputes and disagreements over establishment or modification of contract terms are important features of constructive labor-management relations, as alternatives to economic strife in the settlement of labor disputes.

§ 1404.3 Administrative responsibilities.

(a) *Director.* The Director of FMCS has ultimate responsibility for all aspects of FMCS arbitration activities and is the final agency authority on all questions concerning the Roster or FMCS arbitration procedures.

(b) *Office of Arbitration Services.* The Office of Arbitration Services (OAS) maintains a Roster of Arbitrators (the "Roster"); administers Subpart C of these regulations (Procedures for Arbitration Services); assists, promotes, and cooperates in the establishment of programs for training and developing new arbitrators; collects information and statistics concerning the arbitration function, and performs other tasks in connection with the function that may be assigned by the Director.

(c) *Arbitrator Review Board.* The Arbitrator Review Board (the "Board") shall consist of a presiding officer and such members and alternate members as the Director may appoint, and who shall serve at the Director's pleasure and may be removed at any time. The Board shall be composed entirely of full-time officers or employees of the Federal Government. The Board shall establish its own procedures for carrying out its duties.

(1) *Duties of the Board.* The Board shall:

(i) Review the qualifications of all applicants for listing on the Roster, interpreting and applying the criteria set forth in § 1404.5;

(ii) Review the status of all persons whose continued eligibility for listing on the Roster has been questioned under § 1404.5;

(iii) Make recommendations to the Director regarding acceptance or rejection of applicants for listing on the Roster, or regarding withdrawal of listing on the Roster for any of the reasons set forth herein.

Subpart B—Roster of Arbitrators; Admission and Retention

§ 1404.4 Roster and Status of Members.

(a) *The Roster.* The FMCS shall maintain a Roster of labor arbitrators consisting of persons who meet the criteria for listing contained in § 1404.5 and whose names have not been removed from the Roster in accordance with § 1404.5(d).

(b) *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.

(c) *Status of Arbitrators.* Persons who are listed on the Roster and are selected or appointed to hear abritration 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.

(d) *Role of FMCS.* FMCS has no power to:

(1) Compel parties to arbitrate or agree to arbitration;

(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.

(e) *Nominations and Panels.* On request of the parties to an agreement to arbitrate or engage in fact-finding, or where arbitration or fact-finding may be provided for by statute, 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.

(f) *Rights of persons listed on the Roster.* No person shall have any right to be listed or to remain listed on the Roster. FMCS retains 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 preparation of panels or the appointment of arbitrators or fact finders which include consideration of such factors as background and experience, availability, acceptability, geographical location and the expressed preferences of the parties.

§ 1404.5 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 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 will be listed on the Roster upon a determination that they:

(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

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 chosen by 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 workmen's 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 shall in either case 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 should not be construed as anything more than compliance with a request and does not necessarily reflect the contractural 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.

[6732-01-C]

FMCS Form R-43
Sep 1975

Form Approved
OMB NO. 23 R0007

FEDERAL MEDIATION AND CONCILIATION SERVICE
WASHINGTON, D.C. 20427

REQUEST FOR ARBITRATION PANEL

To: Director, Arbitration Services
Federal Mediation and Conciliation Service
Washington, D.C. 20427

Date _____

1. (For Company)

Name of Company _____

Name and Address of Representative to Receive Panel _____ (NAME)
_____ (STREET)
_____ (CITY, STATE, ZIP)

Telephone (include area code) _____

2. (For Union)

Name of Union and Local No. _____

Name and Address of Representative to Receive Panel _____ (NAME)
_____ (STREET)
_____ (CITY, STATE, ZIP)

Telephone (include area code) _____

3. Site of Dispute _____ (CITY, STATE, ZIP)

4. Type of Issue _____ (DISCHARGE, HOLIDAY PAY, SICK LEAVE, ETC.)

5. 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
- ☐ Federal Government
- ☐ State Government
- ☐ Local Government
- ☐ Public Utilities, Communications, Transportation (including trucking)
- ☐ Retail, Wholesale and Service Industries
- ☐ Other (Specify) _____

7. Special Requirements _____
(SPECIAL ARBITRATOR QUALIFICATIONS, TIME LIMITATIONS ON HEARING OR DECISION, GEOGRAPHICAL RESTRICTIONS, ETC.)

8. Signatures

_____ (COMPANY)

_____ (UNION)

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 or any FMCS Regional Office. See list on reverse of Copy No. 3.

To be retained by party filing request

[6732-01-M]

(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.

(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, the Service shall comply with the request providing that 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 of an arbitrator from a panel:

(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.

(3) Informal agreement of the parties by whatever method they choose.

(c) The Service will, on joint or unilateral request of the parties, submit a panel or, when the applicable collective bargaining agreement authorizes, will 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.

(d) The arbitrator, upon notification of appointment, is required to communicate with the parties immediately to arrange for preliminary matters, such as date and place of hearing.

§ 1404.14 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 § 1404.4(b). 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). Filing 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 not to 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.

[FR Doc. 79-7188 Filed 3-8-79; 8:45 am]

[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, 202-653-5373.

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 1955, 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. 1608 (29 U.S.C. 667)).

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; 8:45 am]

[7710-12-M]

Title 39—Postal Service

CHAPTER I—UNITED STATES POSTAL SERVICE

PART 955—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:

James A. Cohen, Judicial Officer, U.S. Postal Service, Washington, D.C. 20260, (202) 245-4915.

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(a)(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(h) 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:

EFFECTIVE DATE AND APPLICABILITY

§ 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 not 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, 1979. At the election of the appellant, §§ 955.36 and 955.37 shall also apply to appeals relating to contracts entered into before March 1, 1979, if the Contracting Officer's final decision is dated March 1, 1979, 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 120 days after the Board receives written notice of the appellant's election to utilize this procedure. The details of this procedure appeals in paragraph (c) of this Rule. An appellant may elect the ACCELERATED procedure rather than the SMALL CLAIMS (EXPEDITED) procedure for any appeal eligible for the SMALL CLAIMS (EXPEDITED) procedure.

(2) In appeals where the amount in dispute is $50,000 or less, the appellant may elect to have the appeal processed under an ACCELERATED procedure requiring decision of the appeal, whenever possible, within 180 days after the Board receives written notice of the appellant's election to utilize this procedure. The details of this procedure appear in paragraph (d) of this Rule.

(3) The appellant's election of either the SMALL CLAIMS (EXPEDITED) procedure or the ACCELERATED procedure may be made either in his notice of appeal or by other written notice at any time thereafter.

(4) In deciding whether the SMALL CLAIMS (EXPEDITED) procedure or the ACCELERATED procedure is applicable to a given appeal the Board shall determine the amount in dispute by adding the amount claimed by the appellant against the respondent to the amount claimed by respondent against the appellant. If either party making a claim against the other party does not otherwise state in writing the amount of its claim, the amount claimed by such party shall be the maximum amount which such party represents in writing to the Board that it can reasonably expect to recover against the other.

(c) The SMALL CLAIMS (EXPEDITED) Procedure.

(1) This procedure shall apply only to appeals where the amount in dispute is $10,000 or less as to which the appellant has elected the SMALL CLAIMS (EXPEDITED) procedure.

(2) In cases proceeding under the SMALL CLAIMS (EXPEDITED) procedure, the following time periods shall apply (i) within ten days from the respondent's first receipt from either the appellant or the Board of a copy of the appellant's notice of election of the SMALL CLAIMS (EXPEDITED) procedure, the respondent shall send the Board a copy of the contract, the contracting officer's final decision, and the appellant's claim letter or letters, if any; (ii) within 15 days after the Board has acknowledged receipt of the notice of election, either party desiring an oral hearing shall so inform the Board. If either party requests an oral hearing, the Board shall promptly schedule such a hearing for a mutually convenient time consistent with administrative 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 under § 955.12 without a hearing.

(3) In cases proceeding under the SMALL CLAIMS (EXPEDITED) procedure, pleadings, discovery, and other prehearing activity will be allowed only as consistent with the requirement to conduct the hearing on the date scheduled or, if no hearing is scheduled, to close the record on a date that will allow decision within the 120-day limit. The Board, in its discretion, may shorten time periods prescribed elsewhere in these Rules as necessary to enable the Board to decide the appeal within 120 days after the Board has received the appellant's notice of election of the SMALL CLAIMS (EXPEDITED) procedure. In so doing the Board may reserve whatever time up to 30 days it considers necessary for preparation of the decision.

(4) Written decision by the Board in cases processed under the SMALL CLAIMS (EXPEDITED) procedure will be short and contain only summary findings of fact and conclusions. Decisions will be rendered for the Board by a single Administrative Judge. If there has been a hearing, the Administrative Judge presiding at the hearing may, in his discretion, 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 the record and payment purposes and to establish the date of commencement of the period for filing a motion for reconsideration under § 955.20.

(5) Decisions of the Board under the SMALL CLAIMS (EXPEDITED) procedure will not be published, will have no value as precedents, and in the absence of fraud, cannot be appealed.

(d) The ACCELERATED Procedure

(1) This procedure shall apply only to appeals where the amount in dispute is $50,000 or less as to which the appellant has made the requisite election.

(2) In cases proceeding under the ACCELERATED procedure, the parties are encouraged, to the extent possible consistent with adequate presentation of their factual and legal positions, to waive pleadings, discovery, and briefs. The Board, in its discretion, may shorten time periods prescribed elsewhere in these Rules as necessary to enable the Board to decide the appeal within 180 days after the Board has received the appellant's notice of election of the ACCELERATED procedure, and may reserve 30 days for preparation of the decision.

(3) Written decisions by the Board in cases processed under the ACCELERATED 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 with the concurrence of the Chairman or Vice Chairman or other designated Administrative Judge, or by a majority among these two and an additional

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 both parties, 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.

(e) 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 requiring:

(1) testimony at a deposition—the deposing 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 him 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:

(i) 15 days before a scheduled deposition where the attendance of a witness at a deposition is sought;

(ii) 30 days before a scheduled hearing where the attendance of a witness at a hearing is sought.

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 to the case 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 for compliance, 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 shall command 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 subpoena 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 the subpoena. The failure to make payment of such charges on demand may be deemed by the Board as a sufficient ground for striking the testimony of the witness and the evidence the witness has 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. 79-7153 Filed 3-8-79; 8:45 am]

[6560-01-M]

Title 40—Protection of the Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

[FRL 1052-6]

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 Federally-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,

Sixth & Walnut Streets, Philadelphia, Pa. 19106, (215) 597-9893.

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:

Air Enforcement Branch, U.S. EPA, Region III, Curtis Building, Sixth & Walnut Streets, Philadelphia, Pa. 19106.

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 43333), a notice proposing approval of a delayed compliance order issue 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.)

Dated: February 28, 1979.

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 orders:

§ 65.531 EPA Approval of State delayed compliance orders issued to major stationary sources.

* * * * *

Source	Location	SIP regulation involved	Date of FR proposal	Final compliance date
Brockway Glass Co. Inc	Vienna	Regulation VII.	Sept. 25, 1978	Dec. 30, 1978

[FR Doc. 79-7120 Filed 3-8-79; 8:45 am]

[6560-01-M]

[FRL 1052-3]

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 air emissions from its oil and coal fired boilers in Wellsburg, West Virginia 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:

Patrick McManus (3EN12), U.S. EPA, Region III, Curtis Building, Sixth & Walnut Streets, Philadelphia, Pennsylvania 19106, 215/597-9893.

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:

Air Enforcement Branch, U.S. EPA, Region III, Curtis Building, Sixth & Walnut Streets, Philadelphia, Pennsylvania 19106.

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 Banner Fibreboard Co. 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 Banner Fibreboard 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 Banner Fibreboard Co. on a schedule to bring its oil and coal-fired boilers in Wellsburg into compliance as expeditiously as practicable with Regulation II, "To Prevent and Control Particulate Air Pollution From Combustion of Fuel in Indirect Heat Exchangers", 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 Banner Fibreboard Co. 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 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.

(42 U.S.C. 7413(d), 7601.)

Dated: February 28, 1979.

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.

* * * * *

Source	Location	SIP regulation involved	Date of FR proposal	Final compliance date
Banner Fibreboard Co	Wellsburg.	Regulation II	Sept. 25, 1978	July 1, 1979

[FR Doc. 79-7121 Filed 3-8-79; 8:45 am]

[6560-01-M]

[FRL 1052-1]

PART 65—DELAYED COMPLIANCE ORDERS

Approval of a Delayed Compliance Order Issued by West Virginia Air Pollution Control Commission to Pennzoil 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 Pennzoil Company. The Order requires the company to bring air emissions from its Elk Refining Division in Falling Rock into compliance with certain regulations contained in the federally-approved West Virginia State Implementation Plan (SIP). Because of the Administrator's approval, Pennzoil Company 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, Sixth and Walnut Streets, Philadelphia, Pennsylvania 19106, 215/597-9893.

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:

Air Enforcement Branch, U.S. EPA, Region III, Curtis Building, Sixth and Walnut Streets, Philadelphia, Pennsylvania 19106.

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 VII, "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.

(42 U.S.C. 7413(d), 7601.)

Dated: February 28, 1979.

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.

Source	Location	SIP regulation involved	Date of FR proposal	Final compliance date
Pennzoil Co	Falling Rock.	Regulation VII.	Sept. 25, 1978	Nov. 5, 1978

[FR Doc. 79-7122 Filed 3-8-79; 8:45 am]

[6560-01-M]

[FRL 1051-8]

PART 65—DELAYED COMPLIANCE ORDERS

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:

Patrick McManus (3EN12), U.S. EPA, Region III, Curtis Building, Sixth & Walnut Streets, Philadelphia, Pennsylvania 19106, 215/597-9893.

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:

Air Enforcement Branch, U.S. EPA, Region III, Curtis Building, Sixth & Walnut Streets, Philadelphia, Pennsylvania 19106.

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 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 as expeditiously as practicable with Regulation II, "To Prevent and Control Particulate Air Pollution From Combustion of Fuel in Indirect Heat Exchangers", 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 Pennsylvania Glass Sand Corp. to delay 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(d), 7601.)

Dated: February 28, 1979.

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.

Source	Location	SIP regulation involved	Date of FR proposal	Final compliance date
Pennsylvania Glass Sand Corp	Berkeley Springs.	Regulation II	Sept. 25, 1978	June 30, 1979

[FR Doc. 79-7123 Filed 3-8-79; 8:45 am]

[6560-01-M]

[FRL 1051-7]

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 Groups 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:

Thomas W. Shiland (3EN12), U.S. EPA, Region III, Curtis Building, Sixth & Walnut Streets, Philadelphia, Pennsylvania 19106, 215/597-7915.

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:

Air Enforcement Branch, U.S. EPA, Region III, Curtis Building, Sixth & Walnut Streets, Philadephia, Pennsylvania 19106.

SUPPLEMENTARY INFORMATION: On October 27, 1978, 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, 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 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.)

Dated: February 28, 1979.

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 § 65.251 to reflect approval of the following delayed compliance order:

§ 65.251 EPA Approval of State delayed compliance orders issued to major stationary sources.

Source	Location	SIP regulations involved	Date of FR proposal	Final compliance date
Glidden Pigments Group of SCM Corp	Baltimore	10.03.38.02A and 10.03.38.03E	Oct. 27, 1978	July 1, 1979

[FR Doc. 79-7124 Filed 3-8-79; 8:45 am]

[6560-01-M]

SUBCHAPTER E—PESTICIDE PROGRAMS

[OPP-2500 11A; FRL 1071-4]

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 7695), 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 reissue 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:

Maureen Johns Grimmer, Project Leader, (TS-766), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460 (202-755-8036).

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, 86 Stat. 983; Pub. L. 94-140, 89 Stat. 755; Pub. L. 95-396, 92 Stat. 819; 7 U.S.C. 136 et seq.; hereinafter referred to as "FIFRA").

BACKGROUND

Final rules for the registration, reregistration, and classification of pesticides (40 CFR Part 162) were published in the FEDERAL REGISTER July 3, 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 Center Statistics 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 petroleum 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 proposal, 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 some types of products. They said that the EPA proposal is not consistent with Section 3(a) of the Poison Prevention Packaging Act which requires the special packaging to be technically feasible, practicable, and appropriate for the substance. 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 which included a full description of the package, a report of the testing protocol data, and compatibility data. Most commenters believe that the requirement to submit the data is not necessary. They pointed out the additional work the Registration Division would have reviewing the data. Several suggestions were made on how to make the requirement less burdensome. They included dropping the requirement completely, submitting only an attestation that the package will meet the standards, submitting a letter of notification, and maintaining the data records in the registrant's file while keeping them available for inspection. EPA also believes that a more streamlined process would be advantageous to the agency and registrants. Accordingly, § 162.16(e) has been changed in the final regulations. Because the registration files must be kept current, an application for amended registration indicating a change to special packaging still must be submitted. The application must include a certification that the package meets the standards of § 162.16(d). Instead of requiring the registrant to submit a detailed description of the package, protocol data, and compatibility data, this information must be retained in the registrants' files, subject to agency inspection or request for submission under new § 162.16(f) for as long as the registration is valid. This will eliminate the requirements for the registrant or applicant to submit the data and for the agency to review the data. The Agency will approve the application based on the certification in the application that the registrant has complied with all provisions.

The waiver of the requirement to submit data applies only to the information exclusively required by § 162.16. Any data that are required to be submitted by Part 162 for an amended registration (e.g. stability data) must be submitted with the application.

TEST PROTOCOL

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. By 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 which is developed by a packaging manufacturer may be relied upon for different pesticide products and by different registrants. Testing each product's package would result in duplicative testing for many designs 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 use 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 under § 162.16(c)(4) 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-COMPLYING 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 Academy 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 help him apply the 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, EPA assumes 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 LD_{50} 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 (§ 162.16(c)(2)(v)). Most commenters agreed that 1.5g/kg is an appropriate level. The calculations used to determine the acute oral LD_{50} criterion were based on the average weight of a small child, the amount such a child could easily 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 scarring) 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 if it is applied to data generated under the skin irritation testing protocol in the 1975 proposed Registration Guidelines, many household products will unjustifiably be required to be specially packaged. The Registration Guidelines are currently under revision. A skin irritation testing protocol was proposed on August 22, 1978, in Subpart F (Human Hazard) of the Proposed Guidelines for Registering Pesticides, 43 FR 37335. All comments received on this proposal will be fully considered. In addition, EPA will also carefully weigh the forthcoming recommendations of the Occupational Safety and Health Adminstration's Standards Advisory Committee on Cutaneous Hazards. Several commenters preferred the skin irritation protocol recommendations of a June 1977 report prepared by 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.

The FIFRA Scientific Advisory Panel endorsed the NAS/NRC 1138 Committee skin irritation protocol for testing consumer products. This protocol will be acceptable to EPA for determining whether or not a pesticide product must be specially packaged under this regulation. This policy is only stated in the preamble, it will be handled more appropriately in the final Registration Guidelines. Until the Guidelines become effective, registrants should consult with the Registration Division prior to testing to discuss the applicability of that protocol to their product.

EPA received many comments which stated that the eye effects criteria were too strict. They pointed out the fact that if common soap was regulated under FIFRA, it would have to be specially packaged under the proposed eye effects criteria. FIFRA authorized the Administrator to establish special packaging standards to protect children from *serious* injury or illness. Many of the low degrees of corneal involvement seen in animal testing are reversible even in the sensitive eyes of the rabbit, and, therefore, do not represent a permanent impairment of vision and/or potential for serious injury.

The Agency has modified the eye effects criteria to read as follows: is corrosive to the eye (causes irreversible destruction of ocular tissue) or causes corneal involvement or irritation persisting for 21 days or more (§ 162.16(c)(3)(iii)). The new criteria will require an observation period of 21 days which is consistent with the eye irritation protocol proposed in the Human Hazard Guidelines which requires an observation period of at least 13 days or until all signs of reversible toxicity subside.

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 conducted in accordance with FIFRA Section 12(a)(2)(P) 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 (a)(2)(P)). 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 revoking § 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 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 set forth in the Act and in § 162.3. In addition, as used in this section:

(1) The term "package" means the immediate container or wrapping in which any pesticide is contained for consumption, use or storage. "Package" does not include:

(i) Any shipping container or wrapping used solely for the transportation of any pesticide in bulk or in quantity to manufacturers, packers or processors, or to wholesale or retail distributors thereof; or

(ii) Any shipping container or other wrapping used by retailers to ship or deliver any pesticide to consumers unless it is the only such container or wrapping.

(2) The term "residential application" means application of a pesticide (other than application by a commercial applicator) directly to humans or pets or application of a pesticide in, on or around all structures, vehicles or areas associated with the household or homelife or noncommercial areas where children spend time, including, but not limited to:

(i) Gardens, non-commercial greenhouses, yards, patios, houses, pleasure marine craft, mobile homes, campers and recreational vehicles, non-commercial campsites, home swimming pools and kennels;

(ii) Articles, objects, devices or surfaces handled or contacted by humans or pets in all structures, vehicles or areas listed above; and

(iii) Educational, lounging and recreational areas of preschools, nurseries and day camps.

(3) The term "special packaging" means packaging that is designed and constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time, and that is not difficult for normal adults to use properly.

(4) The term "unit package" means a package that is labeled with directions to use the contents in a single application or which consists of individually packaged dosage units.

(c) *Pesticides requiring special packaging.* (1) *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.

(2) *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_{50} of 2000 mg/kg or less;

(ii) Has an inhalation LC_{50} 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_{50} 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.

(3) *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 (c)(2) 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 uses.

(4) *Unit packaging.* Pesticides requiring special packaging and which use unit packaging shall either package each unit package in a special package or use special packaging for 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 effectiveness specifications set forth in paragraph (2) of this section when in actual use as a pesticide container. This requirement may be satisfied by appropriate scientific evaluation of the compatibility of the substance with the special packaging 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 effectiveness specified in paragraph (2) of this section for the reasonably expected lifetime of the package, taking into account the number of times the package is customarily opened and closed. This requirement may be satisfied by appropriate technical evaluation based on physical wear and stress factors, force required for activation, and other relevant factors.

(2) *Effectiveness specifications.* The special packaging, when tested by the method referred to in paragraph (3) of this section, shall meet the following specifications:

(i) Child-resistant effectiveness of not less than 85 percent without a demonstration and not less than 80 percent after a demonstration of the proper means of opening the package. In the case of unit packaging, child-resistant effectiveness of not less than 80 percent.

(ii) 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 certificaton 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.

(1) A full description of the package including:

(i) A full description of the container 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 characteristic of the substances 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(q)(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.

(Sections 3 and 25(c)(3) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (P.L. 92-516, 86 Stat. 973; P.L. 94-140, 89 Stat. 755; 7 U.S.C. 136 et seq.).)

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA) SCIENTIFIC ADVISORY PANEL

REVIEW OF FIFRA SECTION 25(c)(3) FINAL REGULATIONS ON SPECIAL PACKAGING OF PESTICIDES

The FIFRA Scientific Advisory Panel completed review of Section 25(c)(3) final regulations in an open meeting held in Arlington, Virginia, on October 3, 1978.

Maximum public participation has been encouraged at all meetings of the Panel. In respect to formal review of the draft final regulation on Safety Packaging of Pesticides, a Federal Register Notice announcing the meeting was published on September 18, 1978. In addition to public notice in the Federal Register, telephonic calls, and special mailings were sent to the general public who had previously expressed an interest in activities of the Panel. Written statements relative to the draft rulemaking were received from the following sources: Environmental Defense Fund; the Procter and Gamble Company (two submissions); and the American Cyanamid Company. In addition, oral comments were received from EPA staff; the Environmental Defense Fund; representatives of the pesticide industry, and the general public.

In consideration of all matters brought out during the Panel meeting, matters detailed in written statements, and careful study of all documents submitted by the Agency, the Panel submits the following report:

The Panel wishes to thank Mr. Edwin Johnson, Deputy Assistant Administrator of the Office of Pesticide Programs, for his active participation, interest, and cooperation throughout the meeting of the Panel. Additionally, the Panel is most appreciative of the excellent presentation and technical comments of Ms. Maureen Grimmer, esq., and Dr. Bruce Jaeger of the Office of Pesticide Programs, Environmental Protection Agency (EPA).

The FIFRA Scientific Advisory Panel is of the opinion that the final draft of the regulation on Special Packaging of Pesticides, submitted to the Panel as final rulemaking on September 19, 1978, deals effectively with this procedure with a limited number of specific comments.

The following comments are submitted by the Panel in response to specific questions posed by the Agency:

1. What is the appropriate eye irritation criteria for special packaging, the Toxicity Categories, and classification:

Response: The Panel unanimously concurs with the EPA position as outlined on page 20 of the draft document. Additionally, the Panel unanimously recommends that the Agency delete the statement in footnote 1 on page 20 which stipulates that eye effects shall be determined with the use of the slit-lamp technique. The Agency should recommend to applicants to adopt appropriate procedures as outlined in the NAS 1138 Committee Report.

2. What is the more appropriate eye irritation protocol, the Guidelines proposal or the NAS/NRC 1138 Committee Protocol recommendation.

Response: The Panel unanimously recommends that the Agency adopt the NAS/NRC 1138 Committee Protocol recommendation or other appropriate eye irritation studies. *Note:* Specific reference is made to test procedure outlined on pages 41-54,

Principals and Procedures for Evaluating the Toxicity of Household Substances 1977. A report prepared by the Committee for the Revision of NAS Publication 1138, 130 pages, National Academy of Science, 2101 Constitution Avenue, N.W., Washington, D.C. 20418.

3. Should monkey eye data take precedence over rabbit eye data?

Response: The Panel unanimously supports the position as stated in the NAS/NRC 1138 Committee document relative to the appropriate species for testing for eye irritation. *Note:* The albino rabbit is the species of choice, with the monkey (especially the rhesus) as the preferred second species when confirmatory data are necessary (p. 41 NAS 1138 Report cited previously).

4. With regard to special packaging, is the 1138 Committee protocol more appropriate than the Guidelines proposal?

Response: The Panel unanimously recommends adoption of the dermal skin irritation test as described in the NAS/NRC 1138 Committee report. (Note: The NAS protocol is a four-hour test on non-abraded skin as detailed on pages 29-30 of the NAS 1138 report.)

5. Should the acute oral LD50 criteria for special packaging be 1.5g/kg or .5g/kg?

Response: The Panel unanimously supports the Agency position that that acute oral LD50 criteria for special packaging be established at 1.5g/kg.

The Panel wishes to express unanimous concurrence in the position articulated by Ms. Hinkle of the Environmental Defense Fund regarding the following points:

1. Packaging of pesticides in glass bottles and other easy-to-break containers. The Agency should establish standards to ensure that breakable pesticide containers are properly packed in shipping containers to avoid breakage from the point of origin to the ultimate consumer. Of special concern is breakage and human exposure while products are displayed in retail stores.

2. Availability of Pesticide Incident Information. The Agency should develop and maintain an adequate reporting system which is reflective of the national experience as a whole. The current situation would appear to be greatly inadequate.

For the Chairman:

Certified as an accurate report of findings:

Dated: October 30, 1978.

H. WADE FOWLER, Jr.,
Executive Secretary,
FIFRA Scientific Advisory Panel.

[FR Doc. 79-7240 Filed 3-8-79;8:45 am]

[6820-61-M]

Title 41—Public Contracts and Property Management

CHAPTER 101—FEDERAL PROPERTY MANAGEMENT REGULATIONS

SUBCHAPTER G—TRANSPORTATION AND MOTOR VEHICLES

APPENDIX—TEMPORARY REGULATIONS

[FPMR Temp. Reg. G-40]

REQUIRED USE OF STANDARD CARRIER ALPHA CODES ON STANDARD FORM 1113, PUBLIC VOUCHER FOR TRANSPORTATION CHARGES

Use by Commercial Carriers Billing the U.S. Government

AGENCY: Transportation and Public Utilities Service, General Services Administration.

ACTION: Temporary regulation.

SUMMARY: This regulation requires each commercial carrier or forwarder billing charges on Standard Form 1113, Public Voucher for Transportation Charges, to include its Standard Carrier Alpha Code (SCAC) in the block provided therefor on the form and prohibits Federal executive agencies from paying charges billed on any SF 1113 which lacks the SCAC identifier. The Interstate Commerce Commission recently ordered carriers under its regulation to include SCAC identifiers on all tariffs effective on and after March 1, 1979. The use of the standardized identifiers on SF 1113 as well will benefit both the Government and the commercial carrier industry by permitting greater utilization of computer and other mechanized data systems in transportation transactions.

DATES: Effective date: March 1, 1979. Expiration date: February 28, 1981. Comments due on or before: June 30, 1979.

ADDRESS: Comments should be addressed to: General Services Administration (TA), Washington, D.C. 20406.

FOR FURTHER INFORMATION CONTACT:

Miles B. Manchester, Acting Assistant Commissioner for Transportation Audits, 202-275-5466.

SUPPLEMENTARY INFORMATION: The General Services Administration has determined that this regulation will not impose unnecessary burdens on the economy or on individuals and, therefore, is not significant for the purposes of Executive Order 12044.

(Sec. 205(c), 63 Stat. 390; 40 U.S.C. 486(c).)

In 41 CFR Chapter 101, the following temporary regulation is listed in the appendix at the end of Subchapter G.

[Federal Property Management Regs.; Temporary Reg. G-40]

REQUIRED USE OF STANDARD CARRIER ALPHA CODES ON STANDARD FORM 1113, PUBLIC VOUCHER FOR TRANSPORTATION CHARGES

1. *Purpose.* This regulation requires inclusion of commercial carrier Standard Carrier Alpha Code (SCAC) identifiers on SF 1113 as a condition precedent to payment of charges by Federal executive agencies.

2. *Effective date.* This regulation is effective for each SF 1113 bearing a Payee's Certificate dated on and after March 1, 1979.

3. *Expiration date.* This regulation expires February 28, 1981.

4. *Applicability.* The provisions of this regulation apply to all carriers and forwarders billing charges on SF 1113 for freight, express, or passenger transportation services furnished for the account of the United States and to all military and civilian agencies and offices making payments of charges for those services.

5. *Background.* Government and industry have been working together in recent years to standardize data which will permit uniformity of application and better utilization of computer and other mechanized systems. These goals have been advanced as described below.

a. The complete and proper execution of SF 1113 is one condition precedent to the payment and audit of charges billed thereon. Preliminary to the issuance by GSA of the March 1977 revised edition of SF 1113, comments were solicited from Government agencies and transportation carriers regarding its format which included an SCAC block. No objections were registered to making the SCAC block an integral part of the form.

b. The Transportation and Public Utilities Service, GSA, is currently in the process of converting its accounts receivable/accounts payable system for transportation audit transactions from an in-house carrier code to SCAC. This conversion will facilitate the eventual automation of that system.

c. The Interstate Commerce Commission (ICC), by Docket No 35819 served March 9, 1978, ordered carriers under its regulation to establish a system for assigning to every tariff standard carrier identification codes in lieu of the ICC consecutive construction then in use and stated that such standard carrier identification codes must be shown "on every effective tarrif or schedule on file March 1, 1979, and on every tariff or schedule indicated to become effective after that date." This requirement was met by the industry's filing of National Motor Freight Traffic Association, Inc., Directory of Standard Multi-Modal Carrier and Tariff Agents Codes (SCAC and STAC), ICC NMF 101-B.

6. *Action required of carriers*—a. *Preparation of SF 1113.* Each carrier shall insert in the block provided therefor on SF 1113 (and SF 1113A, Public Voucher for Transportation Charges (Memo)) the SCAC assigned to that carrier in ICC NMF 101-B, applicable supplements thereto, or subsequent reissues thereof.

b. *Assignment of SCAC identifiers.* Inquiries concerning codes published in the directory or the assignment of new codes should be addressed, as appropriate for the mode involved, to the following:

Bus Carriers: Mr. P. J. Campbell, National Bus Traffic Association, Inc., 506 South Wabash Avenue, Chicago, Ill. 60605.

Freight Forwarders: Mr. H. G. Roeschke, Freight Forwarders Tariff Bureau, Inc., 140 Cedar Street, New York, N.Y. 10006.
Railroads: Mr. W. J. Hardin, Western Railroad Association, room 300, 300 West Adams Street, Chicago, Ill. 60606.
Water Carriers: Mr. A. Carling, Waterways Freight Bureau, suite 402, 1334 G Street NW., Washington, D.C. 20005.
Motor Carriers and Other Modes Not Named Herein: Mr. N. J. Zovolta, National Motor Freight Traffic Association, Inc., 1616 P Street NW., Washington, D.C. 20036.

7. *Action required of agencies.* Each military disbursing office and civilian paying office shall ensure during its administrative examination of carriers' bills that the SCAC identifier is entered on each SF 1113 and SF 1113A. If the code is omitted, the forms and all supporting papers shall be returned to the carrier unpaid with a request that the SCAC be added to the forms.

8. *Agency comments.* Comments concerning the impact of this regulation on agency operations or programs should be submitted to the General Services Administration (TA), Washington, D.C. 20406, no later than June 30, 1979, for consideration and possible incorporation into a permanent regulation.

9. *Effect on other issuances.* When the provisions of this regulation are in conflict with other regulations and related directives, the provisions of this regulation will govern.

JAY SOLOMON,
Administrator of General Services.

FEBRUARY 28, 1979.

[FR Doc. 79-7172 Filed 3-8-79; 8:45 am]

[4110-85-M]

Title 42—Public Health

CHAPTER I—PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER D—GRANTS

PART 52—GRANTS FOR RESEARCH PROJECTS

Miscellaneous Amendments

AGENCY: Public Health Service, HEW.

ACTION: Final rule.

SUMMARY: This notice amends regulations applicable to grants made for research projects under sections 301, 303, 356, 394, 1004 and 1205, Public Health Service Act. The amendments eliminate conflicts in HEW grants administration policies and extend applicability to projects supported under section 501 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, and section 410 of the Drug Abuse Office and Treatment Act of 1972. Certain technical and clarifying changes have also been made.

EFFECTIVE DATE: April 9, 1979.

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 operated for profit and what administrative policies should apply. Please send all written comments on this issue to Mr. Ted Moore at the above address.

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 29, 1976. The definition of "project period" in the current regulations is in conflict with stated PHS policy.

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.

3. Other miscellaneous definitions for "Act," "Department," "grantee," "research project grant," and "project" are being added for clarification.

4. The present regulations cover section 103 of the Clean Air Act and section 204 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 501 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 356 and 1004 of the Public Health Service Act, respectively.

5. 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, on August 2 HEW 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, Part 52 contains several other cross-references to other applicable HEW regulations. In the interest of simplicity, reference to these and Part 74 are combined in one, simplified provision, § 52.27. Subpart E, setting forth the requirements for grantee accountability, is now fully covered by Part 74 and this subpart is therefore deleted.

6. With regard to the proposed sex nondiscrimination provision, which would have applied only "[w]here the recipient is an educational institution," the Department of Justice comments that they felt this was too restrictive because Title IX of the Education Amendments of 1972 applies to all federally assisted "education programs and activities." The provision has been incorporated into the new, simplified § 52.27 without the stated limitation.

7. 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 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.

8. In addition, §§ 52.1 and 52.10 are combined into one simplified applicability clause, § 52.10 deleted, and certain other clarifying and editorial changes have been made in the interest of simplicity. Although this has resulted in several changes in phraseology, no substantive change is intended.

Accordingly, Part 52 of Title 42, Code of Federal Regulations, is amended as set forth below.

Your attention is directed to § 52.11(a)(2) 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 be made to profitmaking organizations, amendments will be made changing the eligibility requirements in § 52.11(a)(2).

Dated: February 12, 1979.

JULIUS B. RICHMOND,
Assistant Secretary for Health.

Approved: March 3,1979.

HALE CHAMPION,
Acting Secretary.

1. The Table of Contents is amended to read as follows:

PART 52—GRANTS FOR RESEARCH PROJECTS

Subpart A—Applicability and Definitions

Sec.
52.1 To which programs do these regulations apply?
52.2 Definitions.

Subpart B—Eligibility, Award, and Termination

52.11 Who is eligible to apply for a grant?
52.12 How to apply for a grant.
52.13 Evaluation and disposition of applications.
52.14 Grant awards.

Subpart C—Grant Conditions—Obligations of Grantee

52.20 Use of funds; changes.
52.21 Principal investigators.
52.22-52.23 [Reserved]
52.24 Animal welfare.
52.25 [Reserved]
52.26 Other conditions.
52.27 Other HEW regulations that apply.

Subpart D—Expenditures by Grantee

52.30 Allocation of costs.
52.31 Direct costs in general.
52.32 Indirect costs.
52.33 Particular direct costs.

2. The issuing authority is amended to read as follows:

AUTHORITY: Sec. 215, 58 Stat. 690, as amended, 63 Stat. 835 (42 U.S.C. 216); sec. 301, 58 Stat. 691, as amended, 60 Stat. 423, 62 Stat. 467, 601, 1017, 70 Stat. 490, 74 Stat. 1053, 85 Stat. 785, 86 Stat. 687, 88 Stat. 346, 360 (42 U.S.C. 241); sec. 303, 70 Stat. 929, as amended, 84 Stat. 1241, 88 Stat. 132, 346 (42 U.S.C. 242a); sec. 356, 82 Stat. 1174 (42 U.S.C. 263d); sec. 394, 79 Stat. 1062, as amended, 84 Stat. 63, 64, 66, 67, 87 Stat. 92, 88 Stat. 372 (42 U.S.C. 280b-5); sec. 1004, 89 Stat. 306, 352, as amended, 91 Stat. 389 (42 U.S.C. 300a-2); sec. 1006, 89 Stat. 308 (42 U.S.C. 300a-4); sec. 501, 90 Stat. 1038 (42 U.S.C. 4585); sec. 1205, 87 Stat. 597 (42 U.S.C. 300d-4); sec. 410, 68 Stat. 84, as amended, 90 Stat. 247, 90 Stat. 1040 (21 U.S.C. 1177).

3. Section 52.1 of Subpart A is amended to read as follows:

§ 52.1 To which programs do these regulations apply?

(a) The regulations of this part apply to grants for the support of health-related research projects in programs relating to:

(1) The cause, diagnosis, treatment, control, or prevention of the physical or mental diseases, injuries, or impairments to human life, as authorized by sections 301, 303, and related provisions of the Act (42 U.S.C. 241, 242a);

(2) Electronic product radiation control programs designed to protect the public, and safety from electronic product radiation, as authorized by section 356 of the Act (42 U.S.C. 263d);

(3) Medical library science and related activities, and for the development or dissemination of new knowledge, techniques, systems, and equipment for processing, storing, retrieving, and distributing information pertaining to health sciences, as authorized by section 394 of the Act (42 U.S.C. 280b-5);

(4) Emergency medical techniques, methods, devices, and delivery, as authorized by section 1205 of the Act (42 U.S.C. 300d-4);

(5) The behavioral and biomedical etiology, treatment, mental and physical health consequences, and social and economic consequences, of alcohol abuse and alcoholism, as authorized by section 501 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4585);

(6) The improvement of drug maintenance techniques or programs, as authorized by section 410 of the Drug Abuse Office and Treatment Act of 1972 (21 U.S.C. 1177); and

(7) Research in the biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population, as authorized under section 1004 of the Act.

(b) These regulations do not apply to general research grants, grants 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 63 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(c). 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 award 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 activi-

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. Ineligibility for a grant award under this paragraph continues until terminated in the public interest by the Secretary.

(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 and 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.

* * * * *

(b) *Disposition.* On the basis of the Secretary's evaluation of an application 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 required by law, 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 words "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 "grant" for the word "such" in the second sentence of paragraph (e).

10. 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 § 52.13(b) 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 presently reserved is amended to read as follows:

§ 52.24 Animal Welfare.

The provisions in the Department Grants Administration Manual (Chapter 1-43) 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 50, Subpart D.	PHS grant appeals procedure.
45 CFR Parts 6 and 8	Inventions and patents.
45 CFR Part 16	Department grants appeals process.
45 CFR Part 46	Protection of human subjects.
45 CFR Part 74	Administration of grants (including grants to individuals).
45 CFR Part 75	Informal grant appeals procedures (indirect costs rates and other cost allocations).
45 CFR Part 80	Nondiscrimination under programs receiving Federal assistance through the Department—Effectuation of Title VI of the Civil Rights Act of 1964.
45 CFR Part 81	Practice and procedure for hearings under Part 80.
45 CFR Part 84	Nondiscrimination on the basis of handicap in federally assisted programs.
45 CFR Part 86	Nondiscrimination on the basis of sex in federally assisted education programs and activities.

§ 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-

nient provision all HEW regulations which are applicable to project grants, and Subpart F is therefore deleted in its entirety.

[FR Doc. 79-7236 Filed 3-8-79; 8:45 am]

[4110-07-M]

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:

C. H. Campbell, Legal Assistant, Office of Policy and Regulations, 6401 Security Boulevard, Baltimore, Maryland 21235, telephone 301-594-7453.

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 may 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.

Subsequently, section 371 of Pub. L. 95-216 (enacted December 20, 1977) changed the SSI hearing examiner's status to career-absolute positions as hearing examiners under 5 U.S.C. 3105 (renamed "Administrative Law Judges" by section 2(b) of Pub. L. 95-251, enacted March 27, 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 the regulations.

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.

(Secs. 1102, 1631, of the Social Security Act; 49 Stat. 647 as amended, 86 Stat. 1475 as amended; 42 U.S.C. 1302, 1383; Secs. 2, 3 of Pub. L. 94-202; Section 371 of Pub. L. 95-216).

(Catalog of Federal Domestic Assistance Program No. 13.807, Supplemental Security Income Program.)

Dated: March 3, 1979.

JOSEPH A. CALIFANO, Jr.,
Secretary of Health, Education, and Welfare.

[FR Doc. 79-7235 Filed 3-8-79; 8:45 am]

[4910-06-M]

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 conditioner 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

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 development of an 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 (c) 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 supplement the terms of an order as warranted by the record, if an emergency situation is found to exist.

Paragraph (d) provides that the decision of the presiding officer is administratively final, unless appealed under section 211.79.

Section 211.75 governs the introduction of evidence. As a general rule, the section is intended to permit the introduction of relevant and probative evidence. FRA believes that questions of reliability and prejudice should be considered by the presiding officer as considerations bearing on the weight to be accorded particular evidence. However, the section permits the exclusion of evidence determined to be unduly repetitive or so extensive and wanting in relevance or probative effect that its admission would impair the prompt, orderly, and fair resolution of the proceeding.

Section 211.77 permits any aggrieved party to appeal the decision of an administrative law judge to the Administrator within twenty (20) days. This section is intended to permit cross appeals in appropriate cases.

Based on its experience under these interim rules and further analysis of the need, if any, for more detailed procedures, the FRA will issue permanent rules of practice for the review of emergency orders within the next twelve months.

Since this rulemaking does not affect any substantive right or duty and pertains solely to procedures and practices before FRA, notice and public procedure thereon are unnecessary. 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 208(a), 84 Stat. 972, 974-975 (45 U.S.C. 432, 437(a)) and 5 U.S.C. §§ 554-559.

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 officer; 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 930.213.

(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. However, 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 repetitive; 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.

Issued at Washington, D.C. on March 6, 1979.

JOHN M. SULLIVAN,
Administrator.

[FR Doc. 79-7164 Filed 3-8-79; 8:30 am]

[7035-01-M]

Title 49—Transportation

CHAPTER X—INTERSTATE COMMERCE COMMISSION

SUBCHAPTER A—GENERAL RULES AND REGULATIONS

PART 1001—INSPECTION OF RECORDS

AGENCY: Interstate Commerce Commission.

ACTION: Final rule.

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 over 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.

DATES: Effective 9:00 a.m., March 1, 1979. Expires 11:59 p.m., March 15, 1979.

FOR FURTHER INFORMATION CONTACT:

J. Kenneth Carter, Chief, Utilization and Distribution Branch, Interstate Commerce Commission, Washington, D.C., 20423, Telephone (202) 275-7840, Telex 89-2742.

SUPPLEMENTARY INFORMATION: The Order is printed in full below.

Decided: 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 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—11126).

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:

James Wells, Chief, Cost Evaluation Branch, Rail Services Planning Office, 1900 L Street, NW., Washington, D.C. 20036, (202) 254-7552.

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 rate of return was set 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 differs 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, 1975, we determined that the use of U.S. Treasury obligations 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 that NLV by the increase in the wholesale 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, 1976, 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.

Price Escalator

ORTA recommends that RSPO establish a price escalator for leasing rail properties by using the President's Price Guideline of 9.5 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 these 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. Homme, Jr.,
Secretary.

[FR Doc. 79-7242 Filed 3-8-79; 8:45 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 Range and the Unimak Island Portion of the Aleutian 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 Range and the Unimak Island portion of the Aleutian Islands National Wildlife Refuge in accordance with applicable State and the 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 governs 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.

Dated: February 23, 1979.

LE ROY W. SOWL,
Alaska Area Director,
U.S. Fish and Wildlife Service.

[FR 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

proposed rules

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

[3410-02-M]

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[7 CFR Part 1062]

[Docket No. A0-10-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 proposed amendment.

SUMMARY: This final decision denies a 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:

Robert F. Groene, Marketing Specialist, Dairy Division, Agricultural Marketing Service, U.S. Department of Agriculture, Washington, D.C. 20250, (202) 447-4824.

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding: Notice of hearing: Issued May 31, 1978, published June 6, 1978 (43 FR 24540). Recommended decision: Issued November 17, 1978, published November 22, 1978 (43 FR 54642). Extension of Time for Filing Exceptions: Issued December 7, 1978, published December 13, 1978 (43 FR 58193). Partial final decision: Issued January 3, 1979, published January 8, 1979 (44 FR 1741). Final order: Issued January 18, 1979, published January 24, 1979 (44 FR 4933).

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 Bridgeton, Mo., on June 21-22, 1978, pursuant to 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.

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.
4. Pricing of diverted 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 directly 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 spokeman 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, 25 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 area. 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 spokeman 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

spokesman said that if milk in the Bentonville area had to move through the Springfield supply plant for delivery to Fayetteville, the milk would have to be shipped 220 miles. However, if the milk were permitted to be shipped directly from Bentonville to Fayetteville, it would only have to be shipped 26 miles, a savings of 194 miles. Similarly, the spokesman said, the Berryville milk supply 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 could be 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 opposed Kraft'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. This, 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 cooperative is to supply milk to pool distributing plants." 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 Class I utilization running 65 percent in May and with declining production in the grain belt, it is getting more and more costly for handlers 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, th 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 achieve was not related to 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 pricing of milk associated with the Bentonville plant, that the company had no plans to deliver milk from the Bentonville area to its plants in Springfield. He indicated that when such milk was not needed for Class I at Fayetteville the milk would be diverted to Bentonville.

Because the proposed Springfield supply plant has not been 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 performance standards for pool supply plants (i.e., level of shipments by the plant operator) would be equally 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 normally 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, Kraft's 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 exceptor 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 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 through diversions from the 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 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-Ozards 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 extend 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.

(This decision constitutes the Department's final Impact Analysis Statement for this proceeding.)

Signed at Washington, D.C., on March 6, 1979.

P. R. "Bobby" Smith,
Assistant Secretary for Marketing and Transportation Services.

[FR Doc. 79-7162 Filed 3-8-79; 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 304, 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"). Titles 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. Shockey, 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 Bleier, 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 VIII 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, such as a person that controls 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 with another 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 federal funds 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 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 depository banks during a calendar year. A depository bank is defined as a bank that maintains a correspondent account for another bank. A related interest is a company controlled by, or a political or campaign committee that benefits or is controlled by, an executive officer or principal stockholder of record. These reporting requirements do not apply to directors, unless they are executive officers or principal stockholders of record. For the purposes of the reporting requirements, a depository bank does not include a bank that maintains a correspondent account(s) that does not exceed $100,000 in the aggregate at any time during the reporting year. The agencies are considering a lower triggering amount for smaller banks. In particular, the agencies are considering a cut-off based upon a percentage of the depositing bank's total deposits.

Executive officers and principal stockholders must include in the report filed with the bank's board of directors (1) the "maximum amount of indebtedness" of the executive officer or principal stockholder and of each of that person's related interests to each depository bank; (2) the amount of indebtedness outstanding ten days before the report is filed of the executive officer or principal stockholder and of each of that person's related interests to each depository bank; (3) the range of interest rates on the indebtedness; and (4) the terms and conditions of the indebtedness. Separate amounts are to be reported for the executive officer or principal stockholder and for each of that person's related interests.

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 the cost and burden to insured banks that would be imposed by adopting either alternative. Comment is also requested on whether the "highest amount" should mean (1) the highest average daily, weekly, or monthly balance during the calendar year, (2) the highest end-of-the-month balance during the calendar year, or (3) the highest amount calculated on some other basis.

Title VIII requires each insured bank to compile the reports submitted to it by its executive officers and principal stockholders of record and to furnish such compilation annually to the appropriate bank supervisory agency. The format for the compilation will be published at a later date. The reports submitted by such persons to the board of directors of the insured bank must be maintained at the bank for five years and should not be forwarded to the appropriate Federal banking agency unless requested. The appropriate agency may require the reports to be retained by the bank for an additional period of time.

Finally, Title VIII requires each insured bank to file an annual report with the appropriate Federal banking agency. In the report, the bank must list by name each executive officer and principal stockholder of record that files a report with the bank's board of directors concerning indebtedness from depository banks. The insured bank also reports the "aggregate amount of all extensions of credit" made to such persons by depository banks. This single figure is calculated by totaling the "maximum amounts of indebtedness" reported by the executive officers and principal stockholders of record. This report will be part of the report filed by the insured bank under Title IX and will be made available to the public upon request.

b. *Title IX*—Title IX, which amends section 7 of the Federal Deposit Insurance Act, requires each insured bank to file a report annually with its appropriate Federal banking agency. In that report, the insured bank lists each of its executive officers and principal stockholders of record and the aggregate amount of extensions of credit by the bank to such persons and their related interests. The agencies propose to define "aggregate amount" as the total of the highest amounts of indebtedness owed to the insured bank by each of the bank's executive officers and principal stockholders of record and each of that person's related interests. As an alternative, the agencies are considering defining "aggregate amount" as the sum of all extensions of credit made during the reporting year. These reports will be made available to the public at the bank and at 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." It should be noted that under Regulation O, a person is not considered to control a company or a bank solely because of that person's position as a director or executive officer of the 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. 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. Until final action is taken on the proposals, however, banks should refer to the definitions of terms contained in the proposed regulations (in particular, the defini-

tion of "correspondent account") for guidance in complying with the prohibitions of Title VIII.

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 of insured banks by January 10, 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 FIRA) 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

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§ 215.9 Reports by member banks.

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(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 by name of each principal stockholder of record of the member bank; and

(2) The aggregate amount of all extensions of credit made by the member bank to its executive officers and principal stockholders of record and their related interests. For the purposes of this paragraph, "aggregate amount of all extensions of credit" means the sum of the highest amounts of indebtedness owed to the member bank during the year by each executive officer or principal stockholder of record and each of the reporting person's related interests. Principal stockholder of record has the meaning given in section 215.21(h) of Subpart B below.

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2. Sections 215.1 through 215.10 are designated as new Subpart A, which is titled:

Subpart A—Loans by Member Banks

3. A new Subpart B is added to Part 215 to read as follows:

Subpart B—Loans by Correspondent Banks

Sec.

215.20 Authority, purpose, and scope.
215.21 Definitions.
215.22 Prohibited transactions.
215.23 Reports by executive officers and principal stockholders of record.
215.24 Reports by member banks.
215.25 Civil penalties.

AUTHORITY: Title VIII of the Financial Institutions Regulatory and Interest Rate Control Act of 1978, Pub. L. 95-630; Secs. 11(i) and 22(h)(7) of the Federal Reserve Act (12 U.S.C. 248(i) and 375b(7) and 12 U.S.C. 1817(k)(1)).

Subpart B—Loans by Correspondent Bank

§ 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. 248(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 extension of credit by one of the banks to an executive officer, director or principal shareholder of the other bank. This Subpart also establishes procedures to implement the reporting and public disclosure requirements of Title VIII of FIRA with respect to member banks and executive officers and principal stockholders of record of member banks.

§ 215.21 Definitions.

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

(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] (12 U.S.C. 3106(d)).

(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.[2]

(c) "Control of a company or bank," "executive officer," "extension of credit," and "immediate family" shall have the meanings provided in Subpart A.

(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 a member 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, or 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 bank or 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 who directly or indi-

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[1] Under this definition, a foreign bank's branch in a State would be a bank but, unless the branch's deposits were insured by the FDIC, the branch would not be an "insured bank" and would not, therefore, be subject to the reporting requirements of sections 215.23 and 215.24, below.

[2] The definition of a company in this Subpart differs from that contained in Subpart A. The definition in Subpart A excludes insured banks and includes sole proprietorships.

rectly 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]

§ 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.

(4) No bank that has outstanding an extension of credit to an executive officer, director, or principal shareholder of another bank shall open a correspondent account at the 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.[4]

(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 that 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 215.9(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(b)(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 amount 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 ia added to read as follows:

[3] The definition of related interest in this Subpart differs from that in Subpart A. The definition in Subpart A excludes insured banks.

[4] 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.

PART 349—LOANS BY CORRESPONDENT BANKS

Sec.
349.1 Authority, purpose and scope.
349.2 Definitions.
349.3 Prohibited transactions.
349.4 Reports by executive officers and principal stockholders of record.
349.5 Reports by insured nonmember banks.
349.6 Civil penalties.

AUTHORITY: Title VIII of the Financial Institutions Regulatory and Interest Rate Control Act of 1978, Pub. L. 95-630 Secs. 7 and 9 of the Federal Deposit Insurance Act (12 U.S.C. 1817, 1819).

§ 349.1 Authority, purpose and scope.

(a) *Authority.* This Part 349 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 7 and 9 of the Federal Deposit Insurance Act (12 U.S.C. §§ 1817, 1819). 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 Part 349 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 extension of credit by one of the banks to an executive officer, director or principal shareholder of the other bank. This Part 349 also establishes procedures to implement the reporting and public disclosure requirements of Title VIII of FIRA with respect to insured nonmember banks and executive officers and principal stockholders of record of insured nonmember banks.

§ 349.2 Definitions.

For the purposes of this Part 349, the following definitions apply:

(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] (12 U.S.C. § 3106(d)).

(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.[2]

(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, or 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 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.

(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.

(4) No bank that has outstanding an extension of credit to an executive officer, director, or principal shareholder of another bank shall open a correspondent account at the 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 Part 349 and that are not employed by the bank, and (2) does not involve more than the normal risk of repayment or present other unfavorable features.

§ 349.4 Reports by executive officers and principal stockholders of record.

(a) If during any calendar year an executive officer or principal stockholder of record of an insured nonmember bank had outstanding an extension of credit from a depository bank(s) of the insured nonmember 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 insured nonmember bank.[4]

(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 that 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 to each depository bank outstanding as of December 31 of the calendar year for which the report is made;

(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 indebted-

[1] Under this definition, a foreign bank's branch in a State would be a bank but, unless the branch's deposits were insured by the FDIC, the branch would not be an "insured bank" and would not, therefore, be subject to the reporting requirements of sections 349.4 and 349.5.

[2] The definition of a company in this Part 349 differs from that contained in Subpart A of Federal Reserve Board Regulation O (12 C.F.R. Part 215). The definition in Subpart A of Regulation O excludes insured banks and includes sole proprietorships.

[3] The definition of related interest in this Part 349 differs from that in Subpart A of Federal Reserve Board Regulation O. The definition in Subpart A of Regulation O excludes insured banks.

[4] 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.

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(k)(1) of the Federal Deposit Insurance Act (12 U.S.C. § 1817(k)(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(b)(1) above.

§ 349.6 Civil penalties.

As specified in subsection 106(b)(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 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.

FEDERAL DEPOSIT INSURANCE CORPORATION
HOYLE L. ROBINSON,
Acting Executive Secretary.

[FR Doc. 79-7309 Filed 3-8-79; 8:45 am]

[6355-01-M]

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 conformance with new voluntary standards, before making any decision whether to issue a final mandatory standard.

FOR FURTHER INFORMATION CONTACT:

Carl W. Blechschmidt, Office of Program Management, Consumer Product Safety Commission, Washington, D.C. 20207, (301) 492-6557.

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 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 failing 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. 92-573, 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.

SADYE E. DUNN,
Secretary, Consumer Product Safety Commission.

[FR Doc. 79-7152 Filed 3-8-79; 8:45 am]

[4110-03-M]

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 (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of September 13, 1974 (39 FR 33103), FDA issued a proposal, under the OTC drug review procedures in § 330.10 (21 CFR § 330.10), 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 (I) 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 0002) submitted new data on the safety and effectiveness of triclocarban 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 00015) 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 0003) 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 (HER 0001) to consider previously submitted data (OTC Volume 020093) on the safety and effectiveness of secondary amyltricresols and orthohydroxyhpenylmercuric chloride as active antimicrobial ingredients. No new data were submitted with this petition. Xttrium 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 mongraph 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 (HFA-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.

Dated: February 26, 1979.

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

[FR Doc. 79-6764 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-O'MALLEY 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 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 Educational Assistance, Office of Indian Education 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 regulation. Pub. L. 95-561, Sec. 1102(a) directs the Secretary to develop alternative methods for the equitable distribution of any supplemental program 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 51 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 each tribe, as defined in 25 CFR, Part 273.2(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 significant rule and does not require a regulatory analysis under Executive Order 12044 and 43 CFR Part 14.

I have determined that these proposed regulations are not a major Federal action within the scope of the National Environmental Policy Act of 1969, 42 U.S.C. 4223(2)(c).

The primary authors of this document are Bill Riefenberry, 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) 237-0405, 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 exceptions to the provisions of Paragraph (a) of this section based upon the special cultural, linguistic, social or educational needs of the communities involved.

Dated: March 2, 1979.

FORREST J. GERARD,
Assistant Secretary, Indian Affairs.

[FR Doc. 79-7237; Filed 3-8-79; 8:45 am]

[4830-01-M]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[26 CFR Part 26]

[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 date 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 (LR-2-77), Washington, D.C. 20224.

FOR FURTHER INFORMATION CONTACT:

George Bradley or Charles Hayden of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, D.C. 20224, 202-566-3935, not a toll-free call.

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 (43 FR 59849).

The rules of § 601.601(a)(3) 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 9:45 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:

DAVID E. DICKINSON,
Assistant Director, Legislation and Regulations Division.

[FR Doc. 79-7139 Filed 3-8-79; 8:45 am]

[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 2903B, Waterside 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 (919-541-5437).

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 is 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 307(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 officers 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 advance notice of intent to promulgate regulations 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 in rules, regulations and program directives a mechanism for assuring consistency of application among the Regional Offices. 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 those 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 26388), 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 a system to assist States and EPA Regional Offices in making determinations of BACT. For instance, EPA will distribute 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 areas require all new major stationary sources to apply LAER as a condition for receiving a permit to construct. LAER determinations will also 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 topic of the annual Regional Office or State and local agency audit. If the audit uncovers instances of noncompliance with the directive, the auditing team would then recommend that the Regional Office follow the directive. Under the proposed regulation, the Regional Offices would have to implement all of the recommendations of the audit team.

Mechanisms for assuring Regional Consistency would be developed where their inclusion in rules, regulations, and program directives is deemed reasonable and appropriate by the responsible EPA headquarters official.

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 advance 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 commenters recommended 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 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 considers cost in setting new 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(d) of the Act. EPA also considers cost in reviewing determinations of best and reasonably available control technologies. Furthermore, EPA considers the economic impact of State implementation plans that it 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 non-judicial review of 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 inconsist encies 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 Work 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, 1977, 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 State 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 AQCR. 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 unform 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-

ments. Therefore, some incentives will be removed for industries planning to locate in one State as opposed to another because of inconsistent application of the Act's requirements. The regulations will tend to preclude economic incentives or disincentives because of varying interpretations of the Act's requirements. There will be no discernable energy impact.

PLAN TO EVALUATE THE EFFECTIVENESS OF REGIONAL CONSISTENCY REGULATIONS

Section 2(d)(8) of Executive Order 12044 requires that each new significant regulation have a plan to evaluate its effectiveness. The Regional Office and State audit procedures go a long way to provide a plan for evaluation of these regulations. However, it is still necessary to evaluate how effective the audits and dissemination of policy guidance are. Thus, EPA has developed a plan to evaluate the effectiveness of this regulation. Approximately 6 months after completion of the State and Regional Office audit reports, whichever is later, EPA will place a notice in the FEDERAL REGISTER soliciting public comment on implementation of the Regional Consistency regulations. The States and local agencies and the public will be asked to comment on the fairness and uniformity mechanisms, audit report and procedures, and the dissemination of EPA policy guidance. A separate copy of the notice will be sent to all State agencies and major local agencies. These comments will be summarized and published in the FEDERAL REGISTER. A copy of the evaluation plan is available in the docket (OAQPS 79-11).

Dated: March 1, 1979.

BARBARA BLUM,
Acting Administrator.

EPA proposes to amend Title 40, Chapter I, Subchapter C, of the *Code of Federal Regulations* by adding a new Part 56 as follows:

PART 56—REGIONAL CONSISTENCY

Sec.
56.1 Definitions.
56.2 Scope.
56.3 Policy.
56.4 Mechanisms for fairness and uniformity—Responsibilities of Headquarters employees.
56.5 Mechanisms for fairness and uniformity—Responsibilities of Regional Office employees.
56.6 Dissemination of policy and guidance.
56.7 Regional Office audits.
56.8 State and local agency performance audits.

AUTHORITY: Section 301(a)(2) of the Clean Air Act as amended (42 USC 7601).

§ 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," "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 or enforcement of the 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; and

(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 Headquarters deems reasonable and appropriate the inclusion of the mechanisms under this section with the rule, regulation, or program directive. The determination that a mechanism is unnecessary shall be explained in writing by the appropriate responsible official in Headquarters and must accompany the relevant rule, regulation, or program 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 Regional Office, including the Regional Administrator, shall assure that actions taken under the Act are carried out fairly and in a manner that is consistent with the activities of other Regional Offices and shall—

(1) Comply with the mechanisms 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 Regional Office shall seek and obtain written concurrence of the appropriate 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 guidance.

(a) The Assistant Administrator for Air, Noise, and Radiation shall establish as expeditiously as practicable but no later than one year after promulgation of this part the programs listed in this section for the dissemination of policy and guidance. He or she shall distribute material under the programs to the Regional Offices and State and local agencies, and shall make the material available to the public.

(1) A comprehensive air programs policy and guideline system containing the following:

(i) A compilation of all relevent EPA program directives and guidance, except for rules and regulations, concerning the requirements under the Act.

(ii) A procedure whereby each Headquarters office with air pollution control responsibility will enter new and revised guidance into the compilation.

(iii) 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 finding 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.

(2) A monthly summary of interpretations of the Act, rules, regulations, or program directives made under § 56.5(b) of this part.

(3) A semi-annual compilation of the summary of interpretations of the Act, rules, regulations, and program directives made under § 56.5(b) of this part.

(b) Each Headquarters office with air pollution control responsibility will participate in the development and implementation of the system outlined in paragraph (a) of this section.

(c) At the initiation of any major program the responsible headquarters official will, if he or she determines it appropriate, develop a guidance program consisting of videotape presentations, regional workshops, manuals, other media, or combinations of these.

§ 56.7 Regional Office audits.

(a) (1) Within three months after promulgation of this part, the Administrator shall form a Regional Office Audit Committee comprising representatives of EPA Headquarters offices, including staff offices, and selected Regional Office personnel with air pollution control responsibilities. The Assistant Administrator for Air, Noise, and Radiation or his or her designee shall chair the Committee.

(2) The Administrator shall annually review the composition of the Regional Office Audit Committee and make any changes that he or she deems appropriate.

(3) The Administrator shall consult with Headquarters Offices with air pollution control responsibilities before forming or revising the committee.

(b) (1) The Regional Office Audit Committee shall develop criteria for use in auditing Regional Office programs for performance in implementing their responsibilities delegated under Section 301(a)(1) of the Act in a manner consistent with any mechanisms for assuring fairness and consistency developed under Section 56.4 of this part. These criteria must also assure an adequate quality audit of each State's adherence to the requirements of the Act and performance in implementing and enforcing the Act.

(2) The Audit Committee shall within one year after promulgation of this part incorporate those criteria into a manual for use in performing audits of Regional Offices. The manual must identify the activities to be audited. The audit must also address the uniformity of air pollution control regulation between adjacent States. The Audit Committee shall revise the manual from time to time to reflect changes in national priorities.

(3) The Audit Committee shall publish notice in the FEDERAL REGISTER of the availability of the audit manual and entertain public comments on the manual.

(c) At least once annually, the Regional Office Audit Committee shall use the audit manual to audit the performance of the Regional Offices.

(d) Within 60 days after the completion of an audit, the Audit Committee shall provide a draft audit report to the Regional Administrator of the Regional Office audited. The report must set forth findings and include any instances of inconsistent application of EPA rules, regulations, and program directives, and recommendations for any corrective action required.

(e) Within 30 days after receipt of the draft audit report, the Regional Administrator may provide comments to the Audit Committee.

(f) Within 90 days after submission of the draft audit report to the Regional Administrator, the Audit Committee shall provide a final audit report to the appropriate Regional Administrator, the appropriate headquarters program and staff offices, and the Administrator. The Audit Committee shall also publish notice in the FEDERAL REGISTER of the availability of the report.

§ 56.8 State and local agency performance audits.

(a)(1) Within one year after promulgation of this part, each Assistant Administrator and each Director of a Staff Office in the Office of the Administrator with air pollution control responsibilities, together with Regional Office personnel with air pollution control responsibilities as selected by the Administrator, shall develop criteria for use in auditing State and local air pollution control programs for performance in implementing and enforcing the Clean Air Act. The criteria must include State agency activities for which national consistency is required. The Offices that develop the criteria shall provide for consultation with affected State and local agencies in the development of the criteria.

(2) The Assistant Administrator for Air, Noise, and Radiation shall incorporate the criteria into a manual for use in performing the audits. He or she shall provide notice in the FEDERAL REGISTER on the availability of the manual and entertain public comment on the manual. He or she shall revise the manual from time to time in consultation with the offices that developed the audit criteria to reflect changes in national priorities.

(b) The manual must identify the specific activities to be audited. The audit must be limited to a review of

the performance of the Stat in implementing and enforcing the Act and the manner in which the State or local agency has complied with the Act, appropriate EPA regulations and policy, and any conditions of a delegation of authority from EPA. The audit must also address the degree to which air pollutin control regulations between adjacent jurisdictions of local and regional governments are incompatible.

(c) At least once annually, each Regional Administrator shall use the audit manual to audit the performance of each State and each local agency that has responsibility under the Clean Air Act.

(d) Within 60 days after the completion of the audit, the Regional Administrator shall provide a a draft audit report to the Director of the audited agency. The report must set forth findings and include any instances of inconsistent application of Federal statutes, regulations, and policy, and recommendations for any corrective action required.

(e) Within 30 days after receipt of the draft report, the Director of the audited agency may provide comments to the Regional Administrator.

(f)(1) Within 90 days after submission of the draft audit report to the director of the agency, the Regional Administrator shall provide a final audit report to the EPA Administrator and the following:

(i) For State agencies, the Governor of the State and the director of the State air pollution control agency.

(ii) For local agencies, the chief executive of the government having jurisdiction over the local agency and the director of the local air pollution control agency.

(2) The Regional Administrator shall also publish notice of the availability of the audit report in the FEDERAL REGISTER.

(g) At his or her discretion, the Regional Administrator may perform the audit required under this section with the periodic audit required by EPA grant regulations, except that the audit report required by this section must be prepared as a separate document.

[FR Doc. 79-6938 Filed 3-8-79; 8:45 am]

[4110-02-M]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of Education

[45 CFR Part 161h]

FINANCIAL ASSISTANCE FOR ENVIRONMENTAL EDUCATION PROJECTS

Proposed Rules

AGENCY: Office of Education, HEW.

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 2025, FOB-6, 400 Maryland Avenue, SW., Washington, D.C. 20202.

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 H 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 in Title III of the Elementary and Secondary Education Act for involvement of private schools. The proposed regulations simplify existing regulations and incorporate 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 100d.

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. The new regulations will be titled Education Division General Administrative Regulations (EDGAR). 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 make a substantial contribution to the overall 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 provisions 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.

Any comments from the public on these proposed regulations that also relate to EDGAR will be considered in the revision of both these regulations and EDGAR.

If EDGAR is not issued as final regulations in time for making grants under this program in fiscal year 1980, the Office of Education will consider various alternatives including the following:

(1) An interim adoption, for this program, of the general grant regulations in 45 CFR Part 74 (which also apply to other agencies in the Department), and the sections in the existing OE General Provisions Regulations that are not affected by the revised policies in Part 74; or

(2) An interim adoption, for this program, of Part 74 and any necessary additional regulations proposed in EDGAR.

In addition, applicants are encouraged to read the statute which authorizes the program, since these regulations do not incorporate provisions that are clearly stated in the statute. Copies of the statute and other relevant material will be made available to applicants with the application packet.

Dated: December 27, 1978.

JOHN ELLIS
Acting U.S. Commissioner of Education.

Approved February 7, 1979.

JOSEPH A. CALIFANO, Jr.,
Secretary of Health, Education, and Welfare.

(Catalog of Federal Domestic Assistance Number 13.522, Environmental Education Act).

The Commissioner redesignates Part 183 of 45 CFR as Part 161h and proposes to revise the regulations to read as follows:

PART 161h—FINANCIAL ASSISTANCE FOR ENVIRONMENTAL EDUCATION PROJECTS

Subpart A—General

Sec.

161h.1 What is the Environmental Education Program?
161h.2 [Reserved]
161h.3 What are the definitions that apply specifically to this program?
161h.4 Who is eligible to receive grants?

Subpart B—What Kind of Projects Does the Office of Education Assist Under This Program?

161h.10 What are the purposes of the projects?
161h.11 What categories of projects are supported?
161h.12 What is a comprehensive multi-year project?
161h.13 What is a general project?
161h.14 What is a mini-grant project?
161h.15 Will priorities for funding be established?

Subpart C—How Does One Apply for a Grant?

161h.20 [Reserved]
161h.21 To Whom must an applicant submit its application for comment?

Subpart D—How Is a Grant Made?

161h.30 What selection criteria does the Commissioner use?

Subpart E—What Conditions Must a Grantee Meet?

161h.40 Must a grantee help defray part of its project's cost?
161h.41 Are there restrictions on the type of costs a grant may support?
161h.42 What other restrictions apply to the use of grants?
Appendix

AUTHORITY: Part H of Title III of the Elementary and Secondary Education Act as amended by Pub. L. 95-561 (20 U.S.C. 3011-3018)

Subpart A—General

§ 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.

(3) Consortia of eligible applicants.

(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 3016)

Subpart B—What Kind of Projects Does the Office of Education Assist Under This Program?

§ 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;

(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 those activities after the project period ends.

(c) A comprehensive multi-year project requires more than 12 months to achieve its objective(s) 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)

§ 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 objective(s).

(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 objective(s).

(20 U.S.C. 3016)

§ 161.15 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 30 possible points.

(c) The criteria contained in this section 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, 3016)

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 (d))

§ 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)

§ 161.h42 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) The way the applicant plans to use its resources and personnel to achieve each objective. (10 points)

SELECTION CRITERION—QUALITY OF KEY PERSONNEL

(a) The Commissioner reviews each application for information that shows the quality of the key personnel the applicant plans to use on the project.

(b) The Commissioner looks for information that shows—

(1) The qualifications of the project director (if any);

(2) The qualifications of each of the other key personnel used in the project;

(3) The qualifications of any of the following persons who are hired for the project—

(i) Any member of the immediate family of a person on the project staff;

(ii) Any member of the governing body of the grantee; or

(iii) Any member of the immediate family of a person on that governing body.

(4) The time that each person referred to in paragraphs (b) (1)-(3) plans to commit to the project; and

(5) The extent to which the applicant, as part of its nondiscriminatory employment practices, encourages applications for employment from persons who are members of groups that have been traditionally underrepresented, such as members of racial of ethinic minority groups, women, handicapped persons, and the elderly.

(c) To determine the qualifications of a person, the Commissioner considers evidence of past experience in fields related to the objectives of the project, as well as other information that the applicant provides. (7 points)

SELECTION CRITERION—BUDGET AND COST EFFECTIVENESS.

(a) The Commissioner reviews each application for information that shows that the project has and adequate budget and is cost effective.

(b) The Commissioner looks for information that shows—

(1) The budget for the project is adequate to support the project activities; and

(2) Costs are reasonable in relation to the objectives of the project. (5 points)

SELECTION CRITERION—EVALUATION PLAN

(a) The Commissioner reviews each application for information that shows the quality of the evaluation plan for the project.

(b) The Commissioner looks for information that shows an objective, quantifiable method of evaluation. (5 points)

SELECTION CRITERION—ADEQUACY OF RESOURCES

(a) The Commissioner reviews each application for information that shows that the applicant plans to devote adequate resources to the project, including resources to meet the needs of persons to be served by the project who are members of groups that have been traditionally underrepresented, such as—

(1) Members of racial or ethnic minority groups;

(2) Women;

(3) Handicapped persons; and

(4) The elderly.

(b) The Commissioner looks for information that shows—

(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.

ADDRESSES: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT:

Doug Slotten, Policy and Rules Division, (202-632-9342).

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 Commissions's Public Reference Room at 1919 M Street, NW., Washington, D.C.

FEDERAL COMMUNICATIONS COMMISSION,
LARRY F. DARBY,
Chief, Common Carrier Bureau.

ATTACHMENT A

Jon W. Owens, General Manager, Ace Telephone Association, 207 East Ceder Street, Houston, Minnesota 55943.

Jeremiah Courtney, Esq., Philips B. Patton, Esq., Jack R. Smith, Esq., The Ad Hoc Telecommunications Users Committee, 2120 L Street, N.W., Washington, D.C. 20037.

Joseph M. Kittner, Esq., Norman P. Leventhal, Esq.; McKenna, Wilkinson & Kittner, 1150 Seventeenth Street, N.W., Washington, D.C. 20036, Counsel for American Broadcasting Companies, Inc., CBS Inc., National Broadcasting Company, Inc.

Robert J. Kaufman, Esq., American Broadcasting Companies, Inc., 1330 Avenue of the Americas, New York, New York 10019.

Joseph DeFranco, Esq., CBS Inc., 1800 M Street, N.W., Washington, D.C. 20036.

Howard Monderer, Esq., National Broadcasting Company, Inc., 1800 K Street, N.W., Washington, D.C. 20006.

Edward Goldstein, Esq., Assistant Financial Officer, Edward Friedman, Esq., Alfred A. Green, Esq., Francine J. Berry, Esq., American Telephone and Telegraph Company, 195 Broadway, New York, New York 10007.

David Gorin, John G. Demas, Arthur Andersen & Co., 1345 Avenue of the Americas, New York, New York 10019.

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.

Janice E. Kerr, Esq., J. Calvin Simpson, Esq., Lawrence Q. Garcia, Esq., Public Utilities Commission of the State of California, 5066 State Building, San Francisco, California 94102.

Duane L. Day, President, Cascade Utilities, P.O. Box 188, Estacada, Oregon 97023.

Eugene H. Irminger, Vice President and Controller, Central Telephone & Utilities Corporation, O'Hare Plaza, 5725 East River Road, Chicago, Illinois 60631.

Robert McKell, President, Chillicothe Telephone Company, Chillicothe, Ohio 45601.

S. S. Carpenter, Personnel Director, Clifton Forge-Waynesboro Telephone Company, Executive Office, P.O. Box 2008, Staunton, Virginia 24401.

Earl F. Phillips, General Manager, Coastal Utilities, Inc., P.O. Box 558/100 Ryon Avenue, Hinesville, Georgia 31313.

Garry R. MacCormack, Secretary-Treasurer, Colorado Independent Telephone Association, P.O. Box 48, Colorado City, Colorado 81019.

Laurence Singer, Esq., Fager & Singer, Suite 300, 1737 DeSales Street, N.W., Washington, D.C. 20036, Counsel for Consumer Federation of America.

Richard A. Gnospelius, Coopers & Lybrand, 1251 Avenue of the Americas, New York, New York 10020.

Helen E. Foultz, President, Coopersburg Telephone Company, 562 Thomas Street, Coopersburg, Pennsylvania 18036.

E. Williams Henry, Esq., Lawrence P. Keller, Esq., Ginsbury, Feldman and Bress, 1700 Pennsylvania Avenue, N.W., Washington, D.C. 20006, Counsel for Continental Telephone Corporation.

Robert O. Karr, President, The Craw-Kan Telephone Cooperative Association, Inc., Girard, Kansas 66743.

Jack L. Bentley, General Manager, Delta County Telephone Company, 132 Grand Avenue, P.O. Box 730, Paonia, Colorado 81428.

Dean E. Anderson, Manager, Deuel Telephone Cooperative Association, Clear Lake, South Dakota 57226.

W. R. Buchanan, President, Eastern Missouri Telephone Company, 215 West Church, Bowling Green, Missouri 63334.

Mike Fitzpatrick, Ernst & Ernst, 1800 One Washington Plaza, Tacoma, Washington 98402.

Edward J. Neckvatal, Jr., General Manager, Farmers Telephone, 129 East Maple Street, Lancaster, Wisconsin 53813.

David L. Swafford, Executive Director, Florida Public Service Commission, Fletcher Building, 101 East Gaines Street, Tallahassee, Florida 32304.

Lawrence C. Ware, General Manager, Garden Valley Telephone Company, Erskine, Minnesota 56535.

E. A. Gordon, Treasurer, 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.

Richard M. Cahill, Esq., Adalbert K. Wnorowski, Esq., GTE Service Corporation and its affiliated domestic telephone operating companies, One Stamford Forum, Stamford, Connecticut 06904.

Charles H. Lindsey, Executive Vice President, Georgia Telephone Association, 1900 Century Boulevard, Suite 8, Atlanta, Georgia 30345.

Howard Ellis, President & Manager, Haviland Telephone Co., Inc., Haviland, Kansas 67059.

Irene M. Baldwin, Vice-President, Home Telephone Company, Inc., Galva, Kansas 67443.

Illinois Telephone Cooperative Association, P.O. Box 299, Louisville, Illinois 62858.

Herbert E. Marks, Esq., Stephen R. Bell, Esq., Laurel R. Bergold, Esq., Wilkinson, Cragun, & Barker, 1735 New York Avenue, N.W., Washington, D.C. 20006, Counsel for Independent Data Communications Manufacturers Association, Inc.

J. Roger Wollenberg, Esq., David R. Anderson, Esq., William T. Lake, Esq., Gail F. Schultz, Esq., William, Cutler, & Pickering, 1666 K Street, N.W., Washington, D.C. 20006, Counsel for International Business Machines Corporation.

J. Gordon Walter, Esq., Donald G. Cherry, Esq., International Business Machines Corporation, Old Orchard Road, Armonk, New york 10504.

James R. Maret, Esq., Iowa State Commerce Commission, 300 Fourth Street, Des Moines, Iowa 50309.

J. Kent Jerome, Secretary-Treasurer, Iowa Telephone Association, 1601 22nd Street, Suite 209, West Des Moines, Iowa 50265.

Robert C. Carson, President, J.B.N. Telephone Company, Inc., Wetmore, Kansas 66350.

Wallace R. Johnson, Certified Public Accountant, Box 343, Fergus Falls , Minnesota 56537.

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.

Michael H. Bader, Esq., Kenneth A. Cox, Esq., William J. Potts, Jr., Esq., John M. Pelkey, Esq., Haley, Bader and Potts, 1730 M Street, N.W., Washington, D.C. 20036, Counsel for MCI Telecommunications Corporation.

John R. Worthington, Esq., MCI Telecommunications Corporation, 1150—17th Street, N.W., Washington, D.C. 20036.

E. R. Harrington, Secretary-Treasurer, Madison Telephone Company, Inc., Madison, Kansas 66860.

Eldon M. Snowden, General Manager, McDonough Telephone Cooperative, Inc., P.O. Box 359, Colchester, Illinois 62326.

W. S. Howard, President, Millington Telephone Company, Inc., 4880 Navy Road, Millington, Tennessee 38053.

C. J. McCurry, Executive Vice President, Missouri Telephone Association, Box 785, Jerrerson City, Missouri 65101.

R. S. McClelland, Jr., Executive Vice President, Missouri Telephone Company, Executive Offices, 200 East Walnut Building, P.O. Box 878, Columbia, Missouri 65201.

Francis E. Bowers, President, Moultrie Independent Telephone Company, Lovington, Illinois 61937.

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 FCC 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. 20044.

David Cosson, Esq., Robert J. Leigh, Esq., National Telephone Cooperative Association, 2626 Pennsylvania Avenue, N.W., Washington, D.C. 20037.

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, 720 Joyce Lake, Drawer K, 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 Governor Nelson A. Rockefeller Empire State Plaza, Albany, New York 12223.

Peter Van Kampen, Execuitive Vice President, New York State Telephone Association, Inc., 111 Washington Avenue, Albany, New York 12210.

Leroy H. Hemingway, Deputy Commissioner, Director, Utility Program, Public Utility Commissioner of Oregon, Labor & Industries Building, Salem, Oregon 97310.

Nicholas P. Miller, Esq., Preston, Thorgrimson, Ellis, Holman & Fletcher, 1776 F Steeet, 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 66075.

Hazel L. Parker, President, Pymatuning Independent Telephone Company, Reynolds Development, Post Office Box No. 606, Greenville, Pennsylvania 16125.

Rochester Telephone Corporation, 100 Midtown Plaza, Rochester, New York 14646.

Robert W. Feragen, Administrator, Rural Electrification Administration, Washington, D.C. 20250.

H. J. Austerman, General Manager, Rural Telephone Service Co., Inc., Lenora, Kansas 67645.

Garry R. MacCormack, President, The Rye Telephone Company, Inc., P.O. Box 48, Colorado City, Colorado 81019.

James Smith, Manager, St. Croix Telephone Co., 154 E. 2nd Street, New Richmond, Wisconsin 54017.

F. Thomas Tuttle, Esq., Kevin H. Cassidy, Esq., Satellite Business Systems 8003 Westpark Drive, McLean, Virginia 22102, Counsel for Satellite Business Systems, Pierson, Ball & Dowd, 1200 18th Street, N.W., Washington, D.C. 20036.

Alan W. Pedersen, Vice President, Accounting and Separations, Southern Kansas Telephone Company, Inc., 112 South Lee Avenue, Clearwater Kansas 67026.

Robert W. Ross, Esq., Southern Pacific Communications Company, 1801 K Street, N.W. Suite 221, Washington, D.C. 20006.

T. C. Lewis, President, The Sullivan County Telephone Co., Forksville, Pennsylvania 18616.

James Best, Controller, Telephone Utilities, Inc., P.O. Box E, Ilwaco, Washington, 98624.

Eugene L. Andrus, Manager, 3 Rivers Telephone Cooperative Fairfield, Montana.

John G. Foster, President, Twin Valley Telephone, Inc., Miltonvale, Kansas 67466.

Thomas J. O'Reilly, Esq., United States Independent Telephone Association, 1801 K Street, N.W., Suite 1201, Washington, D.C. 20006.

Peter M. Andersen, Esq., U.S. Telephone and Telegraph Corporation, A Subsidiary of ITT, 67 Broad Street, New York, New York 10004.

John M. Lothschuetz, Esq., Michael T. Hyde, Esq., United Telecom Service, Inc., on behalf of member companies of the United Telephone System, 1800 K Street, N.W., Suite 1102, Washington, D.C. 20006.

Warren E. Baker, Esq., Post Office Box 11315, Kansas City , Missouri 64112.
Dale W. Hemmy, Certified Public Accountant, H. G. Siepert & Company, 1920 West Hart Road, Beloit, Wisconsin 53511, representing United Telephone Company.
S. M. Jensen, Vice President—General Manager, Unitel of Nebraska, Box 500, Blair, Nebraska 68008.
Robert D. Sarver, Plant and Engineering, Vice president, Universal Telephone, Inc., Universal Building, 234 West Wisconsin Avenue, Milwaukee, Wisconsin.
Charles J. Cicchetti, Ph.D., Chairman, Frederick C. Huebner, CPA, Administrator, Accounts and Finance Division, Wisconsin Public Service Commission, Hill Farms State Office Building, Madison, Wisconsin, 53702.
Todd Sanders, President—General Manager, Yell County Telephone Company, Post Office Box 308, Danville, Arkansas 72833.
Woodrow Graber, President, Zenda Telephone Company, Inc., Zenda, Kansas 67159.
J. Randolph MacPherson, Esq., Defense Communications Agency, Washington, D.C. 20305.

[FR Doc. 79-7020 Filed 3-8-79; 8:45 am]

[3110-01-M]

OFFICE OF MANAGEMENT AND BUDGET

Office of Federal Procurement Policy

[48 CFR Parts 3, 4, 5, 20, 25, 28]

FEDERAL ACQUISITION REGULATION PROJECT

Availability and Request for Comment

AGENCY: Office of Federal Procurement Policy, Office of Management and Budget.

ACTION: Notice of Availability and Request for Comment on draft Federal Acquisition Regulation.[1]

SUMMARY: The Office of Federal Procurement Policy is making available for public and Government agency review and comment segments of the draft Federal Acquisition Regulation (FAR) regarding Ethics, Contractor Records Retention, 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. The 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.

DATE: Comments must be received on or before May 3, 1979.

ADDRESS: Obtain copies of the draft regulation from and submit comments to William W. Thybony, Assistant Administrator for Regulations, Office of Federal Procurement Policy, 726 Jackson Place, NW, Room 9025, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT:

William Maraist, or Strat Valakis, (202) 395-3300.

SUPPLEMENTARY INFORMATION: The fundamental purpose of the FAR is to reduce proliferation of regulations; to eliminate conflicts and redundancies; and to provide an acquisition regulation that is simple, clear and understandable. The intent is not to create new policy. However, because new policies may arise concurrently with the FAR project, the notice of availability of draft regulations will summarize the section or part available for review and describe any new policies therein.

The following subparts of the draft Federal Acquisition Regulation are available upon request 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 even the 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, business or group seeking to obtain contractual or other business or fanancial relationship with their agency. A Gratuities clause is provided for review 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 gratuity prohibition. Government employees involved in the acquisition process will be required to review their agency's Standard of Conduct and Ethics regulations, at least annually. Disciplinary action will be taken against Government employees for violation of the standards in accordance with their 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 review.

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 initiating contractor debarment or suspension measures. 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. 2306(b) and 41 U.S.C. 254(a). These statutes require a warranty by the contractor against contingent fees in every negotiated contract. They permit, as an exception to the warranty, contingent fee arrangements between contractors and bonafide 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.

PART 4—ADMINISTRATIVE MATTERS

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

[1] The Draft Acquisition Regulation was filed as a part of the original document.

contractors of excessive records retention requirements while ensuring that the records review requirements of the Comptroller General and contracting agencies are met. It specifies the types of records to be retained and the retention periods.

PART 5—PUBLICIZING CONTRACT ACTIONS

5.1 Dissemination of information.

This subpart prescribes several mandatory and optional methods of disseminating information on proposed contracts. It requires that contracting officers maintain a reasonable number of copies of solicitations publicized in the Commerce Business Daily to be available to those not initially solicited. It also implements P.L. 95-507 requirement regarding citation of applicable laws or agency rules for small businesses.

5.2 Synopses of proposed contracts.

This subpart implements the Small Business Act (15 U.S.C. 637(e)) which empowers the Secretary of Commerce to obtain notices (synopses) of all proposed defense agency contracts of $10,000 and above and all civilian agency contracts of $5,000 and above and publicize them in the Commerce Business Daily (CBD). It provides a number of exceptions to this requirement. This subpart requires that the synopses be transmitted to the CBD no less than 10 days before issuing solicitations to allow concerns not on current bidders lists time to prepare offers. It also requires that in negotiated acquisitions over $500,000 contracting offices shall publish names and addresses of prospective offerors in the CBD to enable small business concerns and others interested in subcontracting to contact prospective prime contractors early in the acquisition process.

5.3 Synopses of contract awards.

This subpart requires the synopses in the CBD of all sole source awards exceeding $10,000 and, for subcontracting 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 make maximum information in the acquisition process available to the public. However, a high 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 designations 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 applies 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.

25.2 Buy American Act—Construction materials.

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 offerors 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 becuase 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 us 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. FETTIG,
Administrator.

[FR Doc. 79-7171 Filed 3-8-79; 8:45 am]

notices

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

[3410-16-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 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.

(Catalog of Federal Domestic Assistance Program No. 10.904, Watershed Protection and Flood Prevention Program, Pub. L. 83-566, 16 U.S.C. 1001-1008.)

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 11,920-acre watershed. The planned works of improvements include land treatment on about 10,700 acres and the installation of structural measures consisting of channel work on about 26 miles of drainage main, laterals and sublaterals with appurtenances.

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.

(Catalog of Federal Domestic Assistance Program No. 10.904, Watershed Protection and Flood Prevention Program, Pub. L. 83-566, 16 U.S.C. 1001-1008.)

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

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 57350.

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 results at the above address.

No administrative action on implementation of the proposal will be taken until May 8, 1979.

(Catalog of Federal Domestic Assistance Program No. 10.904, Watershed Protection and Flood Prevention Program, Pub. L. 83-566, 16 U.S.C. 1001-1008).

Dated: February 27, 1979.

VICTOR H. BARRY, Jr.,
Deputy Administrator for Programs.

[FR 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, has 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. 10.901, Resource Conservation and Development Program—Pub. L. 87-703, 16 U.S.C. 590 a-f, q.)

Dated: March 5, 1979.

VICTOR H. BARRY, Jr.,
Deputy Administrator for Programs,

Soil Conservation Service.

[FR 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 Evnironmental 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, Harmon, 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 83-566, 16 U.S.C. 1001-1008.)

Dated: February 28, 1979.

VICTOR H. BARRY, Jr.,
Deputy Administrator for Programs.

[FR 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 CFR Part 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

Fourth Street, S.W., Huron, South Dakota 57350.

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.

(Catalog of Federal Domestic Assistance Program No. 10.904, Watershed Protection and Flood Prevention Program, Pub. L. 83-566, 16 U.S.C. 1001-1008).

Dated: February 27, 1979.

VICTOR H. BARRY, Jr.,
Deputy Administrator for Programs.

[FR Doc. 79-7223 Filed 3-8-79; 8:45 am]

[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 Meridan 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.

Dated at Washington, D.C., March 5, 1979.

JOHN I. BINKLEY,
Advisory Committee Management Officer.

[FR Doc. 79-7173 Filed 3-8-79; 8:45 am]

[6335-01-M]

NEBRASKA 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 Nebraska Advisory Committee (SAC) of the Commission will convene at 9:00 a.m. and will end at 2:00 p.m. on March 31, 1979, at the Western Nebraska Legal Services, 1724 Second Avenue, Scottsbluff, Nebraska 69361.

Persons wishing to attend this open meeting should contact the Committee Chairperson, or the Central States Regional Office of the Commission, 911 Walnut Street, Room 3103, Kansas City, Missouri 64106.

The purpose of this meeting is to review the provision of public agency services to Western Nebraska minority groups. The committee will also review the activity of staff and subcommittees.

This meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., March 5, 1979.

JOHN I. BINKLEY,
Advisory Committee Management Officer.

[FR Doc. 79-7174 Filed 3-8-79; 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 6:30 p.m. and will end at 8:30 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.

Dated at Washington, D.C., March 6, 1979.

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 provision 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.

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.

Dated at Washington, D.C., March 5, 1979.

JOHN I. BINKLEY,
Advisory Committee Management Officer.

[FR Doc. 79-7176 Filed 3-8-79; 8:45 am]

[6335-01-M]

WISCONSIN 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 Wisconsin Advisory Committee (SAC) of the Commission will convene at 6:30 p.m. and will end at 9:00 p.m. on April 2, 1979, in the Spanish Center, 614 W. National, Milwaukee, Wisconsin 51204.

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 prupose of this meeting is to discuss Vocational Education Study—of analysis of ethnic data, timetable projection for project.

This meeting will be conducted pursuant to the provisions of the Rules and Regulations of the Commission.

Dated at Washington, D.C., March 6, 1979.

JOHN I. BINKLEY,
Advisory Committee Management Officer.

[FR.Doc. 79-7177 Filed 3-8-79; 8:45 am]

[3510-25-M]

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

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 exporting, 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 Testiles
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.

[FR Doc. 79-7158 Filed 3-8-79; 8:45 am]

[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, 5401 West Kennedy Boulevard, Tampa, Florida.

FOR FURTHER INFORMATION CONTACT:

Wayne E. Swingle, Executive Director, Gulf of Mexico Fishery Management Council, Lincoln Center, Suite 881, 5401 West Kennedy Boulevard, Tampa, Florida 33609, Telephone: (813) 228-2815.

Dated: March 6, 1979.

WINFRED H. NEIBOHM,
Executive Director, National Marine Fisheries Service.

[FR Doc. 79-7228 Filed 3-8-79; 8:45 am]

[3510-22-M]

MID-ATLANTIC FISHERY MANAGEMENT COUNCIL

Public Meeting

AGENCY: National Marine Fisheries Service, NOAA.

SUMMARY: The Mid-Atlantic Fishery Management Council, established by Section 302 of the Fishery Conservation and Management Act of 1976 (Pub. L. 94-265), will meet to discuss: (1) surf clam/shark fishery management plans (FMPs); (2) status of FMPs; and (3) other Administrative matters.

DATES: The meeting will convene on Wednesday, April 11, 1979, at 1 p.m. and will adjourn on Friday, April 13, 1979, at approximately 1 p.m. The meeting is open to the public.

ADDRESS: The meeting will take place at the Best Western Airport Motel, Philadelphia International Airport, Philadelphia, Pennsylvania (215) 365-7000.

FOR FURTHER INFORMATION CONTACT:

John C. Bryson, Executive Director, Mid-Atlantic Fishery Management Council, North and New Streets, Room 2115, Federal Building, Dover, Delaware 19901, Telephone: (302) 674-2331.

Dated: March 6, 1979.

WINFRED H. MEIBOHM,
Executive Director, National Marine Fisheries Service.

[FR Doc. 79-7227 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."

2. Section B is modified by deleting Section B-6 and substituting a new Section B-6 as follows:

"6. This permit is valid with respect to the activities authorized herein until December 30, 1981."

This modification is effective on March 9, 1979.

The Permit, as modified, and documentation pertaining to the modification, is available for review in the following offices: Assistant Administrator for Fisheries, National Marine Fisheries Service, 3300 Whitehaven Street, N.W., Washington, D.C.; and Regional Director, National Marine Fisheries Service, Southwest Region, 300 South Ferry Street, Terminal Island, California, 90731.

February 28, 1979.

WINFRED H. MEIBOHM,
Associate Director
National Marine Fisheries Service.

[FR Doc. 79-7231 Filed 3-8-79; 8:45 am]

[3510-22-M]

NORTHWEST FISHERIES CENTER

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), the Scientific Research Permit No. 71 issued to the Northwest Fisheries Center, National Marine Fisheries Service, on January 21, 1975, as modified on October 6, 1975, is further modified as follows:

1. Section A-1 is modified by adding a new subsection c, as follows:

"c. Up to 10 Pacific harbor seals (*Phoca vitulina richardii*)."

2. Section A-3 is modified by deleting subsection b and substituting a new subsection b, as follows:

"b. Up to 10 Pacific harbor seals (*Phoca vitulina richardii*)."

This modification is effective on the date of publication of this Notice in the FEDERAL REGISTER and allows a take by capture, mark and release vice killing of 10 of the 20 animals authorized to be taken by killing.

The Permit, as modified, and documentation pertaining to the modification is available for review in the Office of the Assistant Administrator for Fisheries, National Marine Fisheries Service, 3300 Whitehaven Street, N.W., Washington, D.C.; Regional Director, National Marine Fisheries Service, Southwest Region, 300 South Ferry Street, Terminal Island, California, 90731; and Regional Director, National Marine Fisheries Service, Northwest Region, 1700 Westlake Avenue, North, Seattle, Washington, 98109.

Dated: February 26, 1979.

WINFRED H. MEIBOHM,
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 Accredit Laboratories Which 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 fees and 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 performed 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 45293).

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 $80" 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 "$160".

9. Page 3906, third column, nineteenth line under "Example Calculation". Replace "$2,095" with "$1,935".

Dated: February 28, 1979.

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, 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:

Closing of Patent and Trademark Office, Tuesday, February 20, 1979

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

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.

REVE D. TEGTMEYER,
Assistant Commissioner (Acting Commissioner of Patents and Trademarks

MARCH 6, 1979.

[FR Doc. 79-7216 Filed 3-8-79; 8:45 am]

[6820-33-M]

COMMITTEE FOR PURCHASE FROM THE BLIND AND OTHER SEVERELY HANDICAPPED

PROCUREMENT LIST 1979

Additions

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

SUPPLEMENTARY INFORMATION: On October 20, 1978 and December 22, 1978 the Committee for Purchase from the Blind and Other Severely Handicapped published notices (43 FR 49035 and 43 FR 59868) of proposed additions to Procurement List 1979, November 15, 1978 (43 FR 53151).

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 1979:

SIC 0782: Grounds Maintenance, Bldgs: M254, M311, M312, M317/318, M325, M339, M340, M495, Naval Air Station Miramar, San Diego, California.

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]

PROCUREMENT LIST 1979

Proposed Additions

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. 0815.
Class 7210: Mattress, Innerspring with Vinyl/Nylon Laminated Ticking.
Class 7530: Paper, Teletypewriter Roll, 7530-00-223-7966 (GSA Regions 1, 2, 3, 7, 8, 9, and 10).

Class 7910:

Pad, Floor Polishing Machine—
7910-00-685-6686
7910-00-685-6687
7910-00-685-3908
7910-00-685-6671
7910-00-685-3909
7910-00-685-6672
7910-00-685-3910
7910-00-685-4239
7910-00-685-4242
7910-00-685-4241
7910-00-685-4245
7910-00-685-6656
7910-00-685-6657
7910-00-685-3912
7910-00-685-6659
7910-00-685-3915
7910-00-685-6660
7910-00-685-3914
7910-00-685-4240
7910-00-685-4243
7910-00-685-4244
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.

ACTION: Notice of Meeting: Product Safety Advisory Council.

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 3:45 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 evaluation program and proposed policies concerning the appearance 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 who will make the presentation, the person, company, group or industry on whose behalf the presentation

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 Wm. 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 time, location and agenda of each task group meeting follows:

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 General Crude Oil Company's office, 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 study methodology to be employed by the Government Subcommittee and a review of assignments.

3. Discussion of the timetable of the Government Subcommittee.

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.

4. Discussion of any other matters pertinent to the overall assignment of 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 1992 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.

Issued at Washington, D.C., on March 5, 1979.

GEORGE S. MCISAAC,
Assistant Secretary for Resource Applications.

MARCH 5, 1979.

[FR Doc. 79-7145 Filed 3-8-79; 8:45 am]

[6450-01-M]

Office of Assistant Secretary for International Affairs

PEACEFUL USES OF ATOMIC ENERGY

Proposed 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 a proposed "subsequent arrangement" under the Additional Agreement Between 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 Government of the United States of America and the Governments of the Republic of Austria and Japan.

The subsequent arrangements to be carried out under the above mentioned agreement involves:

(1) Retransfer from West Germany to Austria, RTD/AT(EU)-51, 3.9g U, containing 3.5g U-235, .4g U-238, and 16.0g Thorium. Irradiated fuel spheres for destructive post-irradiation examination at Seibersdorf.

(2) Contract WC-EU-114, United States sale to Italy, 88.7g U, containing 2.1g U-235, and 20g U, containing .8g U-235, for use in the IAEA's Safeguards Analytical Laboratory Evaluation (SALE) program, in order to evaluate the capability of participating laboratories to analyze materials to be safeguarded in the nuclear fuel cycle and to provide the means by which measurement capability may be improved through the interchange of measurement technology.

(3) Contract S-JA-252, United States sale to Japan standard samples containing 175g normal Uranium in the form of Uranium Oxide for use in the calibration of equipment.

In accordance with section 131 of the Atomic Energy Act of 1954, as amended, it has been determined that these subsequent arrangements will not be inimical to the common defense and security.

This subsequent arrangement will take effect no sooner than March 26, 1979.

For the Department of Energy.

Dated: March 1, 1979.

HAROLD D. BENGELSDORF,
Director for Nuclear Affairs International Programs.

[FR Doc. 79-7166 Filed 3-8-79; 8:45 am]

[6450-01-M]

Office of Assistant Secretary for International Affairs

PEACEFUL USES OF ATOMIC ENERGY

Proposed 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 Government 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:

Contract No.	United States to	Description of material
S-BR-27	Brazil	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 crystallite dimensions at the Institueo de Energia Atomica, Sao Paulo, Brazil.
S-CA-263	Canada	20 mg of thorium enriched 80-99% in Th-230, for isotope dilution/mass spectometric 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.
S-CA-264	Canada	10 mg Plutonium oxide, enriched to 92.55% Pu-242 for trace analysis by isotope dilution technique for Atomic Energy of Canada, Ltd., at Whiteshell Nuclear Research Establishment, Pinawa, Canada.
S-CA-266	Canada	10 mg U-234 and 10 g 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.
S-CA-267	Canada	500 curies of tritium gas, to provide a triton beam at the McMaster University, FN Tandem Accelerator, at Ontario, Canada.
WC-CA-17	Canada	Five shipments, each containing .002 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.
MS-EU-330-97	Belgium	7.5 mg Uranium-238, with less than 1 ppm U-235, contained in 25 uranium-vanadium dosimeters, for dosimetry measurements in the BR-2 reactor.
S-EU-531	Belgium	200 mg Neptunium-237 contained in 25 vanadium dosimeters for measuring flux in the BR-2 reactor.
MS-EU-330-98	Belgium	42 mg Plutonium-239 contained in 25 vanadium dosimeters, 42 mg Uranium-235 contained in 25 vanadium dosimeters, and 275 mg Uranium-238 contained in 25 vanadium dosimeters, for measuring flux in the BR-2 reactor.
MS-EU-330-99	West Germany	113 mg Uranium-235 for use as target substance in the heavy ion accelerator UNILAC, Darmstadt, West Germany.
S-EU-538	West Germany	50 mg thorium enriched to greater than 83% in Th-230, and 100 mg Uranium enriched to greater than 99% U-234, for use as target material in nuclear spectroscopy studies at the 7-MV-Van de Graff accelerator at the Johann Wolfgang Goethe, Universitat.
S-JA-229	Japan	1 mg Uranium-236 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.
S-PO-4	Portugal	.1 microcuries Plutonium-236 for radiochemical determination of Pu-239 in the environment by electrodeposition technique at the Laboratorio de Fisica e Engenharia Nucleares at Sacavem, Portugal.

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. BENGELSDORF,
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) 283-3261.

SUPPLEMENTARY INFORMATION: The Economic Regulatory Administration has previously approved the short-term rates through March 31, 1979, 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.

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. 825s, relating to the Southeastern Power Administration (SEPA) were transferred to and vested in the Secretary of Energy. By Delegation Order No. 0204-33, effective January 1, 1979, 43 FR 60636 (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 on 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. The power proposed for sale to these municipal customers was 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. 89-00-1501-564) 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:

$56,000 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, 1979.

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 me on an interim basis and approval by the FERC on final basis. Therefore, SEPA has requested that I continue in effect on an interim basis the short-term rates previously approved by ERA to allow time to secure confirmation and approval of the long-term rates for Laurel Project power.

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. Those 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 18 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 herby 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]

[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), 358 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 whether the violation continued after December 6, 1978. 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.

Any aggrieved person 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. A Notice of Objection must be filed at the following address:

Office of Hearings and Appeals, Department of Energy, 2000 M Street, NW., Washington, DC 20461.

In addition, a copy of each filing must be submitted to the ERA Northeast Enforcement District office at the address set forth herein, and to:

Assistant General Counsel for Administrative Litigation, Office of General Counsel, Department of Energy, Room 7130, 12th & Pennsylvania Avenue, NW., Washington, DC 20461.

Issued this 6 day of March, 1979, in Washington, DC.

BARTON ISENBERG,
Assistant Administrator of Enforcement, Economic Regulatory Administration.

[FR Doc. 79-7190 Filed 3-8-79; 8:45 am]

[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(c)(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 refineries; 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 telex 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 refineries to which 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 hereby 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 9, 1979.

Issued in Washington, D.C. March 3, 1979.

BARTON R. HOUSE,
Assistant Administrator, Fuels Regulation, Economic Regulatory Administration.

The list of refiner-sellers for the period October 1, 1978, through March 31, 1979, is revised as follows. The list sets forth the identity of each refiner-seller, the fixed percentage share of each refiner-seller, and the volumes of crude oil that each such refiner-

seller 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.

Refiner-sellers	Share	Sales obligations (barrels)
Amoco Oil Co	0.099	867,533
Atlantic Richfield Co	.072	1,134,011
Chevron U.S.A., Inc	.096	3,201,817
Cities Service Co	.023	2,057,966
Continental Oil Co.[1]	.034	0
Exxon Co, U.S.A.[2]	.112	0
Getty Refining & Marketing Co	.020	127,632
Gulf Refining & Marketing Co	.085	1,065,486
Marathon Oil Co	.022	137,500
Mobile Oil Corp	.089	984,074
Phillips Petroleum Co	.039	248,914
Shell Oil Co	.107	747,826
Sun Co	.052	426,819
Texaco Inc	.107	1,056,819
Union Oil Co. of California	.043	1,411,620
Total sales		13,468,017

[1] Granted Exception Relief—FEE 1738.
[2] Granted Exception Relief—FEE 2349.

ALLOCATIONS LISTED IN BUY/SELL LIST PUBLISHED SEPT. 5, 1978—ELIGIBLE REFINERIES—OCTOBER 1978 TO MARCH 1979

REGULAR ALLOCATIONS

Refiner	Refinery location	Allocation (barrels)
Asamera Oil, Inc	Denver, Colo	175,208
Bi-Petro, Inc	Pana, Ill	0
Caribou Four Corners	Woods Cross, Utah	0
CRA-Farmland Industries, Inc	Scottsbluff, Nebr	0
CRA-Farmland Industries, Inc	Phillipsburg, Kans	0
Dow/Refinery	Bay City, Mich	446,902
Evangeline Refining Co	Jennings, La	0
Farmers Union Central Exchange	Laurel, Mont	1,296,657
Giant Industries	Bloomfield, N. Mex	0
Hunt Oil Co	Tuscaloosa, Ala	1,155,516
Kentucky Oil & Refining Co	Betsy Layne, Ky	4,807
Little America Refining Co	Sinclair, Wyo	0
Little America Refining Co	Casper, Wyo	24,762
Macmillan RF Oil Co	Norphlet, Ark	152,109
Marion Corp	Mobile, Ala	0
Mid-Tex Refining Corp	Hearne, Tex	0
Mount Airy	Mount Airy, La	0
Newhall Refining Co	Newhall, Calif	0
OKC Corp	Okmulgee, Okla	0
Pennzoil Co. (Atlas)	Shreveport, La	743,337
Plateau, Inc	Bloomfield, N. Mex	0
Plateau, Inc	Roosevelt, Utah	116,027
Pride Refining Co	Abilene, Tex	906,452
Somerset Refining Co	Somerset, Ky	0
Southern Union	Lovington, N. Mex	466,862
Southern Union	Monument, N. Mex	663,930
Southwestern Refining Co	La Barge, Wyo	1,748
Texas American Petrochemicals, Inc	West Branch, Mich	54,432
Thunderbird Resources (Westco)	Cut Bank, Mont	43,462
Thunderbird Resources (Westland)	Williston, N. Dak	0
Western Refining Co	Woods Cross, Utah	0
Wyoming Refining Co	Newcastle, Wyo	39,358
Total		6,292,117

ALLOCATIONS FOR NEWLY CONSTRUCTED AND EXPANDED REFINING CAPACITY AND REACTIVATED REFINERIES

Refiner	Refinery location	Estimated capacity (barrels/day)	Allocation (barrels)
Southernwest	La Barge, Wyo	1,000	45,500
Western Refining	Woods Cross, Utah	1,500	68,250
Plateau, Inc	Bloomfield, N. Mex	6,900	313,950
Total			427,700

ALLOCATIONS ADDED SINCE PUBLICATION OF SEPT. 5, 1978, ALLOCATION LIST

NEW CAPACITY ALLOCATIONS

Refiner	Refinery location	Allocation (barrels)	Date issued
Shepherd	Jennings, La	320,950	11/2/78

EMERGENCY SUPPLEMENTAL ALLOCATIONS

Mt. Airy	Mt. Airy, La	198,400	12/22/78
Gladieux	Fort Wayne, Ind	306,100	12/22/78
Rock Island	Rock Island, Ind	418,500	12/27/78
Southern Union	Lovington, N. Mex	499,200	12/22/78
Crystal	Carson City, Mich	118,900	12/29/78
Lakeside	Kalamazoo, Mich	68,300	12/29/78
Sigmor	Three Rivers, Tex	357,200	1/31/79
South Hampton	Silsbee, Tex	301,600	2/06/79
United Ref	Warren, Pa	697,000	2/07/79
Marion	Theodore, Ala	544,800	2/07/79
Hudson	Cushing, Okla	727,800	2/16/79
CRA	Coffeyville, Kans	707,250	2/21/79
Rock Island	Rock Island, Ind	723,100	2/21/79
Mt. Airy	Mt. Airy, La	312,700	2/16/79
Gladieux	Fort Wayne, Ind	151,900	2/16/79
Southern Union	Lovington, N. Mex	294,500	2/27/79
Total		6,427,250	

TOTAL ALLOCATIONS

	Barrels
Previously Published Regular Allocations	6,292,117
Previously Published New and Expanded Capacity Allocations	427,700
Additional Allocation for New Capacity	320,950
Emergency Supplemental Allocations	6,427,250
Total	13,468,017

[FR Doc. 79-7191 Filed 3-8-79; 8:45 am]

[6450-01-M]

Federal Energy Regulatory Commission

[Docket No. RP75-79]

LEHIGH PORTLAND CEMENT CO. V. FLORIDA GAS TRANSMISSION CO.

Availability of Preliminary Environmental Analysis

In the matter of Lehigh Portland Cement Company v. Florida Gas Transmission Company (Docket No. RP75-79).

Notice is given that on or about March 9, 1979, a preliminary environmental analysis prepared by the staff of the Federal Energy Regulatory Commission (FERC) was made available for public comment.

This analysis examines the environmental impact of alternative natural gas curtailment plans for the Florida Gas Transmission Company system (FGT) in Florida. FGT now operates under a four-priority curtailment plan (FGT 4) that curtails deliveries to customers depending on the type of contract: direct or indirect, firm or interruptible. In Order 467, the Commission issued a statement of policy that curtailment plans should be based on end uses of gas and not on type of contract service. Subsequently, Lehigh Portland Cement Company charged that FGT 4 was contrary to Order 467 and unfair.

In Opinion Nos. 807 (June 24, 1977) and 807-A (September 22, 1977), the Federal Power Commission found FGT 4 to be unjust, unreasonable, unduly discriminatory, and preferential and ordered that a hearing be held to determine a just, reasonable, nondiscriminatory, and nonpreferential curtailment plan based on end use. In addition, FGT was ordered to file a case-in-chief setting forth its views on curtailment. In November 1977, FGT filed, as its case-in-chief, an eight-priority curtailment plan (FGT 8). Thereafter, several other parties to this proceeding and the Commission staff offered their own plans and views on the Florida Gas proposal.

On November 8, 1978, the President signed into law the National Energy Act (NEA). The Natural Gas Policy Act (NGPA) is one part of NEA. Title IV of the NGPA establishes new curtailment policies and requires the Department of Energy and the FERC, in coordination with the Department of Agriculture, to issue rules implementing the new policies. As a result, on November 17, 1978, the Commission suspended the FGT and all other curtailment proceedings, pending issuance of new curtailment regulations.

The Commission staff is currently developing a more comprehensive format for environmental impact statements evaluating natural gas curtailment plans. The new format tracks the issues and effects of alternative curtailment proposals through the five specific factors required by the National Environmental Policy Act of 1969. The staff believes that it will expedite eventual preparation of the draft environmental impact statement in this proceeding to solicit public comments on the new format. 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.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 79-7146 Filed 3-8-79; 8:45 am]

[6450-01-M]

Office of Hearings and Appeals

PHILLIPS PUERTO RICO CORE, INC., ET AL.

Notice of Public Hearing

AGENCY: Department of Energy, Office of Hearings and Appeals.

ACTION: Notice of Hearing Regarding Report Filed by the Commonwealth of Puerto Rico Pursuant to a Decision and Order Issued by the Office of hearings and Appeals on October 17, 1978.

HEARING DATES: March 19 and March 20, 1979.

HEARING LOCATION: El Teatrito, Bureau of the Budget, 254 De La Cruz street, Corner Tetuan, San Juan, Puerto Rico 00904.

FOR FURTHER INFORMATION CONTACT:

Thomas L. Wieker, Deputy Director, Office of Hearings and Appeals, 2000 M street, N.W., Room 8014, Washington, D.C. 20461, (202) 254-9681.

SUMMARY: The Office of Hearings and Appeals of the Department of Energy (DOE) gives notice of a hearing to be held in Puerto Rico to receive comments with respect to a Report filed by the Commonwealth of Puerto Rico pursuant to a Decision and Order issued by the Office of Hearings and Appeals on October 17, 1978. That Decision was issued following the consideration of several Applications for Exception filed by firms operating refineries and petrochemical plants in Puerto Rico. *Phillips Puerto Rico Core, Inc., et al.*, 2 DOE Par. 81,106 (1978).

The Report which the Commonwealth of Puerto Rico filed on January 31, 1979 discusses the manner in which Puerto Rican firms have been implementing the relief approved. More importantly, however, the Report states that a number of very serious chronic problems still exist in the refining and petrochemical industry in Puerto Rico. Those problems, according to the Commonwealth, may place the continued operation of the refining and related petrochemical industry in jeopardy. In order to permit a full discussion to be conducted of the nature of these problems and their possible solutions, the Governor of the Commonwealth has requested that an immediate public hearing be convened in Puerto Rico. According to the Governor's statements, the need for an immediate hearing with respect to these matters has been accentuated by the impact of recent shortages and price increases of naptha. In response to the Governor's request, a hearing will be convened in San Juan, Puerto Rico, on march 19, and March 20, 1979.

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 Public Docket Room, Room B-120, 2000 M Street, N.W., Washington, D.C. 20461, between the hours of 1:00 p.m. and 5:00 p.m., e.d.t., Monday through Friday.

The Report filed by the Commonwealth of Puerto Rico and related documents are available in the Public Docket Room at the present time.

Any further procedural rules needed for the proper conduct of the hearing will be announced at the commencement of the hearing.

Issued in Washington, D.C., March 5, 1979.

MELVIN GOLDSTEIN,
Director,
Office of Hearings and Appeals.

[FR Doc. 79-7165 Filed 3-8-79; 8:45 am]

[6450-01-M]

Southwestern Power Administration

[Rate Order SWPA-1]

NOTICE OF ORDER CONFIRMING, APPROVING, AND PLACING INCREASED POWER RATES IN EFFECT ON AN INTERIM BASIS

AGENCY: Department of Energy, Southwestern Power Administration.

ACTION: Notice of Power Rate Order.

SUMMARY: The Assistant Secretary for Resource Application, under Delegation Order No. 0204-33, 43 FR 60636 (December 28, 1978), has developed, acting by and through the Administrator, Southwestern Power Administration, increased system power rates and power rates under the Aluminum Contract for the Southwestern Power Administration and has confirmed and approved these rates and placed them in effect on an interim basis. He has also submitted them to the Federal Energy Regulatory Commission for confirmation and approval on a final bases.

EFFECTIVE DATES: The effective dates for the increased rates on an interim basis are: April 1, 1979, for Rate Schedules P-3, F-2, F-3, E-2, IC-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, P.O. Drawer 1619, Tulsa, Oklahoma 74101 (918) 581-7529

John J. DiNucci, Office of Power Marketing Coordination, Resource Application, Department of Energy, 12th Street & Pennsylvania Avenue, NW. Washington, DC 20461 (202) 633-8380.

SUPPLEMENTARY INFORMATION: Rate Schedule P-3 for peaking power supersedes Rate Schedule P-2 (Revised). Rate Schedules F-2 (Integrated System) and F-3 (Oklahoma Utility Companies) for firm power supersedes 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(a) of that contract. Federal Power Commission confirmation of the present contract rate expired 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 rates 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 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. 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, 43 F.R. 60636 (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 on 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

Existing Rates

The rates that are the subject of this order supersede the following existing SWPA rates:

Existing rate	Effective
Rate Schedule F-1, Firm Power	Aug. 9, 1957.
Rate Schedule P-2 (Revised), Peaking Power.	June 1, 1970.
Rate Schedule EE, Excess Energy	Aug. 9, 1957.
Rate Schedule IC, Interruptible Capacity.	June 11, 1958.
Contract Rate in Section 2, Contract No. 14-02-001-864, Tex-La Electric Cooperative, Inc. (through TP&L).	June 4, 1968.
Contract Rates in Sections 1.05(A) and 1.06, Contract No. Ispa-514, Arkansas Power & Light Company/Reynolds Metals Company.	Jan. 1, 1974.

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.

Under Contract No. 14-02-001-864, executed in 1958, SWPA sold firm power and energy to the Tex-La Electric Cooperative, Inc. (Tex-La) under the F-1 Rate 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 borderline 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 (Aluminum 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, was confirmed and approved by the Federal Power Commission (FPC) on January 22, 1974, 51 FPC 338.

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 42 percent above 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.

Opportunities for public review and comment on tentative system power rates were announced by notice published in the Federal Register on April 19, 1978 (43 F.R. 16545), and by notices changing dates and extending the time for public comments on May 25, 1978 (43 F.R. 25865), and on August 17, 1978 (43 F.R. 36514). Two Public Information Forums were held on May 18 and June 22, 1978. Public Comment Forums were held on July 20 and August 24, 1978. The time for written comments ended September 13, 1978. During this five-month period, customers of SWPA and other interested parties studied the Current and Revised Power Repayment Studies, the Rate Design Study, and the Tentative Rate Schedules.

AP&L and Reynolds were formally notified on July 3, 1978, as prescribed in Section 1.05(A) of the Aluminum Contract, that the rates had been redetermined by the Assistant Secretary for Resource Applications and would be increased on January 1, 1979, at least to the maximum level allowed by the contract. They were also advised that the government, after completion of its investigation of legal and policy questions and completion of the system rates proceeding, may propose higher rates to them comparable to system rates for other SWPA customers.

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 1878, prepared after consideration of these comments, shows that in order to accomplish repayment, an increase in average annual revenues of $16.5 million, or 33 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 contfnued its examination of the assumptions made in the studies. In keeping with the intent of the Arkansas Electric Cooperative Corporation (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 14-02-0001-938 and 14-02-0001-1114, 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 continued operations under this contract and the other Arkco contract, a net increase in expected system revenues of $2.4 million occurs. This reduces by $2.4 million annually the required gross revenues needed in the rate increase.

REPLACEMENTS

A number of comments were directed to the major power replacement costs for hydro generation included in the Power Repayment Studies. These generally were, first, objections to the inclusion of replacement costs at all; second, questions of possible overlap between the replacement costs and operation and maintenance costs; and third, criticism that the estimates of replacement costs were too high.

In response to the first comment, it should be noted that federal power rates are required by law to be established on a repayment basis, that is, on a showing generally that annual operating costs will be recovered in the year in which they are incurred and that all investment will be amortized within a reasonable period of years, which has been determined to be fifty years in most cases. This requires an analysis of future revenues and costs—in this case to the year 2030—as well as historical revenues and costs. The inclusion of future replacement costs in such repayment studies is necessary and proper, as has long been recognized by the Federal Power Commission and the Secretary of the Interior.

The second and third comments on the treatment of replacements in the SWPA study appear to have some merit. A complete answer would require a project-by-project study by the Corps of Engineers to determine the replacements which have been made in the past and to estimate the replacements that will be required in the future and their expected cost. A study of this magnitude would take several years. However, the Corps has made a study of the Sam Rayburn Dam Project, an isolated project that is not included in the integrated system. This study showed that SWPA's estimates of future power production replacements for the project could be reduced by about 35 percent. This study is accepted as representative of results expected from a system study, and the SWPA estimates of future replacement costs for the integrated system have been reduced by the same percentage. This decision reduces by about $1.2 million annually the required gross revenues needed in the rate increase.

ALUMINUM CONTRACT

The Aluminum Contract was negotiated in 1951 from a war-time need for aluminum and to assist in developing the industrial economy in the Southwest. Final negotiations were handled in the Office of the Secretary of the Interior and the contract was executed on January 29, 1952. The term of the contract is 30 years from the date service commenced on January 1, 1954.

Under the agreement, SWPA sells 150,000 kilowatts and 30,000,000 kilowatt-hours per month (2400 kilowatthours per kilowatt per year) of peaking power and energy to AP&L. AP&L, in turn, sells 110,000 kilowatts at a high load factor to Reynolds at its aluminum reduction plant at Arkadelphia, Arkansas. SWPA may also sell secondary energy to AP&L.

The original rate provisions in the contract were disapproved by the Federal Power Commission. After further contractual negotiations, revised rate provisions in Supplement No. 6, dated April 24, 1952, were approved by the Commission on April 28, 1952. Under this revision, the initial rate was 6 mills per kilowatthour for the first 22,000,000 kilowatthours per month and 3 mills per kilowatthour for the remaining 8,000,000 kilowatthours per month. This rate could be revised and redetermined every five years by the Secretary subject to the approval of the Commission, but could not exceed maximum limits stated in the contract for each five-year period. The contract limit for the last five years, from January 1, 1979, to December 31, 1983, is 122½ percent of the initial rate.

The rates under the contract have been raised every five years to the maximum allowed by the contract. However, these rates have always been less than comparable rates paid by customers purchasing power from the integrated system under system rate schedules. The annual shortfall or deficiency in comparable revenues for the basic 30,000,000 kilowatt-hours per month during the first twenty-five years of the contract varied between approximately $550,000 and $910,000.

The December 1977 Power Repayment Studies assumed that the rate under the Aluminum Contract for the last five-year period, 1979 through 1983, would be set at the maximum allowable under the contract, that is, 122½ percent of the initial base rate. This would yield revenues of approximately $2,300,000 per year. This is about $2,100,000 per year less than the revenues this amount of power and energy would produce under the P-3 Rate Schedule now under consideration.

The proposed treatment of the Aluminum Contract in the power repayment studies received a great deal of criticism from the other customers during the comment period. They argued that it was unfair, discriminatory, and illegal to ask them to make up the past, present, and future deficiencies attributable to the contract.

AP&L and Reynolds, on the other hand, defended the contract as a legally binding commitment that was justified in the interest of national defense. They claim that AP&L purchases only hydroelectric power and takes delivery from the dams and, therefore, is not responsible for SWPA transmission costs, and should not be charged for the cost of punchased 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 mulitiple 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 122½ 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&L to pay for power received during the last five years of the contract at the same rates 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 2030, when the integrated system 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 by future power 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, which was furnished to the 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 covered 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 purchases required 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.

TRUMAN PROJECT

The Harry S. Turman Dam is now under construction by the Corps of Engineers in Missouri. The Corps now estimates that the first of the six 26,677 kilowatt generating units will be in service in October 1979. SWPA is proceeding with plans to construct a 30-mile line from the dam to the SWPA substation at Clinton, Missouri, and is engaged in negotiations with the Associated Electric Cooperative of Missouri concerning further integration arrangements.

Because the project is expected to be in service within the five-year cost evaluation period under the Departmental Manual (DOI 730 DM 4, DOE IMD 1701), the project is included in the Power Repayment Studies, and the study period is extended to the year 2030, which is the 50th year after the full six units will be in service. A number of customers objected to this treatment of the project because it allegedly results in their having to start paying for the project before it is in service.

Inclusion of the project in the study is permitted under the Departmental Manual and is quite proper under the repayment method of ratesetting. Its inclusion extends the study period seven years, during which time revenues from the other projects, which will have been paid out, are available to assist in repaying Truman project costs.

An analysis of repayment studies with and without the Truman project shows that the inclusion of the project requires about a $1.6 million increase in net revenue requirements per year. This figures out at about 10 cents per kilowatt per month. In the interest of ameliorating the impact of the required rate increase on the SWPA customers, the capacity charge will be reduced 10 cents per kilowatt per month until the Truman project is in service.

Questions also were raised about the marketing and integration arrangements for the project and the resulting assumptions as to total project costs. Inasmuch as the details of possible contractural arrangements cannot be determined at this time the estimates of future transmission costs are based upon the assumptions of federal construction of all necessary lines and related facilities.

RATE DESIGN

The present F-1 Rate Schedule for firm power (load factor service), which has been in existence since 1957, includes a capacity charge of $1.60 per kilowatt per month, and increasing block energy charges of 2 mills per kilowatt-hour for the first 150 kilowatt-hours per kilowatt per month, 3 mills for the next 290 kilowatt-hours,

and 5 mills for all kilowatt-hours over 440 per month. A 40 cents per kilowatt per month discount on the capacity 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 directly connected to such 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 F-2 and F-3 supersede Rate Schedule F-1 for firm power service. The F-2 rate adopts the adder principal for transmission and transformation voltage differences, 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 per month. The F-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 F-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 also are separately-stated charges for transformation to load center delivery which SWPA also must pay. All the customers served by the companies under these arrangements receive load center service; the customers pay SWPA the load center firm rate (Rate Schedule F-3). and SWPA 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 per year. The capacity charge is $1.20 per kilowatt per month and the energy charged is 2 mills per kilwatt-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 ($55,700 annually).

Rate Schedule P-3 supersedes Rate Schedule P-2 (Revised). The transmission Service Charge is retained pending the successful completion of negotiations with the Associated Electric Cooperative of 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 change 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 290 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 also 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 150 and the second block applies to the next 340 hours use per kilowatt per month instead of 290. 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 purchases that 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 guaranteeing 1800 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&L), has been increased to equal the costs to SWPA for service from the Texas Power and Light Company (TP&L) to Tex-La for the account of SWPA. TP&L buys power and energy from SWPA at the system peaking rate. When this rate is increased by SWPA, then TP&L must increase the rate it charges SWPA to serve Tex-La. SWPA in turn, to recover costs, must increase its contract rate to Tex-La.

Section 1.05(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 pay 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).

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 limitation 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 in service 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 product an additional $14.9 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:

Rate	Rate superseded
Rate Schedule P-3, Peaking Power.	P-2 (Revised), Peaking Power.
Rate Schedule F-2, Firm Power from Integrated System.	F-1, Firm Power.
Rate Schedule F-2, Firm Power through Oklahoma Utility Companies.	F-1, Firm Power.
Rate Schedule EE-2, Excess Energy.	EE, Excess Energy.
Rate Schedule IC-2, Interruptible Capacity.	IC, Interruptible Capacity.
Contract No. 14-02-001-864, Section 2, Tex-La Electric Cooperative (through TP&L).	Contract No. 14-02-001-864, Section 2, Tex-La Electric Cooperative (through TP&L).

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. Ispa-514, Arkansas Power and Light Company/Reynolds Metals Company (Aluminum Contract), to 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. MCISAAC,
Assistant Secretary, Resource Applications.

RATE SCHEDULE P-3 [1].—Wholesale Rates for Hydro Peaking Power and Seasonal Peaking Power

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 Hydro and/or Seasonal Peaking Power and Peaking Energy.

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 HYDRO AND/OR SEASONAL PEAKING POWER

Peaking energy. A minimum of 1,200 kilowatt-hours of Peaking Energy per kilowatt of Hydro Peaking and/or Seasonal Peaking Power will be furnished during each contract year.

Supplemental peaking energy. Supplemental Peaking Energy (in addition to Peaking Energy) will be furnished if and when determined by SWPA to be available.

A quantity of Hydro and/or Seasonal Peaking Power without associated Peaking Energy may be purchased on a month-to-month basis for use in scheduling Supplemental Peaking Energy, if determined by SWPA to be available.

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.

(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:

$1.40 per kilowatt of Peaking Billing Demand for delivery at 138 or 161 kilovolts.

ENERGY CHARGE

(a) Peaking Energy:

(i) $0.0035 per kilowatt-hour for the first 1,200 kilowatt-hours per kilowatt per year accumulated as scheduled each month.

(ii) $0.007 per kilowatt-hour for energy in excess of the first 1,200 kilowatt-hours per kilowatt per year accumulated as scheduled each month.

(b) Supplemental Peaking Energy: $0.0035 per kilowatt-hour of Supplemental Peaking Energy.

Capacity charge adjustments for conditions of service. (a) A charge of $0.20 per month per kilowatt of Peaking Billing Demand will be added to the total monthly charge for Hydro and/or Seasonal Peaking Power service if delivery of such power and energy is made at 69 kilovolts, or

(b) A charge of $0.55 per month per kilowatt of Peaking Billing Demand will be added to the total monthly charge for Hydro and/or Seasonal Peaking Power service if delivery of such power and energy is made at low or intermediate voltages (less than 69 kilovolts), and

(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.

Billing for unauthorized overrun. For each billing period during which there is a violation involving an unauthorized overrun of SWPA's capacity and/or energy obligation, such capacity overrun shall be billed and paid for at twelve times the above capacity rate adjusted for conditions of service and such energy overrun shall be billed and paid for at eleven times the rate for Peaking Energy set forth in (a)(ii), above.

Transmission service charge. Where transmission service is provided through facilities

[1] Supersedes Rate Schedule P-2 (Revised).

of others beyond the SWPA-owned 138-161 kv transmission system and SWPA incurs costs therefor the customer shall pay, in addition to the capacity and energy charges, a separate transmission service charge each month equal to one-twelfth of the estimated total annual cost to SWPA of providing such transmission service. The amount of such total annual cost shall be computed and determined by SWPA, and a memorandum copy of each determination shall be attached to and become a part of the customer's contract.

Minimum bill. The minimum bill each month is the Peaking Contract Demand times the Capacity Charge adjusted for conditions of service, plus minimum contract energy requirements, plus the Transmission Service Charge, if any.

Peaking actual demand. The term "Peaking Actual Demand" for any month means the maximum rate in kilowatts that electric energy is delivered by SWPA to the customer during any 60-minute period of such month.

Peaking contract demand. The term "Peaking Contract Demand" means the maximum rate in kilowatts which SWPA is, by contract, obligated to deliver Peaking Energy during any 60-minute period of any month.

Peaking billing demand. Except as otherwise provided by contract, the "Peaking Billing Demand" each month means the "Peaking Contract Demand."

Adjustment for reduction in service. If during any month the quantity of Hydro 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—

$$R=\frac{C\times K\times H}{100}$$

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 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 Firm Power and Firm Energy at points of delivery from the transmission lines or 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 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 (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 such quantities as the customer requires to fulfill its system load requirements.

2. SWPA will during each billing period furnish Firm Energy to a customer which has an alternative source of power supply and/or which purchases peaking power and energy from SWPA, in such manner as to parallel the load factor and load pattern of such customer's system load. The quantity of Firm Energy during each billing period shall be computed under the formula—

$$FE=\frac{FCD\times E_1}{MAD}$$

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 Firm Billing Demand for delivery at 138 or 161 kilovolts.

(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:$1.40 per kilowatt of Firm Billing Demand for delivery at 138 or 161 kilovolts.

ENERGY CHARGE

(i) $0.0035 per kilowatt-hour for the first 100 kilowatt-hours per kilowatt of Firm Billing Demand.

(ii) $0.007 per kilowatt-hour for the next 340 kilowatt-hours per kilowatt of Firm Billing Demand.

(iii) $0.014 per kilowatt-hour for energy in excess of the first 440 kilowatt-hours per kilowatt of Firm Billing Demand.

Capacity charge adjustments for conditions of service. (a) A charge of $0.20 per month per kilowatt of Firm Billing Demand will be added to the total monthly charge for Firm Power service if delivery of such power and energy is made at 69 kilovolts, or

(b) A charge of $0.55 per month per kilowatt of Firm Billing Demand will be added to the total monthly charge for Firm Power service if delivery of such power and energy is made at low or intermediate voltages (less than 69 kilovolts), and

(c) A customer which receives Firm Power and Firm Energy 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 Firm Billing Demand which exceed the Firm Actual Demand recorded at the lower voltage for a particular month or for the preceding eleven months.

Billing for unauthorized overrun. For each billing period in which there is a violation involving an unauthorized overrun of SWPA's capacity and/or energy obligation, such capacity overrun shall be billed and paid for at eleven times the above capacity rate adjusted for conditions of service, and such energy overrun shall be billed and paid for at eleven times the rate set forth in (ii), above.

Reimbursement for purchased energy. Where SWPA must purchase energy from another supplier specifically for the purpose of fulfilling the firm requirements of a particular customer, and the kilowatt-hours and the price of each kwh of such purchases can be determined, such customer will reimburse SWPA for such energy at the following monthly rate:

The dollars per kwh for each kwh of such purchased energy delivered to the customer, less $0.007 per kwh of all energy purchased by the customer, if any, in the second step of the energy charge stated above and less $0.014 per kwh of all energy purchased by the customer, if any, in the third step of the energy charge stated above.

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 determined at intervals or continuously at the option of SWPA and will be based upon measured quantities of kilowatt-hours and reactive kilovolt-ampere-hours during the 30-minute period of the customer's maximum rate of use of energy at each particular point of delivery during the month.

The average power factor during any month shall be computed under the formula—

$$APF=\frac{KWH\times 100}{KWH^2+RKVAH^2}$$

with the factors defined as follows:

APF=the average power factor (in percentage) during any 30-minute period during any particular month.

KWH=the quantity of Energy delivered during the 30-minute period of the customer's maximum rate of use of energy at a particular point of delivery during such month.

RKVAH=the quantity of reactive kilovolt-ampere-hours (lagging) furnished at such particular point of delivery coincidental with factor KWH during the month.

For each 1 percent (1%), or major fraction thereof, by which the customer's average power factor is less than 95 percent, the customer's monthly bill for Firm Power and Firm Energy will be increased by 1 percent (1%). No adjustment for power factor under this provision shall be made for a period ending nine months after enactment of this rate schedule.

Minimum bill. The minimum bill each month shall be the Firm Contract Demand times the Capacity Charge adjusted for conditions of service.

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 maximum 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 any 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—

$$R=\frac{C\times K\times H}{TH}$$

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 times the Firm Contract Demand.
C=the capacity charges plus applicable adjustments for conditions of service for Firm Power for such month.
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 F-S[2].—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 Application 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 and Oklahoma.

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 Companies have contracted with SWPA to deliver power and energy for the account of 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 in SWPA-Customer Contract (Contract Demand). All power requirements which exceed the 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 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.

2. Where a customer has an alternative source of power supply, SWPA shall furnish each month the number of kilowatt-hours of Firm Energy as specified in the SWPA-Customer Contract.

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: $1.85 per kilowatt of Billing Demand.

(b) Commencing on the first day of the month following the date the first power generationg unit at the Harry S. Truman Dam is placed in commercial operation in 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 as defined and computed under the SWPA-Customer Contract.

For each 1 percent (1%), or major fraction thereof, by which the customer's 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 Demnd" for any month during the period when the system load requirements of the customers 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 from SWPA and from 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 ammount computed under the formula—

$$R=\frac{C\times K\times H}{TH}$$

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 Firm Contract Demand.
C=the capacity charges for such month.
K=the number of kilowatts of such particular reduction in Firm Power.
TH=the total number of hours in such month.

Rate Schedule EE-2*.—Wholesale Rate 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 EE-2

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[3]—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

[2]Supersedes Rate Schedule F-1 for customers receiving Firm Power and Firm Energy from transmission facilities owned by the Oklahoma Utility Companies.

[3]Supersedes Rate Schedule IC.

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.

Interruptible billing demand. The term "Interruptible 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, if the customer scheduled and received only interruptible capacity from the Government during such day, or

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 firm or peaking power capacity from the Government during such day, or 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, returned 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 TEX-LA ELECTRIC COOPERATIVE, INC. (CONTRACT NO. 14-02-001-864)[1]

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. 14-02-001-864, between Southwestern Power Administration (Government) and Tex-La Electric Cooperative, Inc. (Tex-La).

Capacity and Energy Charges: Sections 2, 3, and 35, respectively, of Contract No. 14-02-001-864, are amended to read as follows:

"Section 2. *Compensation 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 twentieth 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 intergrated 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 twentieth 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

(i) $0.00309 per kilowatt-hour for the first 100 kilowatt-hours per kilowatt per month of 'Billing Demand'.

(ii) $0.00459 per kilowatt-hour for the next 340 kilowatt-hours per kilowatt 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 kilowatt 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 highest Factor 'A' 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—

$$FE=\frac{FD \times TE}{D}$$

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."

[FR Doc. 79-7169 Filed 3-8-79; 8:45 am]

[1]Marked "Rate Schedule 14-02-001-864" for reference purposes only; not so designated in proceedings before the Federal Power Commission.

[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.

Board of Governors of the Federal Reserve System, March 2, 1979.

THEODORE E. ALLISON,
Secretary of the Board.

[FR 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)(8) of the Bank Holding Company Act (12 U.S.C. § 1843(c)(8)) 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 been determined 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 94120:

FIRST BANCORPORATION, Salt Lake City, Utah (industrial loan and insurance activities; Utah): to engage, through its subsidiary, Foothill Thrift and Loan, in the industrial 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.

Board of Governors of the Federal Reserve System, March 2, 1979.

THEODORE E. ALLISON,
Secretary of the Board.

[FR Doc. 79-7128 Filed 3-8-79; 8:45 am]

[6210-01-M]

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 National 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.

Board of Governors of the Federal Reserve System, March 5, 1979.

THEODORE E. ALLISON,
Secretary of the Board.

[FR Doc. 79-7129 Filed 3-8-79; 8:45 am]

[6210-01-M]

FIRST BUSEY CORP.

Formation of Bank Holding Company

First Busey Corporation, Urbana, Illinois, 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 100 percent or more of the voting shares (less directors' qualifying shares) of Busey First National Bank, Urbana, Illinois. 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 Chicago. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 to be received no later than April 12, 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.

Board of Governors of the Federal Reserve System, March 2, 1979.

THEODORE E. ALLISON,
Secretary of the Board.

[FR Doc. 79-7130 Filed 3-8-79; 8:45 am]

[6210-01-M]

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 per cent or more of the voting shares (less directors' qualifying shares) of First National Bank in Clayton, Clayton, New Mexico. 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 pursuant to section 225.4(a)(9)(ii)(a) of the Board's Regulation Y (12 CFR § 225.4(a)(9)(ii)(a)) of property and casualty insurance that is directly related to extensions of credit originated by its subsidiary bank and in the sale pursuant to section 225.4(a)(9)(i) of the Board's Regulation Y (12 CFR § 225.4(a)(9)(i)) of insurance for its banking subsidiary. These activities would be performed from offices of bank at 201 Main Street, Clayton, New Mexico, and the geographic area to be served is Clayton, New Mexico and its surrounding communities, western portions of Cimmaron County, Oklahoma and Dallam County, Texas. 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 interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

The application may be inspected at the offices of the Board of Governors

or at the Federal Reserve Bank of 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.

Board of Governors of the Federal Reserve System, March 1, 1979.

THEODORE E. ALLISON,
Secretary of the Board.

[FR Doc. 79-7131 Filed 3-8-79; 8:45 am]

[6210-01-M]

MAINLAND BANCSHARES, INC.

Formation of Bank Holding Company

Mainland Bancshores, 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 Secretary, Board of Governors of the Federal Reserve System Washington, D.C. 20551 to be received no later than April 1, 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.

Board of Governors of the Federal Reserve System, March 1, 1979.

THEODORE E. ALLISON,
Secretary of the Board.

[FR Doc. 79-7132 Filed 3-8-79; 8:45 am]

[6210-01-M]

MULESHOE BANCSHARES, INC.

Formation of Bank Holding Company

Mulshoe Bancshares, Inc. Muleshoe, 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 National Bank of Muleshoe, Muleshoe, 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 shold 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.

Board of Governors of the Federal Reserve System, March 2, 1979.

THEODORE E. ALLISON,
Secretary of the Board.

[FR Doc. 79-7133 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, Ariz.

Tennessee Valley Bancorp, Inc., Nashville, Tennessee, has 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 expand the insurance underwriting 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 interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of 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.

Board of Governors of the Federal Reserve System, March 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.

Board of Governors of the Federal Reserve System, March 1, 1979.

THEODORE E. ALLISON,
Secretary of the Board.

[FR Doc. 79-7135 Filed 3-8-79; 8:45 am]

[4110-03-M]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

FERTILITY AND MATERNAL HEALTH DRUGS ADVISORY COMMITTEE

Meeting Cancellation

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Fertility and Maternal Health Drugs Advisory Committee meeting scheduled for March 16, 1979 and announced by notice in the FEDERAL REGISTER of February 16, 1979 (44 FR 10128), has been canceled.

FOR FURTHER INFORMATION CONTACT:

A. T. Gregoire, Bureau of Drugs (HFD-130), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3520.

Dated: March 1, 1979.

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

[FR Doc. 79-7022 Filed 3-8-79; 8:45 am]

[4110-03-M]

[Docket No. 78N-0269]

PENNWALT CORP., ET AL.

New Drug Applications; Withdrawal of Approval

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 42 new drug applications and 1 abbreviated new drug application on the grounds that the applicants failed to submit annual reports, as required under the Federal Food, Drug, and Cosmetic Act, and that they waived their opportunities for hearings. The drug products affected by this withdrawal are no longer marketed.

EFFECTIVE DATE: March 19, 1979.

FOR FURTHER INFORMATION CONTACT:

Herbert Behrens, Bureau of Drugs (HFD-105), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4320.

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.

NDA No.	Drug name	Applicant's name and address
3-265	Metropine	Pennwalt Corp., P.O. Box 1710, Rochester, NY 14603.
4-298	Metropine with Phenobarbital	Do.
5-307	Mercuhydrin	Merrell-National Labs., Division of Richardson-Merrell, Cincinnati, OH 45215.
5-616	Liquid Germicidal Detergent	Parke, Davis & Co., Box 118-GPO, Detroit, MI 48232.
6-305	Methadone Hydrochloride	Merck Sharp & Dohme, Division of Merck & Co., Inc., West Point, PA 19486.
6-311	Methadone Hydrochloride	The Upjohn Co., 7171 Portage Rd., Kalamazoo, MI 49002.
8-066	Unacaine HCl Solution	Novocol Chemical Mfg. Co., Inc., 2911-23 Atlantic Ave., Brooklyn, NY 11207.
8-447	Sodium Phosphate P-32	Abbott Laboratories, North Chicago, IL 60064.
8-494	Malcotran	Pennwalt Corp.
8-724	Sodium Sulfacetamide Ophthalmic Ointment	ICN Pharmaceuticals, Inc., 5040 Lester Rd., Cincinnati, OH 45213.
9-211	Neomersyl	The Central Pharmacal Co., 112-128 East Third St., Seymour, IN 47274.
9-510	Aurcoloid-198	Abbott Laboratories.
9-513	Cortisone Acetate	Rexall Drug Co., 3901 North Kingshighway, St. Louis, MO 63115.
9-758	Reserpine	Morton Pharmaceuticals, 1625-39 North Highland, Memphis, TN 38108.
9-769	Bubartal Sodium	Philips Roxane Laboratories, 330 Oak St., Columbus, OH 43216.
9-868	Blockain HCl 0.5%	Sterling Drug Inc., 90 Park Ave., New York, NY 10016.
9-912	Rauw-Tina	Walker, Corp. & Co., Inc., P.O. Drawer 1320, Syracuse, NY 13201.
9-919	Rachromate 51	Abbott Laboratories.
11-313	Niacin	Merrell-National Labs.
11-999	Gastrix	Rowell Laboratories, Inc., 210 Main Street West, Baudette, MN 56623.
12-416	Stedytab Delfetamine	Eastern Research Laboratories, Inc., 302 South Central Ave., Baltimore, MD 21202.
12-529	Metranil Duracap	Meyer Laboratories, 1900 West Commercial Blvd., Ft. Lauderdale, FL 33309.
12-645	Edtac	Star Dental Mfg. Co., Inc., Ford Bridge Rd., Conshohocken, PA 19428.
12-729	Chymotest	Chromalloy Pharmaceuticals Inc., 12741 Capital Ave., Oak Park, MI 48237.
12-737	Wilpo	Dorsey Laboratories, Box 83288, Lincoln, NB 68501.
14-084	Racobalamin-57	Abbott Laboratories.
14-714	Thiaretic	Bluline Laboratories, Inc., 302 South Broadway, St. Louis, MO 63102.
16-136	Carbocaine HCl 4%	Sterling Drug, Inc.
16-274	Hippuran-131	Abbott Laboratories.
16-436	Vasitol	Rowell Laboratories, Inc.
16-498	Pentaerythritol tetranitrate	Arnar-Stone Laboratories, Inc., 601 East Kensington Rd., Mount Prospect, IL 60056.
16-507	Covap	Bluline Laboratories, Inc.
16-646	Chlormerodrin Hg 203	Mallinckrodt, Inc., P.O. Box 5840, St. Louis MO 63134.
16-825	Pertscan-99m	Abbott Laboratories.
16-855	Pentaerythritol tetranitrate	Philips Roxane Laboratories, Inc.
17-026	Technetium Tc 99m	Mallinckrodt, Inc.
17-121	Sodium Pertechnetate Tc 99m	Do.
17-259	Chromic Phosphate P32	Abbott Laboratories.
17-260	Stronscan-85	Do.
17-470	Mektec 99 Automatic Liquid Extractor	Allergan Pharmaceuticals, Inc., 2525 Dupont Drive, Irvine, CA 92713.
17-839	Macrosan-131	Abbott Laboratories.
17-841	Risa-131H	Do.
80-233	Cortisone Acetate	Rexall Drug Co.

Therefore, under the Federal Food, Drug, and Cosmetic Act (Sec. 505(e), 76 Stat. 782 as amended (21 U.S.C. 355(e))), and under authority delegated to the Director of the Bureau of Drugs (21 CFR 5.82), 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 §§ 310.300 or 310.302 (e) and (f) of the new drug regulations (21 CFR 310.300 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 ascorbates 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 9, 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:

Corbin I. Miles, Bureau of Foods (HFF-335), Food and Drugs Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-472-4750.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of July 26, 1973 (38 FR 20053), the Commissioner of Food and Drugs issued a notice advising the public that an opportunity would be provided for oral presentation 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 (copper gluconate and cuprous 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 26, 1973 (38 FR 20051, 20053), 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 increase 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 ingredients, 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:

Substance	Select committee tentative conclusion	Scientific literature review (order No.; price code; price)	Animal study report (order No.; price code; price)	Other information (order No.; price code; price)
Ascorbates:				
L-Ascorbic acid	1	PB-241-969/AS (ascorbic acid); A-18; $13.25..	1. Teratological evaluation of FDA 71-65 (ascorbic acid) in mice and rats, by Food and Drug Research Labs., Inc., under FDA contract (PB-245-518/AS); A03; $4.50.	1. Human intake data taken from "A Comprehensive Survey of Industry on the Use of Food Chemicals Generally. Recognized as Safe (GRAS)," available from the National Technical Information Service, PB-221-920 (set); E-99; $173.00
Sodium L-ascorbate	1			
Calcium L-ascorbate	1			
Ascorbyl palmitate (Palmitoyl L-ascorbate).	1	PB-223-866/AS (ascorbates); A06; $6.50..	2. Teratological evaluation of FDA 71-68 (sodium erythorbate) in mice and rats, by Food and Drug Research Labs., Inc., under FDA contract (PB-245-531/as); A03; $4.50.	2. Toxicity and teratogenicity studies in ascorbic acid; submitted by the University of Arizona.
Erythorbic acid (D-isoscorbic acid)	2			
Sodium erythorbate(Sodium D-isoascorbate).	2			

Substance	Select committee tentative conclusion	Scientific literature review (order No.; price code; price)	Animal study report (order No.; price code; price)	Other information (order No.; price code; price)
			3. Mutagenic evaluation (Tier I) of compound FDA 71-65 (ascorbic acid), by Litton Bionetics, Inc., under FDA contract (PB-245-491/AS); A03; $4.50.	3. Investigations on the toxic and teratogenic effects of GRAS substances on the developing chick embryo: [Sodium ascorbate]; submitted by Ohio State.
			4. Mutagenic evaluation (Tier I) of compound FDA 71-66 (erythorbic acid USP, FCC), by Litton Bionetics, Inc., under FDA contract (PB-245-437/AS); A03; $4.50..	4. Investigations on the toxic and teratogenic effects of GRAS substances on the developing chick embryo: [sodium erythorbate]; submitted by Ohio State.
			5. Mutagenic evaluation (Tier I) of compound FDA 75-64 (sodium ascorbate USP, FCC) by Litton Bionetics, Inc., under FDA contract (PB-279-262/AS); A04; $5.25.	5. Investigations of the toxic and teratogenic effects of GRAS substances to the developing chicken embryo: calcium ascorbate; FDA in-house investigation.
			6. Mutagenic evaluation (Tier I) of compound FDA 75-63 (calcium ascorbate FCC) by Litton Bionetics, Inc., under FDA contract (PB-279-261/AS); A04; $5.25.	6. Investigations of the toxic and teratogenic effects of GRAS substances to the developing chick embryo: Erythorbic acid; submitted by St. Louis University School of Medicine.
				7. Study of mutagenic effects of sodium erythorbate (No. 71-68); submitted by Stanford Research Institute.
				8. Letter dated February 17, 1960 to Pfizer and Co., New York.
				9. Letter dated October 13, 1961 to G. Stanley, New Hampshire.
				10. Memorandum dated November 4, 1977 to S. Foman.
				11. Comparison of metabolism of ascorbic acid and isoascorbic acid; FPC No. 0317; Merck Institute of Therapeutic Research.
				12. Absorption of L-ascorbate across membrane vesicles from guinea pig small intestine and renal cortex; inhibition by D-erythorbate (D-isoascorbate); 1978; *Biochimica et Biophysica Acta;* (in press).
				13. Steady-state turnover body pool of ascorbic acid in man; 1978; *American Journal of Clinical Nutrition;* (in press).
Copper salts:				
Direct food in use:				
Copper gluconate	1	PB-241-961/AS; A05; $6.00. .	1. Mutagenic evaluation (Tier I) of compound FDA 71-62 (copper gluconate) by Litton Bionetics, Inc., (PB-245-490/AS); A03; $4.50..	1. Human intake data taken from "A Comprehensive Survey of Industry on the Use of Good Chemicals Generally Recognized as Safe (GRAS)," available from the National Technical Information Service, PB-221-920 (set); E-99; $173.00.
Cuprous iodide	1	PB-275-749/AS; A03; $4.50...		
Copper sulfate	1			
Food packaging materials:				
Copper sulfate	1		2. Mutagenic evaluation (Tier I) of FDA 75-70, (cuprous iodide technical by Litton Bionetics, Inc., (PB-279-263/AS); A04; $5.25..	2. Letter dated October 29, 1976, with attachments to G. W. Irving, M.D.
				3. Letter dated June 28, 1978 to F. R. Senti, M.D.
				4. Memorandum dated September 12, 1978 from H. I. Chinn.
				5. One year chronic oral toxicity of copper gluconate W10219A in beagle dogs; research report No. 955-0353; Warner-Lambert Research Institute.
				6. Teratological and embryotoxicity study of W10219A (copper gluconate) in mice; report No. 250-0655; Warner-Lambert Research Institute.
				7. Teratological and embryotoxicity study of W10219A (copper gluconate) in rats; report No. 250-0653; Warner-Lambert Research Institute.
				8. Investigation of the toxic and teratogenic effects of GRAS substances to the developing chick embryo: copper gluconate; FDA in-house investigation.
				9. Investigation of the toxic and teratogenic effects of GRAS substances to the developing chick embryo: copper gluconate; FDA in-house memorandum.
				10. Fertility study of W10219A (copper gluconate) in male and female albino Wistar rats; report No. 250-0661; Warner-Lambert Research Institute.

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-ascorbates, ascorbyl palmitate, erythorbic 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 ingedients 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, 9650 Rockville Pike, Bethesda, MD 20014. 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 Hearing Clerk, address noted above, and all request shall be placed on public display in that office. Any such request must be postmarked on or before April 9, 1979, shall state the substance(s) on which an opportunity to present oral views is requested, and shall state how much time is requested for the presentation. As soon as possible thereafter, a notice announcing the date, time, place, and scheduled presentations for any public hearing that may be requested will be published in the FEDERAL REGISTER.

The purpose of the public hearing is to receive data, information, and views not previously available to the Select Committee about the substances listed above. Information already contained in the scientific literature reviews and in the tentative Select Committee report shall not be duplicated, although views on the interpretation of this material may be presented.

Depending on the number of requests for opportunity to make oral presentations, the Select Committee may reduce the time requested for any presentation. Because of time limitations, individuals and organizations with common interests are urged to consolidate their presentations. Any interested person may, in lieu of an oral presentation, submit written views, which shall be considered by the Select Committee. Three copies of such written views, identified with the Hearing Clerk docket number found in brackets in the heading of this document, shall be addressed 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. 79-6765 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. 79-7268 Filed 3-8-79; 8:45 am]

[4110-02-M]

Office of Education

ADVISORY COUNCIL ON DEVELOPING INSTITUTIONS

Meeting

Notice is hereby given, pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), that the next meeting of the Advisory Council on Developing Institutions will be held March 26 and 27, 1979, from 9:00 a.m. to 4:00 p.m. in Room 425-A, Hubert H. Humphrey Building, 200 Independence Avenue, S.W., Washington, D.C. 20201.

The Advisory Council on Developing Institutions was established by Title III of the Higher Education Act of 1965, as amended. The Council is governed by the provisions of Part D of the General Education Provisions Act and of the Federal Advisory Committee Act (Pub. L. 92-463). The Council shall assist the Commissioner in identifying the characteristics of developing institutions through which the purpose of Title III may be achieved, and in establishing the priorities and criteria to be used in making grants under section 304(a) of that Title.

The meeting of the Council shall be open to the public. The proposed agenda includes:

(1) Swearing-in of New Members of the Council.

(2) Review of Committee Management Legislation and Procedures regarding Advisory Councils.

(3) Review of Law and Regulations regarding Title III of Higher Education Act of 1965 as Amended.

(4) Discussion of Grant Award Process including selection and responsibility of panel of readers.

(5) Program Monitoring and Program Reviews.

(6) Technical Assistance to Title III Institutions.

(7) Issues in Postsecondary Reauthorization of Higher Education Legislation, especially Title III, HEA.

(8) Reports of Program Officers on Title III Developing Institution Programs.

(9) General administrative matters including time and place of future meetings, site visits by Council members, and plans for the Annual Report.

(10) Other Administrative Matters and Related Business.

Records shall be kept in the form of the Council's Annual Report. Copies of the Annual Report will be available at a later date to the public at the Office of the Director of the College and University Unit, BHCE, located in Room-3036, ROB-3, 7th and D Streets S.W., Washington, D.C. 20202.

Signed at Washington, D.C. on March 5, 1979.

PRESTON VALIEN,
OE Delegate to the Council.

[FR Doc. 79-7193 Filed 3-8-79; 8:45 am]

[4110-89-M]

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; and

3. School Board Grants for sex desegregation assistance, under section 405 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 180.38 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 180.71(a) and (b) of the program regulations.

Closing date for transmittal of applications: Applications for awards must be mailed or hand delivered by April 23, 1979.

Applications delivered by mail: An application sent by mail must be addressed to the U.S. Office of Education, Application Control Center, Attention: 13.405A for Training Institutes, 13.405B for School Board Grants, and 13.405C for State Educational Agencies, Washington, D.C. 20202.

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 deliverd by hand: An application that is hand delivered must be taken to the U.S. Office of Education, Application Control Center, Room 5673, Regional Office Building 3, 7th and D Streets, S.W., Washington, D.C.

The Application Control Center will aceept 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 174 projects.

The amount of each 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, in evaluating applications for assistance, the financial and other resources that the ap-

plicant has available for meeting problems incident to sex desegregation. These applicants may therefore wish to address this criterion in their applications.(See 45 CFR 180.64(a)(2).)

Applicable regulations: The regulations applicable to this program are:

(a) General Provisions for Office of Education Programs (45 CFR Parts 100, 100a, and appendices), except to the extent that those regulations are inconsistent with 45 CFR Part 180, and

(b) Regulations relating generally to programs under Title IV of the Civil Rights Act of 1964 (45 CFR Part 180).

Further information: For further information contact Ms. Delia E. Alpert, Acting Director, Division of Technical Assistance, EEOP, U.S. Office of Education (Room 2181-J, FOB-6), 400 Maryland Avenue, S.W., Washington, D.C. 20202, Telephone: 202-245-8840.

(42 U.S.C. 2000c-2000c-5)

(Catalog of Federal Domestic Assistance No. 13.405, Civil Rights Technical Assistance and Training Programs.)

Dated: March 5, 1979.

ERNEST L. BOYER,
U.S. Commissioner of Education.

[FR Doc. 79-7147 Filed 3-8-79; 8:45 am]

[4310-70-M]

DEPARTMENT OF THE INTERIOR

National Park Service

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 independent of or in addition to any oral comments given at the public meetings which were conducted during the month of January.

Comments should be addressed to Director, National Park Service, U.S. Department of the Interior, Washington, D.C. 20240. Attention: Chief, Office of Management Policy.

WILLIAM J. WHALEN,
Director, National Park Service.

MARCH 2, 1979.

[FR Doc. 79-7138 Filed 3-8-79; 8:45 am]

[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 appropriate for the extension of Bureau of Indian Affairs financial assistance and/or social services. The locales listed alphabetically below by Bureau Agency Office jurisdiction are those designated for this purpose:

Agency: Pawnee.

Tribes: Kaw, Otoe-Missouria, Ponca, Tonkawa, Pawnee.

"Near reservation" location: North Boundary—From the west of Grant County, along the Oklahoma-Kansas state line, to the east boundary of Kay County. *East Boundary*—Commencing northeast corner of Kay County, south on Kay County line to Kaw City thence southwest to the Arkansas River, following Arkansas River to Cimarron Turnpike. *South Boundary*—From juncture 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.)

25 CFR 20—*Financial Assistance and Social Services Program* regulations have full force and effect when extending Bureau of Indian Affairs assistance and/or services in the above designated "Near reservation" locations.

Further information about these "Near reservation" designations may be obtained from the Chief, Division of Social Services, Bureau of Indian Affairs, 1951 Constitution Avenue, N.W. Washington, D.C. 20245, telephone 703-235-2756.

FORREST J. GERARD,
Assistant Secretary, Indian Affairs.

[FR Doc. 79-7226 Filed 3-8-79; 8:45 am]

[4310-84-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 3½ river miles downstream from the Grave Creek Boat Landing, an area called Whisky Creek. The legal description of the closed land is: Willamette Meridian, T. 33 S., R. 8 W., Sec. 34, NW¼. A pin and box gate is located in the NW¼ 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

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.

Common 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.

[FR Doc. 79-7220 Filed 3-8-79; 8:45 am]

[4310-84-M]

[AA-6663-A through AA-6663-I]

ALASKA

Alaska Native Claims Selection

On January 25 and October 17, 1974, Ekwok Natives Limited, for the Native village of Ekwok, filed selection applications AA-6663-A through AA-6663-I under the provisions of Sec. 12(a) of the Alaska Native Claims Settlement Act of December 18, 1971 (85 Stat. 688, 701; 43 U.S.C. 1601, 1611 (Supp. V, 1975)), for the surface estate of certain lands in the Ekwok area.

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:

U.S. Survey No. 4878, Tract B, situated at the Village of Ekwok, Alaska.
Containing 88.58 acres.

SEWARD MERIDIAN, ALASKA (UNSURVEYED)

T. 9 S., R. 48 W.
Sec. 19, excluding the Nushagak River;
Sec. 20, excluding Native allotment AA-7691 Parcel B;
Secs. 21, 22 and 28, all;
Sec. 29, excluding Native allotment A-054034 Parcel B;
Secs. 30 and 31, all;
Sec. 32, excluding Native allotment AA-6397 Tract A.
Containing approximately 5,360 acres.

T. 10 S., R. 48 W.
Secs. 4, 5, and 6, 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. 4878, Native allotment AA-6380 Parcel B and the Nushagak River;
Sec. 24, excluding Native allotment AA-7768 and the Nushagak River;
Sec. 25, excluding the Nushagak River;
Sec. 26, excluding U.S. Survey No. 3864, U.S. Survey No. 3867, U.S. Survey No. 4878 and the Nushagak River;
Sec. 27, excluding U.S. Survey No. 4878 and Native allotment AA-7678;
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. 4878, Native allotment AA-7678 and the Nushagak River;
Sec. 35, excluding U.S. Survey No. 4878 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-7764 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-7771 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;
Secs. 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 14,898 acres.

T. 11, S., R. 49 W.
Secs. 4 and 5, all;
Sec. 6, excluding Native allotments AA-7687 Parcel A, AA-7716 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-7764 Parcel A;
Secs. 23 to 27, inclusive, all;
Secs. 30 to 36, inclusive, all.
Containing approximately 10,619 acres.

T. 10 S., R. 50 W.
Sec. 1, excluding Native allotment AA-7776;
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. 35, excluding Native allotments AA-7684, AA-7687 Parcel B, AA-7692 and the Nushagak River;
Sec. 36, excluding the Nushagak River.
Containing approximately 5,760 acres.

T. 11 S., R. 50 W.
Sec. 1, excluding Native allotments AA-7687 Parcel A, AA-7716 and the Nushagak River;
Sec. 2, excluding Native allotments AA-7687 Parcel B, 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;
Sec. 35, excluding Native allotment AA-7712 Parcel B and the Nushagak River;
Sec. 36, excluding the Nushagak River.
Containing aproximately 7,475 acres.

T. 9 S., R. 51 W.
Sec. 1, all;
Secs. 8 to 13, inclusive, all;
Sec. 16, all;
Secs. 24 and 25, excluding Native allotment AA-7800 Parcel A.
Containing approximately 6,320 acres.
Aggregating approximately 86,889 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. 688, 704; 43 U.S.C. 1601, 1613(f) (Supp. V, 1975)); and

2. Pursuant to Sec. 17(b) of the Alaska Native Claims Settlement Act of December 18, 1971 (85 Stat. 688, 708; 43 U.S.C. 1601, 1616(b) (Supp. V, 1975)), the following public easements, referenced by easement identification number (EIN) on the easement maps in case file AA-6663-EE are reserved to the United States and subject to further regulation thereby:

a. (EIN 1 D9, D1, L, C1, C5) A streamside easement twenty-five (25) feet in width upland of and parallel to the ordinary high water mark on all banks of the navigable Nushagak River beginning in T. 11 S., R. 50 W., Seward Meridian, for its entire length through the selection area to T. 9 S., R. 48 W., Seward Meridian. Purpose is to provide for public use of waters having highly significant present recreational use.

b. (EIN 4 D9, D1) A streamside 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 border 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.

c. (EIN 5 D9) A fishery management and public use easement upland of the ordinary high water mark in Sec. 10, T. 10 S., R. 49 W., Seward Meridian, on the right bank of the Nushagak River. The easement is two (2) acres in size and is used for fishery management purposes.

d. (EIN 5a D9) A fishery management and public use easement upland of the ordinary high water mark in Sec. 10, T. 10 S., R. 49 W., Seward Meridian, on the left bank of the Nushagak River. The easement is two (2) acres in size and is used for fishery management purposes.

e. (EIN 9 C4) A one (1) acre site easement upland of the ordinary high water mark in Sec. 11, T. 11 S., R. 50 W., Seward Meridian, on the right bank of the Nushagak River. The site is for camping, staging and vehicle use.

f. (EIN 9a C4) An easement for a proposed access trail twenty-five (25) feet in width from site EIN 9 C4 westerly to public lands. The usage of roads and trails will be controlled by applicable State or Federal law or regulation.

g. (EIN 10 C4) A one (1) acre site easement upland of the ordinary high water mark in Sec. 25, T. 10 S., R. 50 W., Seward Meridian, on the right bank of the Nushagak River. The site is for camping, staging and vehicle use.

h. (EIN 10a C4) An easement for a proposed access trail twenty-five (25) feet in width from site EIN 10 C4 westerly to public lands. The usage of roads and trails will be controlled by applicable State or Federal law or regulation.

i. (EIN 11 C4) A one (1) acre site easement upland of the ordinary high water mark in Sec. 21, T. 9 S., R. 48 W., Seward Meridian, on the left bank of the Nushagak River. The site is for camping, staging and vehicle use.

j. (EIN 11a C4) An easement for a proposed access trail twenty-five (25) feet in width from site EIN 11 C4 southeasterly to public lands. The usage of roads and trails will be controlled by applicable State or Federal law or regulation.

k. (EIN 14 C4) A site easement upland of the ordinary high water mark in Sec. 31, T. 9 S., R. 50 W., Seward Meridian, on the right bank of the Kokwok River. The site is one (1) acre in size with an additional twenty-five (25) foot wide easement on the bed of the river along the entire waterfront of the site. The site is for camping, staging and vehicle use.

l. (EIN 14a C4) An easement for a proposed access trail twenty-five (25) feet in width from site EIN 14 C4 southwesterly to public lands. The usage of roads and trails will be controlled by applicable State or Federal law or regulation.

m. (EIN 15 C4) A site easement upland of the ordinary high water mark in Sec. 11, T. 9 S., R. 51 W., Seward Meridian, on the left bank of the Kokwok River. The site is one (1) acre in size with an additional twenty-five (25) foot wide easement on the bed of the river along the entire waterfront of the site. The site is for camping, staging and vehicle use.

n. (EIN 15a C4) An easement for a proposed access trail twenty-five (25) feet in width from site EIN 15 C4 northerly to public lands. The usage of roads and trails will be controlled by applicable State or Federal law or regulation.

o. (EIN 16 C4) A site easement upland of the ordinary high water mark in Sec. 33, T. 9 S., R. 50 W., Seward Meridian, on the left bank of the Kokwok River. The site is one (1) acre in size with an additional twenty-five (25) foot wide easement on the bed of the river along the entire waterfront of the site. The site is for camping, staging and vehicle use.

p. (EIN 16a C4) An easement for a proposed access trail twenty-five (25) feet in width from site EIN 16 C4 northerly to public lands. The usage of roads and trails will be controlled by applicable State or Federal law or regulation.

q. (EIN 34 C) The right of the United States to enter upon the lands hereinabove granted for cadastral, geodetic or other survey purposes is reserved, together with the right to do all things necessary in connection therewith.

r. (EIN 36 E) An easement for an existing winter access trail twenty-five (25) feet in width, paralleling the right bank of the Nushagak River throughout the selection. The usage of roads and trails will be controlled by applicable State or Federal law or regulation.

s. (EIN 37 E) A one (1) acre site easement upland of the ordinary high water mark in Sec. 11, T. 10S., R. 49 W., Seward Meridian, on the left bank of the Nushagak River. The site is for camping, staging and vehicle use.

t. (EIN 38 E) An easement for a proposed access trail twenty-five (25) feet in width from site EIN 37 E southeasterly to public lands. The usage of roads and trails will be controlled by applicable State or Federal law or regulation.

These reservations have not been conformed to the Departmental easement policy announced March 3, 1978 and published as final rulemaking on November 27, 1978, 43 FR 55326. Conformance will be made at a later date in accordance with 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 other Bristol Bay Village Corporations.

The grant of lands shall be subject to:

1. Issuance of a patent confirming the boundary description of the lands hereinabove granted after approval and filing by the Bureau of Land Management of the official plat of survey covering such lands;

2. Valid existing rights therein, if any, including but not limited to those created by any lease (including a lease issued under Sec. 6(g) of the Alaska Statehood Act of July 7, 1958 (72 Stat. 339, 341; 48 U.S.C. Ch. 2, Sec. 6(g) (1970))), contract, permit, right-of-way, or easement, and the right of the lessee, contractee, permittee, or grantee to the complete enjoyment of all rights, privileges, and benefits thereby granted to him. 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-058769, containing 88.58 acres, described as Tract B, U.S. survey 4878, 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, 1928 (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 (85 Stat. 688, 703; 43 U.S.C. 1601, 1613(c) (Supp. V, 1975)), that the grantee hereunder convey those portions, if 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 other Bristol Bay village corporations. A copy of the agreement shall be attached to and become a part of the conveyance document and shall be recorded therewith. A copy of the agreement is located in the Bureau of Land Management easement case file for Ekwok Natives Limited, serialized AA-6663-EE. Any person wishing to examine this agreement may do so at the Bureau of Land Management, Alaska State Office, 701 C Street Anchorage, Alaska 99513.

Ekwok Natives Limited, is entitled to conveyance of 92,160 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 2650.7(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,

Anchorage, Alaska 99510 with a copy served upon both the Bureau of Land Management, Alaska State Office, 701 C Street, Box 13, 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 Appeal Board.
4. If Ekwok Natives Limited, or Bristol Bay Native Corporation objects to any easement which is identified herein for reservation in the conveyance, which is subject to the discretion of the State Director and not reserved pursuant to an express Secretarial directive, a petition for reconsideration must be filed within 30 days from receipt of service with the State Director, Bureau of Land Management, 701 C Street, Box 13, Anchorage, Alaska 99513. A copy of the petition should be served upon the Regional Solicitor, Office of the Solicitor, 510 L Street, Suite 408, Anchorage, Alaska 99501. If a petition for reconsideration is not filed, it will be deemed that the right to contest any such easement has been waived.

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. KAMMINS,
Chief, Division of ANCSA Operations.

[FR Doc. 79-7159 Filed 3-8-79; 8:45 am]

[4310-84-M]

[NM 35771]

NEW MEXICO

Application

MARCH 1, 1979.

Notice is hereby given that, pursuant to Section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by the Act of November 16, 1973 (87 Stat. 576), Gas Company of New Mexico has applied for several 2-inch, 3-inch, 4-inch, 5-inch and 6-inch natural gas pipelines right-of-way across the following lands:

NEW MEXICO PRINCIPAL MERIDIAN, NEW MEXICO

T. 27 N., R. 9 W.,
Sec. 5, lots 1, 2, 8, SW¼NE¼, E½SW¼ and S½SE¼;
Sec. 7, SE¼NE¼, E½SE¼;
Sec. 8, E½E½, W½SW¼, SW¼NE¼ and SW¼SE¼;
Sec. 9, NE¼NW¼, W½NW¼ and SW¼SW¼;
Sec. 17, NW¼NE¼, N½NW¼, SW¼NW¼ and W½SW¼;
Sec. 19, W½NE¼, SE¼NE¼, NE¼NW¼ and E½SE¼;
Sec. 20, SW¼SW¼;
Sec. 29, N½N½, SW¼NW¼, N½SW¼ and NW¼SE¼.
T. 28 N., R. 10 W.,
Sec. 14, SE¼SW¼, N½SE¼ and SW¼SE¼;
Sec. 16, W½SW¼;
Sec. 17, NE¼SE¼ and S½S½;
Sec. 18, lots 2, 3, SW¼NE¼, SE¼NW¼ and SE¼SE¼;
Sec. 19, lots 1, 2, 3, 4, N½NE¼, E½W½ and W½SE¼;
Sec. 20, W½NW¼, NW¼SW¼ and SE¼SE¼;
Sec. 21, E½NE¼, SW¼SW¼ and N½SE¼;
Sec. 22, E½NE¼, SW¼NE¼, SW¼NW¼ and S½;
Sec. 23, W½NE¼, N½NW¼, SE¼NW¼ and SW¼SW¼;
Sec. 26, N½NE¼, SW¼NE¼, N½SW¼, SW¼SW¼ and NW¼SE¼;
Sec. 27, W½E½, NE¼NW¼, S½SW¼ and SE¼SE¼;
Sec. 29, N½NE¼ and NW¼NW¼;
Sec. 30, lot 1, E½NE¼, NW¼NE¼, NE¼NW¼ and NE¼SE¼;
Sec. 32, NE¼NE¼, NE¼SW¼ and N½SE¼;
Sec. 33, NE¼NE¼, NW¼NW¼ and N½SW¼;
Sec. 34, NE¼NE¼, and NW¼NW¼;
Sec. 35, NW¼NW¼.
T. 28 N., R. 11 W.,
Sec. 13, SW¼NE¼, SE¼NW¼, E½SW¼, SW¼SW¼ and SE¼;
Sec. 14, SE¼SE¼;
Sec. 23, N½NE¼;
Sec. 24, SW¼NE¼, E½NW¼, NE¼SW¼ and W½SE¼.

These pipelines will convey natural gas across 39.123 miles of public lands in San Juan County, New Mexico.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, P.O. Box 6770, Albuquerque, New Mexico 87107.

FRED E. PADILLA,
Chief, Branch of Lands and Minerals Operations.

[FR Doc. 79-7143 Filed 3-8-79; 8:45 am]

[4310-55-M]

Fish and Wildlife Service

CONSULTATION ON THE PITTSTON 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, Shead 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. 216) or 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 Cobscook Bay in Eastport, Maine. On September 13, 1978, EPA entered into consultation with the U.S. Fish and Wildlife Service (Service) pursuant to section 7 of the Endangered Species Act, to insure that issuance of the wastewater discharge permit would not jeopardize the continued existence of the peregrine falcon or the bald eagle (which was determined to be an endangered species on February 14, 1978).

On December 21, 1978, 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 22, 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. 79-7187 Filed 3-8-79; 8:45 am]

[4410-05-M]

DEPARTMENT OF JUSTICE

Bureau of Prisons

NATIONAL INSTITUTE OF CORRECTIONS ADVISORY BOARD

Meeting

Notice is hereby given that the National Institute of Corrections Advisory Board in accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463; 86 Stat. 770) will meet on Sunday, March 25, 1979, starting at 9:00 a.m., at the Capital Airport Inn, 1200 Virginia Avenue, Atlanta, Georgia 30320.

At this meeting (one of the regularly scheduled triannual meetings of the Advisory Board), the Board will receive its subcommittees' reports and recommendations as to future thrusts of the Institute.

ROBERT L. SMITH,
Acting Director.

[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

Name of applicant and location of enterprise	Principal product or activity
The Ceco Corporation, Marysville, California	Manufacture of metal overhead garage doors.

[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 42048. 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 Bethlehem were forwarded to the applicant pursuant to 29 CFR 75.11(b)(3) to afford an opportunity for rebuttal. The 30-day time period for Department of Labor review, however, was due to expire on October 13, 1978, prior to the close of the two week 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 Department 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 certification 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 be permitted by the hearing officer to participate in these proceedings as an interested party. The U.S. 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 by filing in the office of the Chief Administrative Law Judge, U.S. Department of Labor, Room 720, Vanguard Building, 1111 20th Street, N.W., Washington, D.C. 20036, not later than March 26, 1979, a written request setting forth the applicant's name and address and the name, address and the title or position of any person who will represent the applicant. The hearing officer shall rule on all applications and inform the applicants and the parties of the rulings.

(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

the basis of the record upon which the certification of noncompliance was made, request for reconsideration, any legal briefs submitted and any fact-finding conducted subsequent to the request for reconsideration and shall:

(a) Recommend to the Assistant Secretary for Employment and Training that the certification of noncompliance be affirmed; or

(b) Recommend to the Assistant Secretary for Employment and Training that the certification of noncompliance be revoked; or

(c) Direct that a hearing be held on the case.

(7) If the case has been set for hearing, the hearing officer shall notify all parties:

(a) Of the date, time, and place of the hearing; and

(b) That the hearing may be rescheduled upon written request and for good cause shown.

D. HEARING PROCEDURES

(1) If a hearing has been ordered by the hearing officer pursuant to paragraph C(6)(c) above, the hearing officer shall have all the powers necessary to conduct a fair and full hearing, including the powers:

(a) To regulate the course of the proceedings;

(b) To dispose of procedural requests, objections, and comparable matters;

(c) To confine the presentations to the issues specified in the notice of hearing, or, where no issues are specified, to matters within the Secretary of Labor's statutory scope of authority;

(d) To regulate the conduct of those present at the hearing by appropriate means;

(e) In the hearing officer's discretion, to permit cross-examination of any witness;

(f) To take official notice of material facts not appearing in the evidence in the record, so long as parties are entitled, on timely request, to an opportunity to show the contrary; and

(g) In the hearing officer's discretion, to keep the record open for a reasonable, stated time to receive written recommendations, and supporting reasons, and additional data, views, and arguments from any person who has participated in the oral proceeding.

(2) Based on the evidence adduced at the hearing and any evidence appearing in the record, the hearing officer shall recommend to the Assistant Secretary for Employment and Training such rulings as are appropriate to the issues in question.

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 March 5, 1979.

RAY MARSHALL,
Secretary of Labor

[FR Doc. 79-7206 Filed 3-8-79;8:45 am]

[4510-27-M]

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. Procurement officals requesting pre-award clearances should use these direct-line numbers effective immediately. The Memorandum amends the Heads of Agencies Memorandum dated September 20, 1978, Subject: "FY 1979 Preaward Clearance Requests."

Dated: February 1, 1979.

WELDON J. ROUGEAU,
Director, Office of Federal Contract Compliance Programs.

ACTION NOTICE 79-8/ADM

Memorandum to: Heads of all Agencies.
From: Weldon J. Rougeau, Director.
Subject: OFCCP Regional Office Contact Points for Pre-Award Clearance Requests.

With the full consolidation of the compliance agencies now completed, all pre-award clearance requests pursuant to 41 CFR 60-1.20(d) must be directed to the Office of Federal Contract Compliance Programs (OFCCP) Regional Office where the work is to be performed.

The following is an updated list of OFCCP Regional Office telephone numbers which are the contact points for pre-award clearance requests:

	States	Address	Telephone
Region:			
I	Maine, New Hampshire, Massachusetts, Connecticut, Rhode Island, and Vermont.	OFCCP/ESA—Boston, U.S. Department of Labor, JFK Fed. Off. Bldg., Room 1612-C, Boston, MA 02203.	8/223-1559 (617)223-1559
II	New York, New Jersey, Puerto Rico, and Virgin Islands.	OFCCP/ESA—New York, U.S. Department of Labor, 1515 Broadway, Room 3308, New York, NY 10036.	8/662-4978 (212)399-4978
III	Pennsylvania, Maryland, Delaware, Virginia, West Virginia, and D.C.	OFCCP/ESA—Philadelphia, U.S. Department of Labor, Gateway Bldg.—Room 15430, 3535 Market Street, Philadelphia, PA 19104.	8/596-1213 (215)596-1213
IV	North Carolina, South Carolina, Kentucky, Tennessee, Mississippi, Alabama, Georgia, and Florida.	OFCCP/ESA—Atlanta, U.S. Department of Labor, 1371 Peachtree Street, Room 729, Atlanta, GA 30309.	8/257-4211 (404)881-4211
V	Ohio, Indiana, Michigan, Illinois, Wisconsin, and Minnesota.	OFCCP/ESA—Chicago, U.S. Department of Labor, 230 South Dearborn Street, Room 1614, Chicago, IL 60604.	8/353-1929 (312)353-1929
VI	Louisiana, Arkansas, Oklahoma, Texas, and New Mexico.	OFCCP/ESA—Dallas, U.S. Department of Labor, 555 Griffin Square Bldg., Room 503, Dallas, TX 75202.	8/729-4773 (214)767-4773
VII	Missouri, Iowa, Nebraska, and Kansas.	OFCCP/ESA—Kansas City, U.S. Department of Labor, Fed. Off. Bldg.—Room 2000, 911 Walnut Street, Kansas City, MO 64106.	8/758-2695 (816)374-2695
VIII	North Dakota, South Dakota, Montana, Wyoming, Colorado, and Utah.	OFCCP/ESA—Denver, U.S. Department of Labor, Fed. Off. Bldg.—Room 1412, 1961 Stout Street, Denver, CO 80294.	8/327-5013 (303)837-5013
IX	California, Nevada, Arizona, Hawaii, and Guam.	OFCCP/ESA—San Francisco, U.S. Department of Labor, Tishman Bldg.—Second Floor, 525 Market Street, San Francisco, CA 94105.	8/556-4904 (415)556-4904
X	Alaska, Idaho, Oregon, and Washington.	OFCCP/ESA—Seattle, U.S. Department of Labor, Fed. Off. Bldg.—Room 1023, 909 First Avenue, Seattle, WA 98174.	8/399-4508 (206)442-4508

The foregoing information will also be published in the FEDERAL REGISTER.

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

[4510-43-M]

Mine Safety and Health Administration

[Docket No. M-79-6-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 it currently uses.

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.

Dated: February 28, 1979.

ROBERT B. LAGATHER,
Assistant Secretary for Mine Safety and Health.

[FR Doc. 79-7209 Filed 3-8-79; 8:45 am]

[4510-43-M]

[Docket No. M-79-13-C]

KANAWHA COAL CO.

Petition for Modification of Application of Mandatory Safety Standard

Kanawha Coal Company, P.O. Box 38, Ashford, West Virginia 25009, 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 liberate methane and so buildup of methane in any working area is unlikely.

5. The petitioner states that the alternative will achieve no less protection for its miners than that provided by the standard.

REQUESTS FOR COMMENTS

Persons interested in the 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.

Dated: February 28, 1979.

ROBERT B. LAGATHER,
Assistant Secretary for Mine Safety and Health.

[FR Doc. 79-7210 Filed 3-8-79; 8:45 am]

[4510-26-M]

Occupational Safety and Health Administration

NATIONAL ADVISORY COMMITTEE ON OCCUPATIONAL SAFETY AND HEALTH

Notice of Meeting

NOTE:—This document originally appeared in the FEDERAL REGISTER for Thursday, March 8, 1979. It is reprinted in this issue to meet the Tuesday/Friday publication schedule assigned to the Labor Department.

Notice is hereby given that the National Advisory Committee on Occupational Safety and Health has formed a Subgroup to consider the development of court required "Fully Effective" benchmarks for state plans. This Subgroup will meet at 9:30 a.m. on March 15 and 16, 1979 at the OSHA Training Institute, 1555 Times Drive, Des Plaines, Illinois. The same Subgroup will continue its deliberations on April 1, at 4:00 p.m. in Room N-5437, the New Department of Labor Building, Third Street and Constitution Avenue, NW., Washington, D.C. The public is invited to attend.

On April 2, 1979, the National Advisory Committee on Occupational Safety and Health will meet in Room N-5437, the New Department of Labor Building, Third Street and Constitution Avenue, NW, Washington, D.C., to hear the report of the Subgroup and to discuss and formulate its recommendations on "Fully Effective" state plan benchmarks for the Assistant Secretary of Labor for Occupational Safety and Health. The committee will also discuss data collection procedures and statistical methods for safety and health applications. This meeting will begin at 9:00 a.m. and, as always, the public is invited.

At its March 2, 1979 meeting, the National Advisory Committee on Occupational Safety and Health (NACOSH) appointed a Subgroup to consider ways of meeting the U.S. District Court requirements for "Fully Effective" benchmarks for state plans. The recommendations of NACOSH are essential to the Agency and the report of this Subgroup will be a basis for the development of these recommendations at the April 2, 1979 meeting of the full committee. I hereby find that an emergency situation exists which makes it impossible to give the full 15 days notice required by OMB Circular A-63.

The National Advisory Committee was established under section 7(a) of the Occupational Safety and Health Act of 1970 (Pub. L. 91-596) to advise the Secretary of Labor and the Secretary of Health, Education, and Welfare on matters relating to the administration of the Act.

FOR ADDITIONAL INFORMATION CONTACT:

Mr. Clarence Page, Division of Consumer Affairs, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3635, Third Street and Constitution Avenue NW., Washington, D.C. 20210, telephone number: 202-523-8024.

Official records of the meeting will be available for public inspection at the Division of Consumer Affairs.

Signed at Washington, D.C., this 6th day of March 1979.

EULA BINGHAM,
Assistant Secretary of Labor.

[FR Doc. 79-7196 Filed 3-7-79; 8:45 am]

[4510-26-M]

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 1178) of the approval of the Utah Plan and the adoption of Subpart E to Part 1952 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 1952.113 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 Administrator, and incorporated as part of the Plan, the State submitted rules and regulations concerning 29 CFR 1910.1000 Air Contaiminants, 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 1953, Title 63-46-1, 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 comparison 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 copying.* 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, 1961 Stout Street, Denver, Colorado 80294; 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 publicaton 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 repetitious.

This decision is effective March 9, 1979.

(Sec. 18, Pub. L. 91-596, 84 Stat. 1608 (29 U.S.C. 667).)

Signed at Denver, Colorado, this 7th day of February 1979.

CURTIS A. FOSTER,
Regional Administrator.

[FR Doc. 79-7214 Filed 3-8-79; 8:45 am]

[4510-22-M]

Office of the Secretary

ADVISORY COMMITTEES

Annual Comprehensive Review

We are currently in the process of conducting the Department's annual comprehensive review of Federal Advisory Committees. I invite you to submit whatever remarks are germane to answering the following questions about each of our advisory committees: (1) Does the Department have a compelling need for it; (2) Is the committee's membership truly balanced; and (3) Has the committee conducted its business as openly as possible, consistent with the law and its mandate? The DOL advisory committees are listed below:

Advisory Committee on Construction Safety and Health
Advisory Council on Employee Welfare and Pension Benefit Plans
Business Research Advisory Council
Federal Advisory Council on Occupational Safety and Health
Federal Advisory Council on Unemployment Insurance
Federal Committee on Apprenticeship
Labor Policy Advisory Committee for Multilateral Trade Negotiations
Labor Research Advisory Council
Labor Sector Advisory Committee on Electrical and Electronic Equipment and Supplies and Nonelectrical Machinery
Labor Sector Advisory Committee on Food and Agricultural Products and Chemical, Plastic and Rubber Products
Labor Sector Advisory Committee on Lumber, Wood and Paper Products and Stone, Clay and Glass Products
Labor Sector Advisory Committee on Services
Labor Sector Advisory Committee on Textile, Apparel and Leather Products and Miscellaneous Manufacturing Industries
Labor Sector Advisory Committee on Transportation Equipment and Primary and Fabricated Metal Products
Minimum Wage Study Commission
National Advisory Committee on Occupational Safety and Health
National Advisory Committee on Women
National Commission on Employment and Unemployment Statistics
National Commission for Manpower Policy
National Commission on Unemployment Compensation

If you wish to comment, please submit your responses within 15 days from the date of this publication to: Mrs. Ruth E. Morgenstern, Departmental Committee Management Officer, Department of Labor, Room S-2517, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed this 6th day of March 1979.

RAY MARSHALL,
Secretary of Labor.

[FR Doc. 79-7205 Filed 3-8-79; 8:45 am]

[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 "qualifying 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.

(2) Maintenance of liaison with the Civil Aeronautics Board; and beginning January 1, 1985, 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).

(4) The implementation, maintenance and publication of a comprehensive list of job openings available with certified air carriers.

(5) Providing a full range of employment services including job search and relocation for protected employees seeking employment in other areas.

(6) Developing and carrying out, in cooperation with LMSA, a program to inform and advise workers about the Airline Employee Protection Program.

(7) Developing agreements for the administration of the program by State Employment Security Agencies, as agents for the United States, and in the absence of an agreement with any State or Agency, a system for performing the functions required to provide benefits to eligible workers.

(8) Developing and maintaining a system for monitoring Federal or State Agency performance in carrying out the provisions of the Act.

b. *The Assistant Secretary for Labor-Management Relations* 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, covering the first right of hire—duty to hire and rehire provision of Section 43(d)(1).

(2) The development and promulgation of policies, regulations, and procedures covering the comprehensive job list required under Section 43(d)(2).

(3) Encouraging negotiations between air carriers and representatives of affected employees with respect to rehiring practices and seniority.

(4) Requesting air carriers to file reports, data and other pertinent information necessary for fulfilling responsibilities under Section 43(d)(2).

c. *The Assistant Secretary for Policy Evaluation and Research* shall assist the Assistant Secretaries for Employment and Training and for Labor-Management Relations in developing major policy aspects of program regulations.

d. The Solicitor of Labor shall provide legal advice and assistance to all Department of Labor officials relating to the implementation of this Order.

5. *Reservations of Authority.* Reserved to the Secretary of Labor are the following:

a. Submission of rules, regulations or reports to the Secretary of Transportation and/or the Congress as appropriate.

b. Entering into agreements and modifications to agreements with any State which will act as agent in carrying out Department of Labor responsibilities under this Act.

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.

RAY MARSHALL,
Secretary of Labor.

[FR Doc. 79-7208 Filed 3-8-79; 8:45 am]

[4510-28-M]

INVESTIGATIONS REGARDING CERTIFICATIONS OF ELIGIBILITY TO APPLY FOR WORKER ADJUSTMENT ASSISTANCE

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, 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 like or directly competitive with articles produced by the worker's 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 eligiblity requirements will be certified as eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act in accordance with the provsions of Subpart 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

ment of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20210.

of the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, U.S. Depart-

Signed at Washington, D.C., this 26th day of February 1979.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner: Union/workers or former workers of—	Location	Date received	Date of petition	Petition No.	Articles produced
Amherst Coal Company, #1 Cleaning Plant (workers).	Fanco, W. Va	2/22/79	2/16/79	TA-W-4, 840	Metalurgical coal.
Arrow Pants (ILGWU)	Lodi, N.J	2/16/79	2/12/79	TA-W-4, 841	Ladies sportswear.
Binnie Bon, Inc. (ILGWU)	Adjuntas, P.R	2/22/79	2/12/79	TA-W-4, 842	Brassiers.
Bow Sportwear (ILGWU)	Lodi, N.J	2/16/79	2/12/79	TA-W-4, 843	Ladies sportswear.
Capehart Corporation Sales Division (workers).	New York, N.Y	2/16/79	1/30/79	TA-W-4, 844	Stereo modulars.
Carol Foundations, Incorporated (ILGWU).	Hato Tejas, Bayamon, P.R.	2/22/79	2/12/79	TA-W-4, 845	Brassiers.
Columbian Rope Co. (ACTWU)	Jefferson, La	2/22/79	2/16/79	TA-W-4, 846	Manila rope and synthetic rope.
G.C. Fashions (workers)	Glencove, N.Y	2/16/79	2/12/79	TA-W-4, 847	Ladies coats.
J. Dee Sportswear, Incorporated, Plant #1 (ACTWU).	Paulsboro, N.J	2/12/79	1/22/79	TA-W-4, 848	Uniforms.
J. Dee Sportswear, Incorporated, Plant#2 (ACTWU).	Paulsboro, N.J	2/12/79	1/22/79	TA-W-4, 849	Uniforms.
Ken Foundations, Inc. (ILGWU)	Carolina, P.R	2/22/79	2/12/79	TA-W-4, 850	Brassiers.
Kingston Dress (workers)	Fayetteville, Tenn	2/16/79	2/8/79	TA-W-4, 851	Women's apparel.
Natalie Knitting Mills (workers)	Chilhowie, Va	2/22/79	2/14/79	TA-W-4, 852	Men's and ladies sweaters and leotards.
OMNICO (workers)	Inwood, N.Y	2/16/79	1/30/79	TA-W-4, 853	Children's, women's and men's sportswear.
Pantry Pride Philadelphia Div. (workers).	Philadelphia, Pa	2/22/79	2/5/79	TA-W-4, 854	Cut, package, and weigh meat.
Textron, Inc., Speidel Division (company).	Overland Park, Kans	2/22/79	2/14/79	TA-W-4, 855	Electronic liquid crystal display watch modules.
Tru-Fit Knitwear, Incorported (ILGWU).	Brooklyn, N.Y	2/11/79	2/10/79	TA-W-4, 856	Ladies sweaters.

[FR Doc. 79-6734 Filed 3-8-79; 8:45 am]

[4510-28-M]

INVESTIGATIONS REGARDING CERTIFICATIONS OF ELIGIBILITY TO APPLY FOR WORKER ADJUSTMENT ASSISTANCE

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assitance, 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 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 Subpart 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.

HAROLD A. BRATT,
Deputy Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner: Union/workers or, former workers of—	Location	Date received	Date of petition	Petition No.	Articles produced
Broderick & Bascom Rope Company (IAM).	Peoria, Ill	2/26/79	2/19/79	TA-W-4,873	Steel wire rope.
Camp Creek Mining Company (UMWA).	Camp Creek, W. Va	2/23/79	2/16/79	TA-W-4,874	Metallurgical coal.
Grandview Mining (UMWA)	Beaver, W. Va	2/23/79	2/16/79	TA-W-4,875	Metallurgical coal.
McKenzie Mining Co., Leatherhead #1 & #2 (UMWA).	Egeria, W. Va	2/23/79	2/16/79	TA-W-4,876	Metallurgical coal.
McKenzie Mining Co., Tipple Mine (UMWA).	Egeria, W. Va	2/23/79	2/16/79	TA-W-4,877	Metallurgical coal.
Tri-Star Mine (UMWA)	Welch, W. Va	2/23/79	2/16/79	TA-W-4,878	Metallurgical coal.

[FR Doc. 79-6735 Filed 3-8-79; 8:45 am]

[4510-28-M]

INVESTIGATIONS REGARDING CERTIFICATIONS OF ELIGIBILITY TO APPLY FOR WORKER ADJUSTMENT ASSISTANCE

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, 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 Subpart 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

Petitioner: Union/workers or former workers of—	Location	Date received	Date of petition	Petition No.	Articles produced
A. Morganstern & Co. (company)	Fredericksburg, Va	2/26/79	2/24/79	TA-W-4, 857	Cuts pants.
Broderick & Bascom Rope Company (USWA).	St. Louis, Mo	2/22/79	2/15/79	TA-W-4, 858	Warehouse of wire rope and general office.
Broderick & Bascom Rope Company (USWA).	Houston, Tex	2/22/79	2/15/79	TA-W-4, 859	Steel wire rope.
Cities Service Co., Plainview Terminal (OCAW).	Plainview, N.Y	2/26/79	2/16/79	TA-W-4, 860	Transports gas.
Duncan Fox Industrial Sales, Inc. (company).	Freehold, N.J	2/22/79	2/13/79	TA-W-4, 861	Purchase and sell textile machinery.
Eaton Corporation, Massillon Plant (Allied Ind. Wkrs).	Massillon, Ohio	2/26/79	2/21/79	TA-W-4, 862	Fasteners, nuts, bolts, retaining rings.
Fair-Rite Products Corporation (company).	Wallkill, N.Y	2/26/79	2/21/79	TA-W-4, 863	Ferrite magnetic cores.
Gardisette, Inc. (workers)	Anderson, S.C	2/26/79	2/21/79	TA-W-4, 864	Custom-made draperies.
Ginny Jones, Inc. (ILGWU)	Brooklyn, N.Y	2/26/79	2/21/79	TA-W-4, 865	Ladies sportswear, and men's and ladies sweaters.
Imperial Reading Corporation (workers).	Lynchburg, Va	2/26/79	2/23/79	TA-W-4, 866	Administrative and support services.
International Shoe Company (workers).	Belle, Mo	2/22/79	2/14/79	TA-W-4, 867	Ladies footwear.
Montalbano Blouse (ILGWU)	Paterson, N.J	2/27/79	2/22/79	TA-W-4, 868	Women's blouses.
Morganstern Pants Company (company).	Fredericksburg, Va	2/26/79	2/24/79	TA-W-4, 869	Sews pants.
Rubber Corporation of Pennsylvania (USW).	West Hazleton, Pa	2/22/79	2/15/79	TA-W-4, 870	Athletic and casual footwear.
Richmond Clothing Company, Inc, (workers).	Richmond, Va	2/26/79	2/21/79	TA-W-4, 871	Men's suits, top coats, slacks, and sportscoats.
Western Tanning, Incorporated (workers).	Delta, Colo	2/26/79	2/22/79	TA-W-4, 872	Tanned leather.

[FR Doc. 79-6733 Filed 3-8-79; 8:45 am]

[4510-28-M]

[TA-W-4508]

MAR-CAL

Termination of Investigation

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 8, 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.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 79-7213 Filed 3-8-79; 8:45 am]

[4510-28-M]

[TA-W-4741 and TA-W-4743]

RAINETTE FASHIONS, JERSEY CITY, N.J., AND SUZZETTE FASHIONS, INC., NEW YORK, N.Y.

Investigations Regarding Certification of Eligibility To Apply for Worker Adjustment Assistance; Correction

In FEDERAL REGISTER Doc. 79-3150 appearing on page 5952 in the FEDERAL REGISTER of January 30, 1979, the dates received in Appendix under petitioners Rainette Fashions TA-W-4741 and Suzzette Fashion, Inc. TA-W-4743 are corrected to read as follows: "January 9, 1979."

Signed at Washington, D.C. this 9th day of February 1979.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 79-7212 Filed 3-8-79; 8:45 am]

[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 222 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 criterion 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 International Economist, Office of Foreign Economic Research.

[FR Doc. 79-7211 Filed 3-8-79; 8:45 am]

[7555-01-M]

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 Lih, 202-632-5867.

March 5, 1979.

M. REBECCA WINKLER,
Committee Management Coordinator.

[FR Doc. 79-7150 Filed 3-8-79; 8:45 am]

[7555-01-M]

EXECUTIVE COMMITTEE OF THE ADVISORY COMMITTEE FOR ENVIRONMENTAL BIOLOGY

Meeting

In accordance with the Federal Advisory Committee Act, as amended Pub. 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.

PLACE: National Science Foundation, 1800 G. Street N.W., Washington, D.C. 20550, Room 338.

TYPE OF MEETING: Closed.

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 COMMITTEE: 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. 79-7148 Filed 3-8-79; 8:45 am]

[7555-01-M]

FEDERAL ADVISORY COMMITTEES

Review

The National Science Foundation is conducting a comperhensive 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 for consideration 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 Polar 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 undertaking 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, it subcommittees and working groups hold approximately 110 meetings annually and issue 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. 79-7186 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 proposd action on certian articles from Japan under Section 301 of the Trade Act. (See FEDERAL REGISTER of January 17, 1979, page 3580). This action was proposed in response to Japanese import restrictions on leather exported from the United States and elsewhere. Those 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; 8:45 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 Lefter, Director, Civil Engineering Service, Office of Construction, Veterans Administration Central Office (phone 202-389-2864), prior to April 5, 1979.

Dated: March 2, 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]

[7035-01-M]

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 28905 (Sub-Nos. 1F and 2F); No. MC-F-13819F]

CSX CORP.—CONTROL—CHESSIE SYSTEM, INC. AND SEABOARD COAST LINE INDUSTRIES INC.

Railroad Operation, Acquisition and Construction; Initial Prehearing Conference Procedures

MARCH 7, 1979.

Finance Docket No. 28905 (Sub-No. 1F), CSX Corporation-Control-Chessie System, Inc., and Seaboard Coast Line Industries, Inc., Finance Docket No. 28905 (Sub-No. 2F), CSX Corporation, Securities; No. MC-F-13819F, CSX Corporation-Control-Seacoast Transportation Company.

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 would 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:

I. 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 petitions 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 liason 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;

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:

a. Annual Reports of the Interstate Commerce Commission to the Congress of the United States of America.

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.

c. Moody's Transportation Manual.

d. Standard & Poor's Security Owner.

e. Bank and Quotation Record, National News Service, Inc., Publisher.

f. Other printed, publicly available, and readily obtainable statistical material.

Parties and prospective parties in the presently pending applicaiton 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.

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-Chessie 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.

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.

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; 9:26 am]

[7035-01-M]

[AB 46 (SDM)]

CHICAGO, ROCK ISLAND & PACIFIC RAILROAD CO.

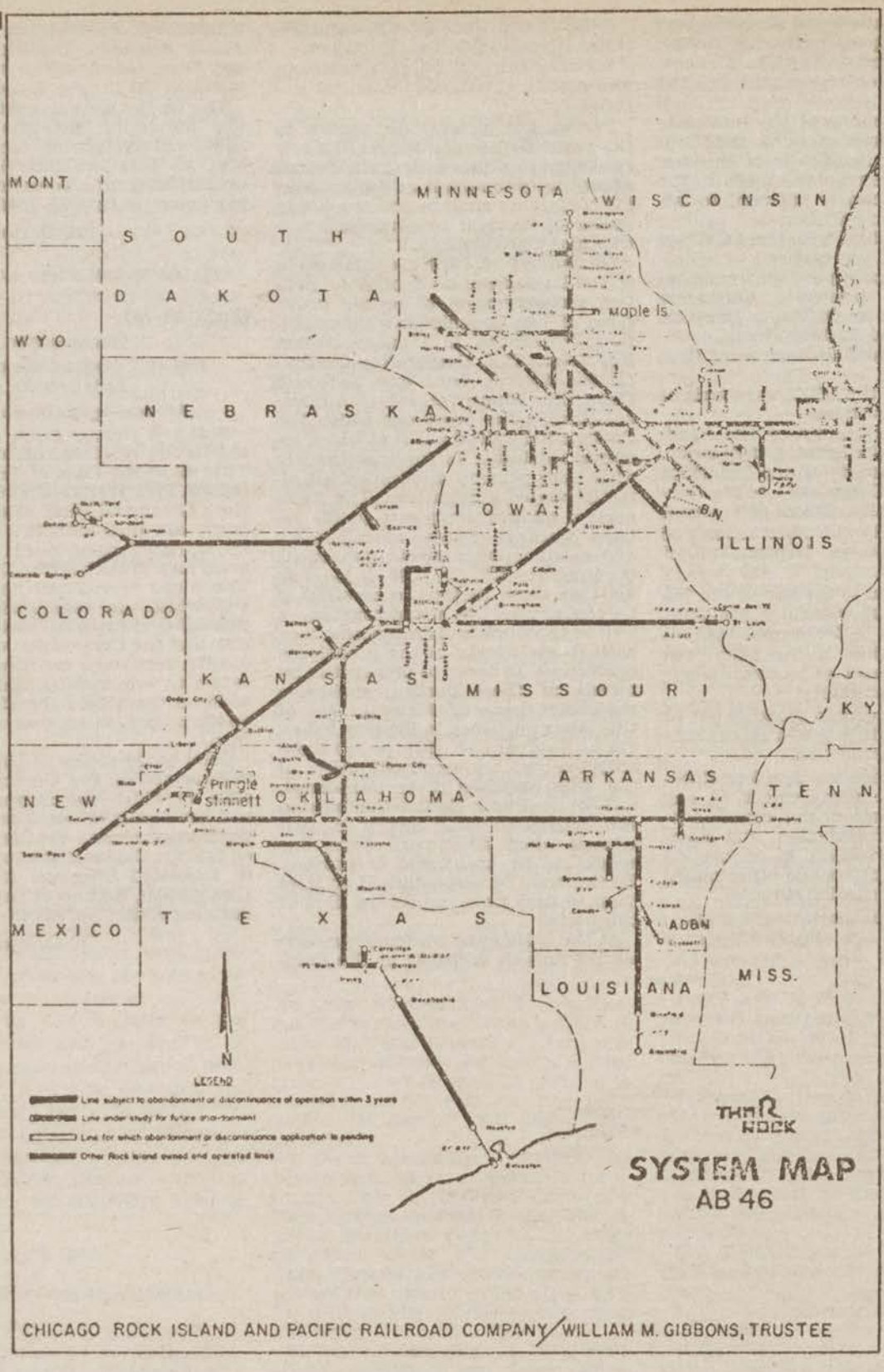
Amended System Diagram Map

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.

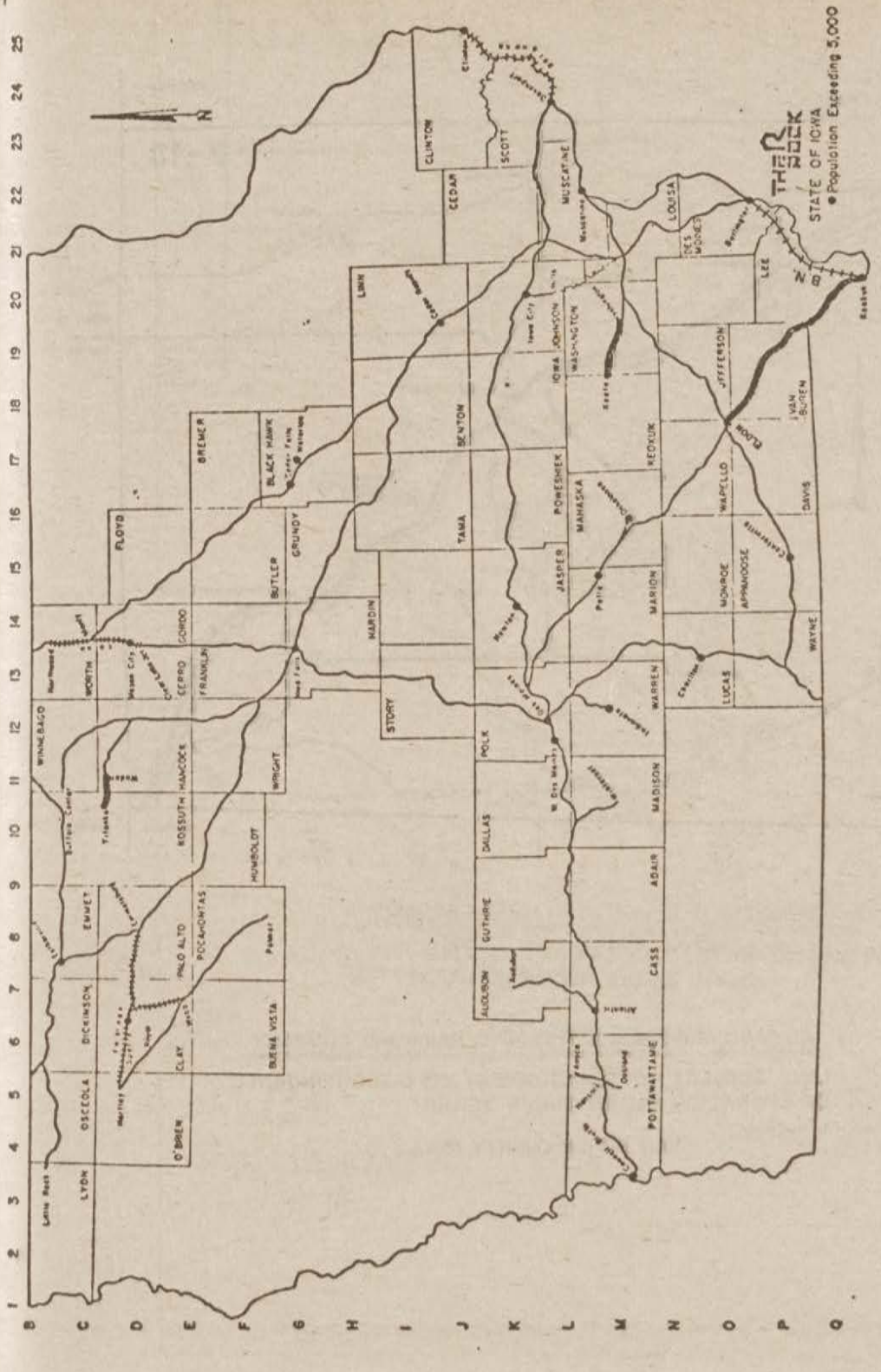
Color-coded copies of the map have been served on the Governor of each state in which the railroad operates and the Public Service Commission or similar agency and the State designated agency. Copies of the map may also be requested from the office of the Commission, Section of Dockets by requesting docket No. AB 46 (SDM).

H. G. HOMME, Jr.,
Secretary.

[7035-01-C]



CHICAGO ROCK ISLAND AND PACIFIC RAILROAD COMPANY/WILLIAM M. GIBBONS, TRUSTEE


THE ROCK
STATE OF IOWA
● Population Exceeding 5,000
CLINTON
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LEE
JEFFERSON
HENRY
VAN BUREN
DAVIS
WAPELLO
KEOKUK
IOWA
JOHNSON
WASHINGTON
LINN
BENTON
TAMA
POWESHIEK
MAHASKA
JASPER
MARION
MONROE
APPANOOSE
WAYNE
LUCAS
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CASS
POTTAWATTAMIE
AUDUBON
GUTHRIE
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STORY
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HARDIN
BUTLER
GRUNDY
BLACK HAWK
BREMER
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MITCHELL
HOWARD
GOROO
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HANCOCK
KOSSUTH
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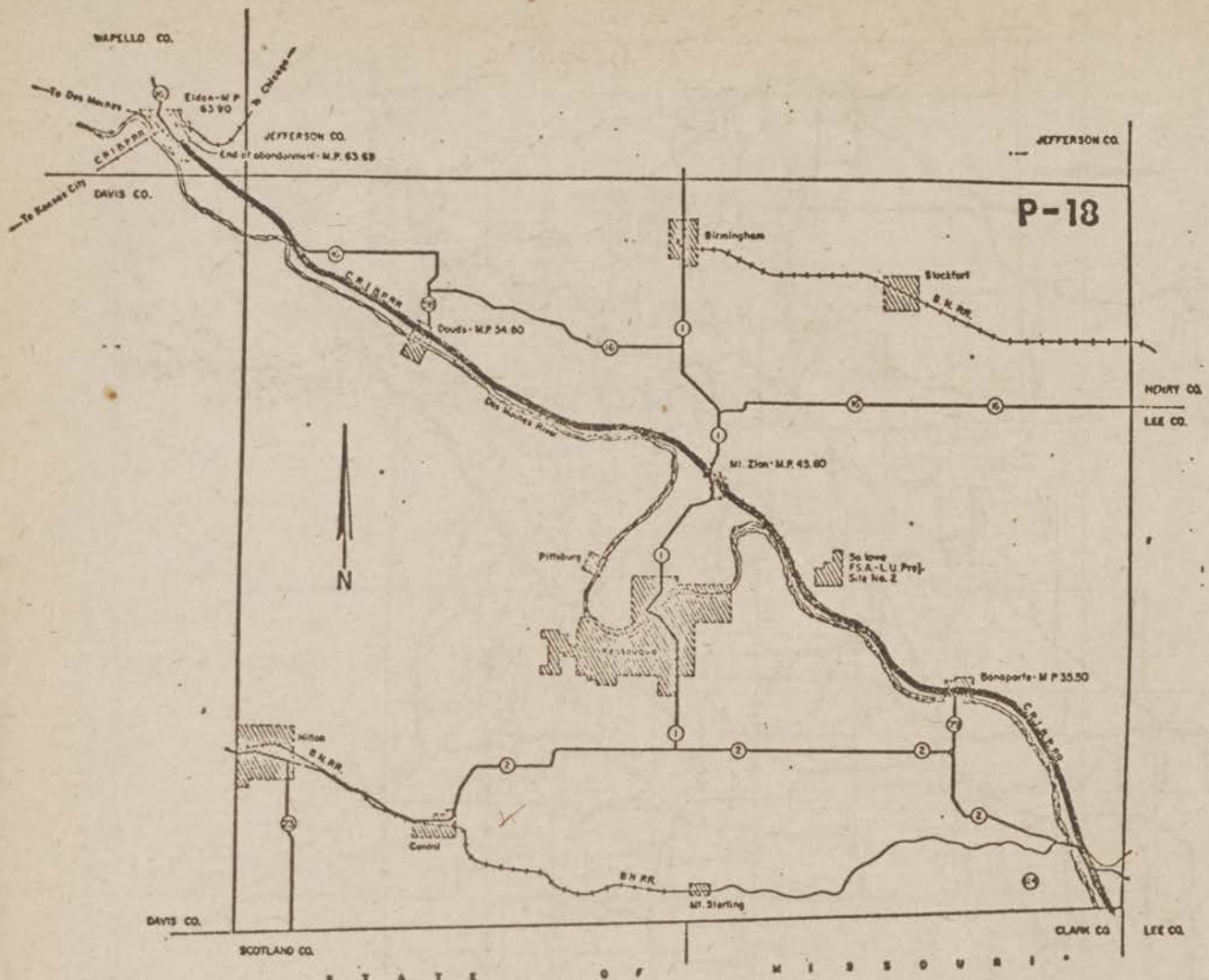
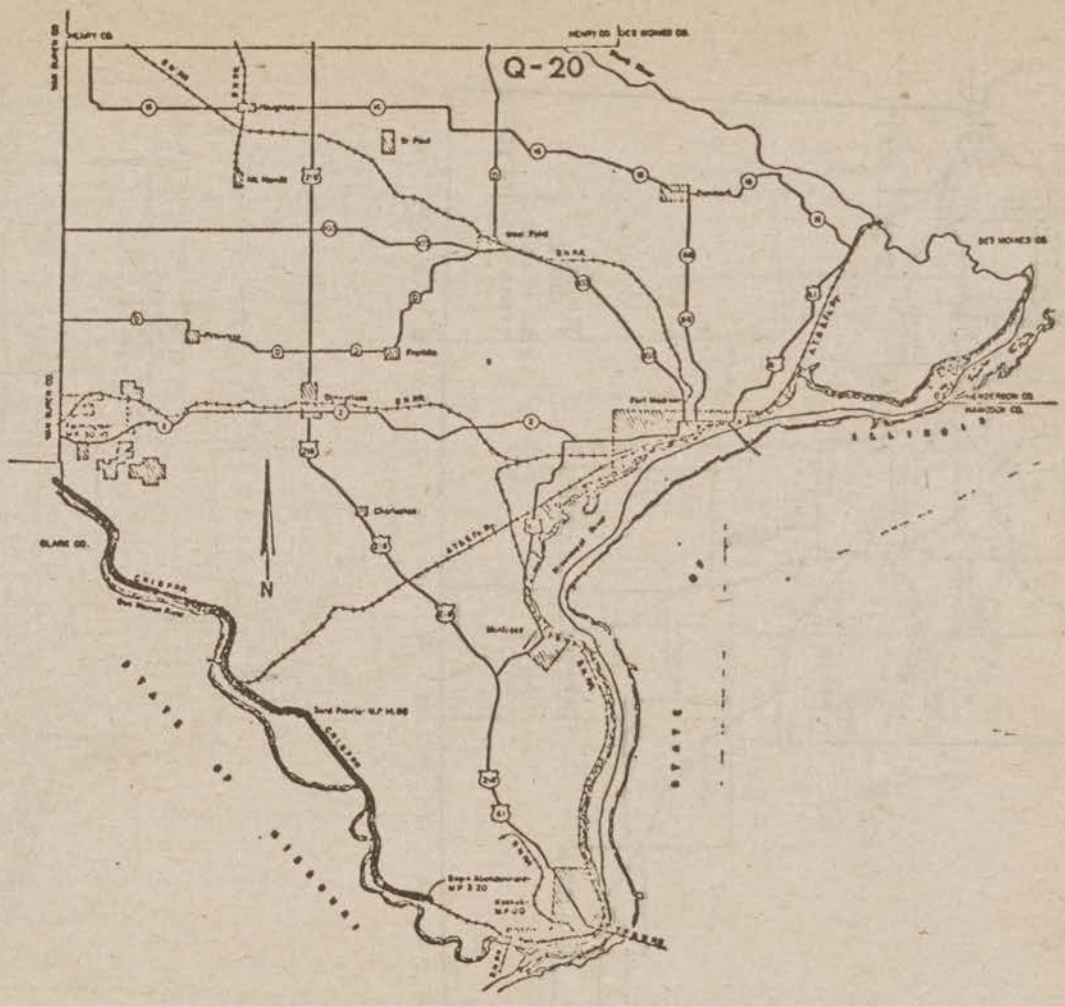


CHICAGO, ROCK ISLAND & PACIFIC RAILROAD COMPANY

LINE SUBJECT TO ABANDONMENT OR DISCONTINUANCE OF OPERATION WITHIN THREE YEARS

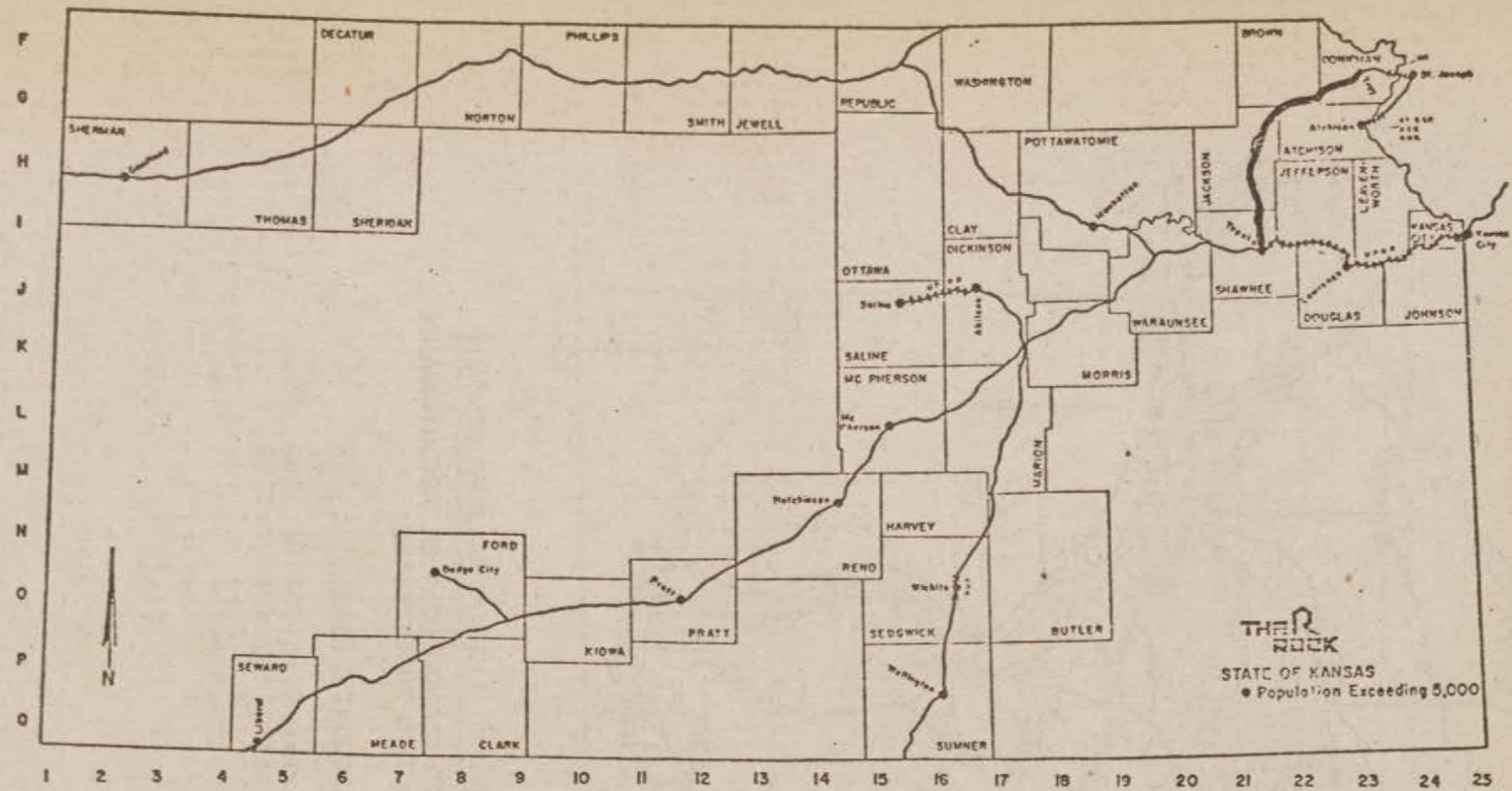
VAN BUREN COUNTY, IOWA



CHICAGO, ROCK ISLAND & PACIFIC RAILROAD COMPANY

LINE SUBJECT TO ABANDONMENT OR DISCONTINUANCE OF OPERATION WITHIN THREE YEARS

LEE COUNTY, IOWA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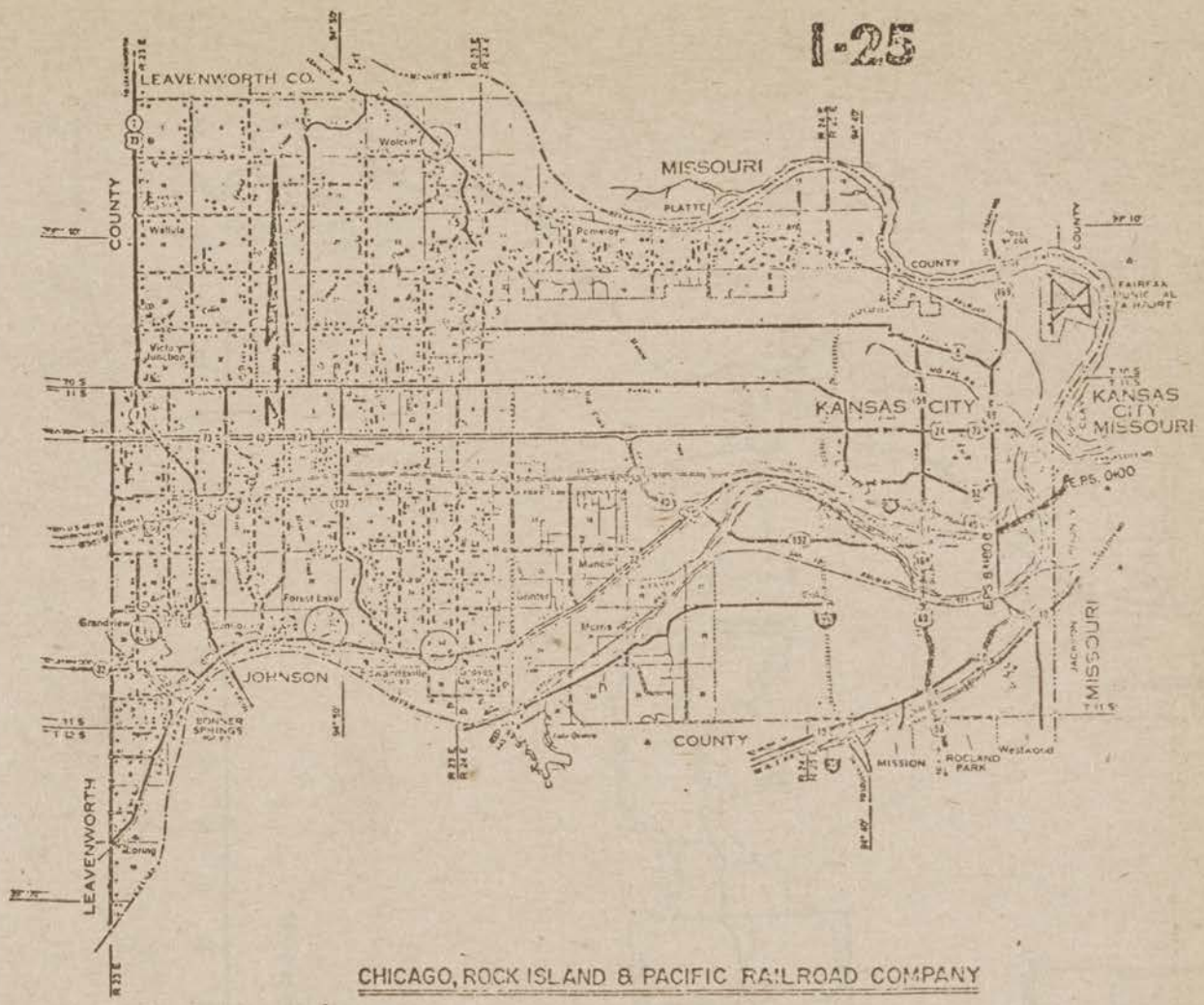
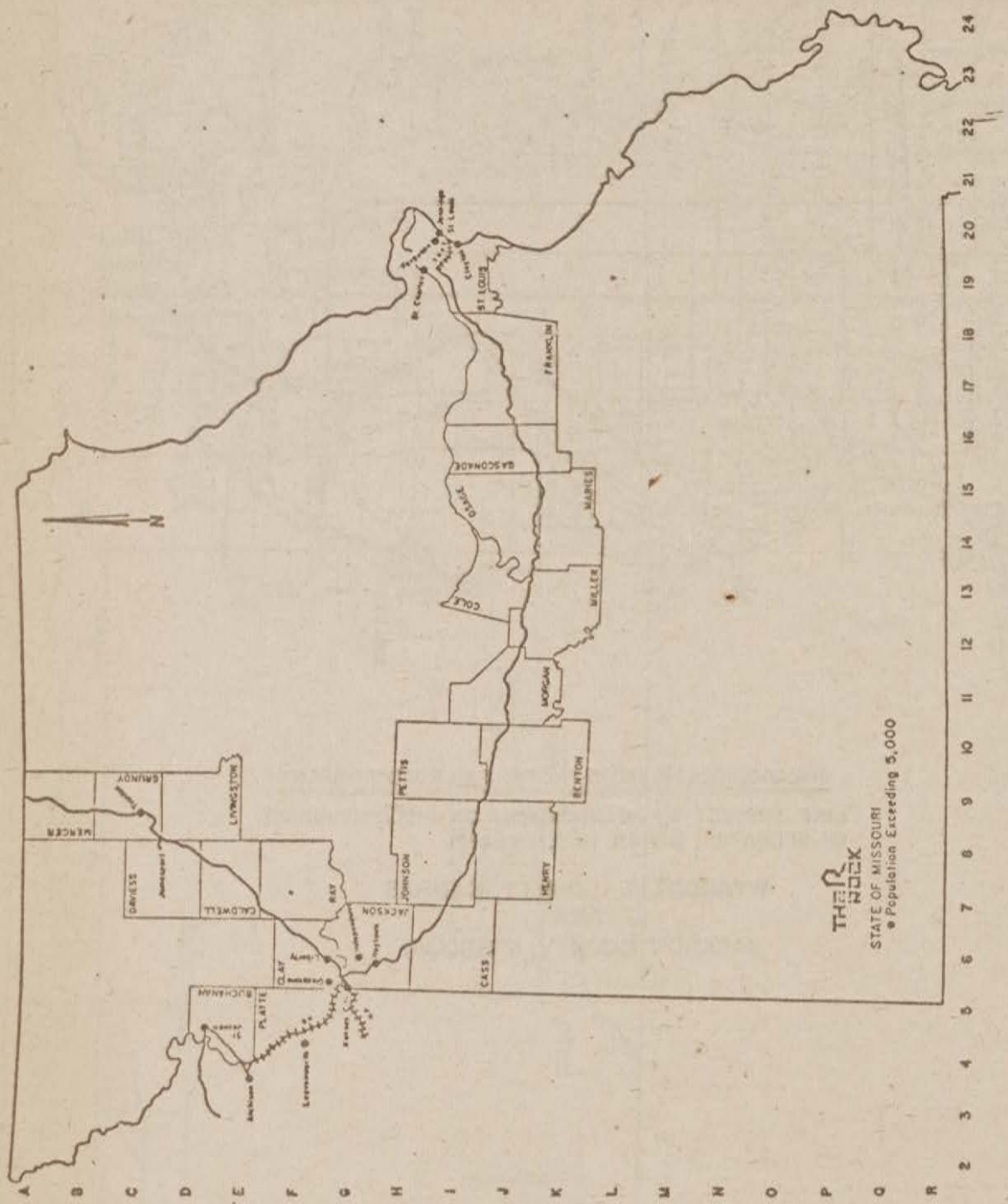


CHICAGO, ROCK ISLAND & PACIFIC RAILROAD COMPANY

LINE SUBJECT TO ABANDONMENT OR DISCONTINUANCE OF OPERATION WITHIN THREE YEARS

WYANDOTTE COUNTY, KANSAS
AND
JACKSON COUNTY, MISSOURI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STATE OF MISSOURI
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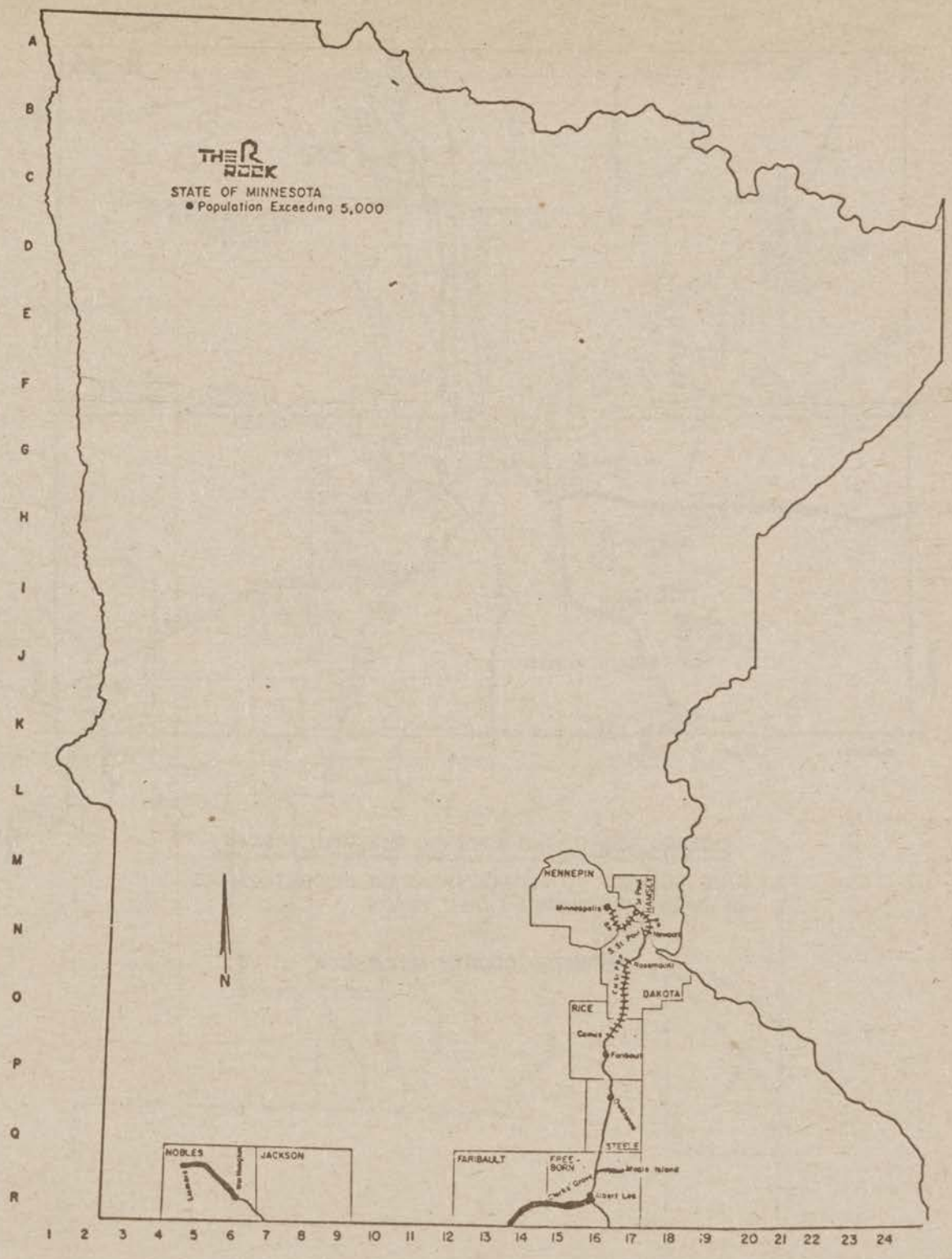
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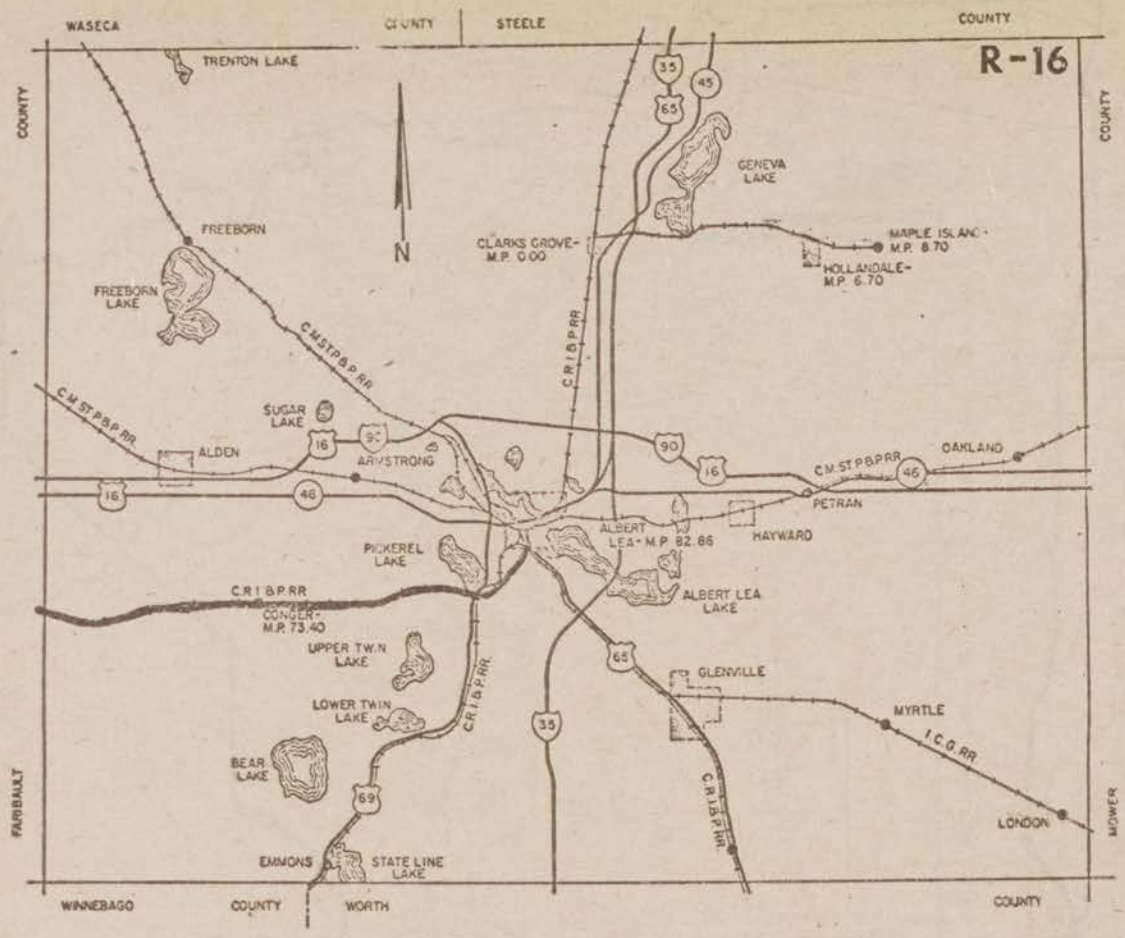
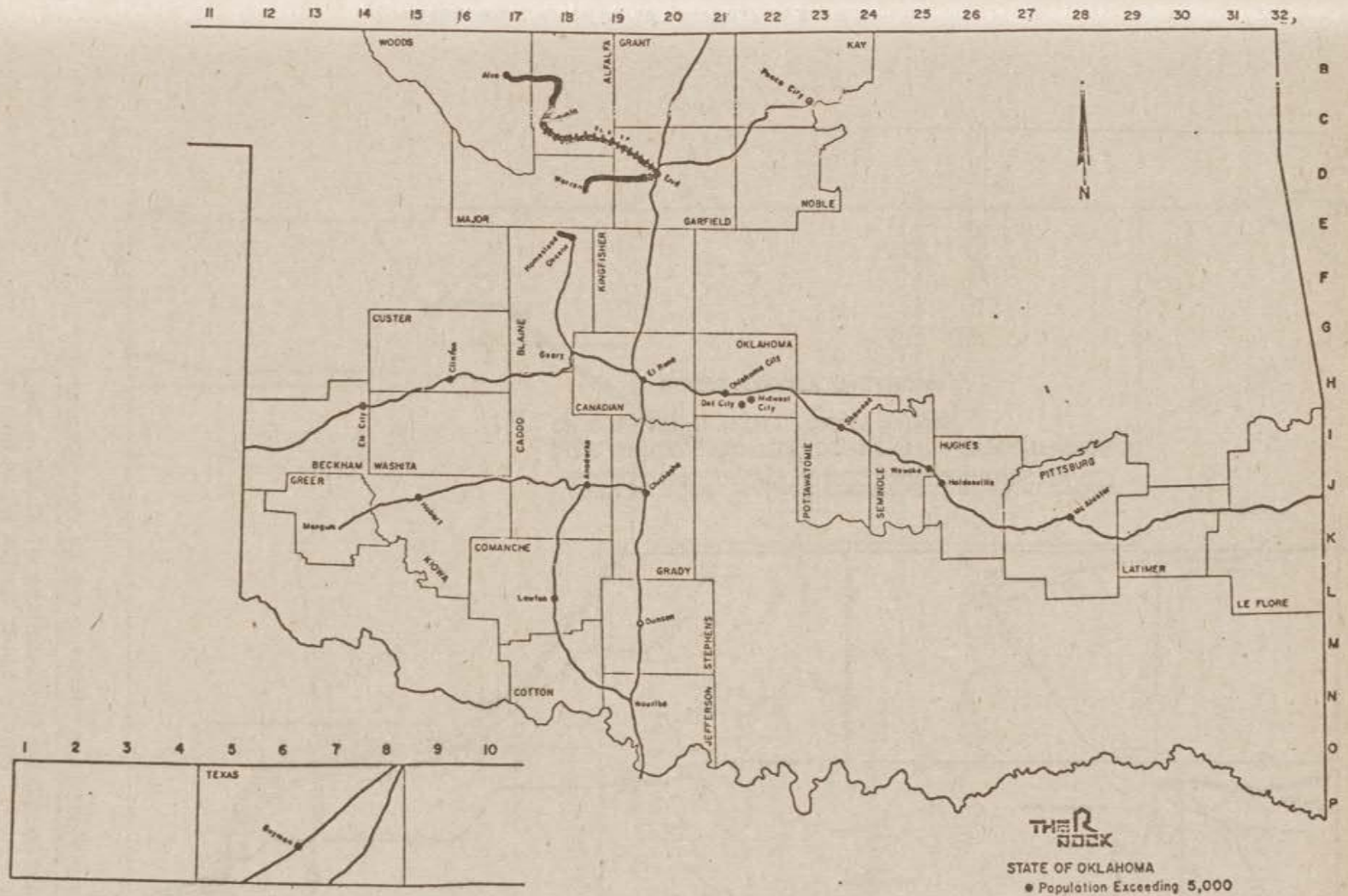
FREE-BORN
Albert Lea



CHICAGO, ROCK ISLAND & PACIFIC RAILROAD COMPANY

LINE SUBJECT TO ABANDONMENT OR DISCONTINUANCE OF OPERATION WITHIN THREE YEARS

FREEBORN COUNTY MINNESOTA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Clinton
Geary
El Reno
OKLAHOMA
Oklahoma City
Del City
Midwest City
CANADIAN
Chandler
Elk City
BECKHAM
WASHITA
CADDO
Anadarko
Chickasha
HUGHES
POTTAWATOMIE
SEMINOLE
Wewoka
Holdenville
PITTSBURG
McAlester
GREER
Mangum
Hobart
KIOWA
COMANCHE
Lawton
GRADY
Duncan
LATIMER
LE FLORE
STEPHENS
COTTON
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JEFFERSON
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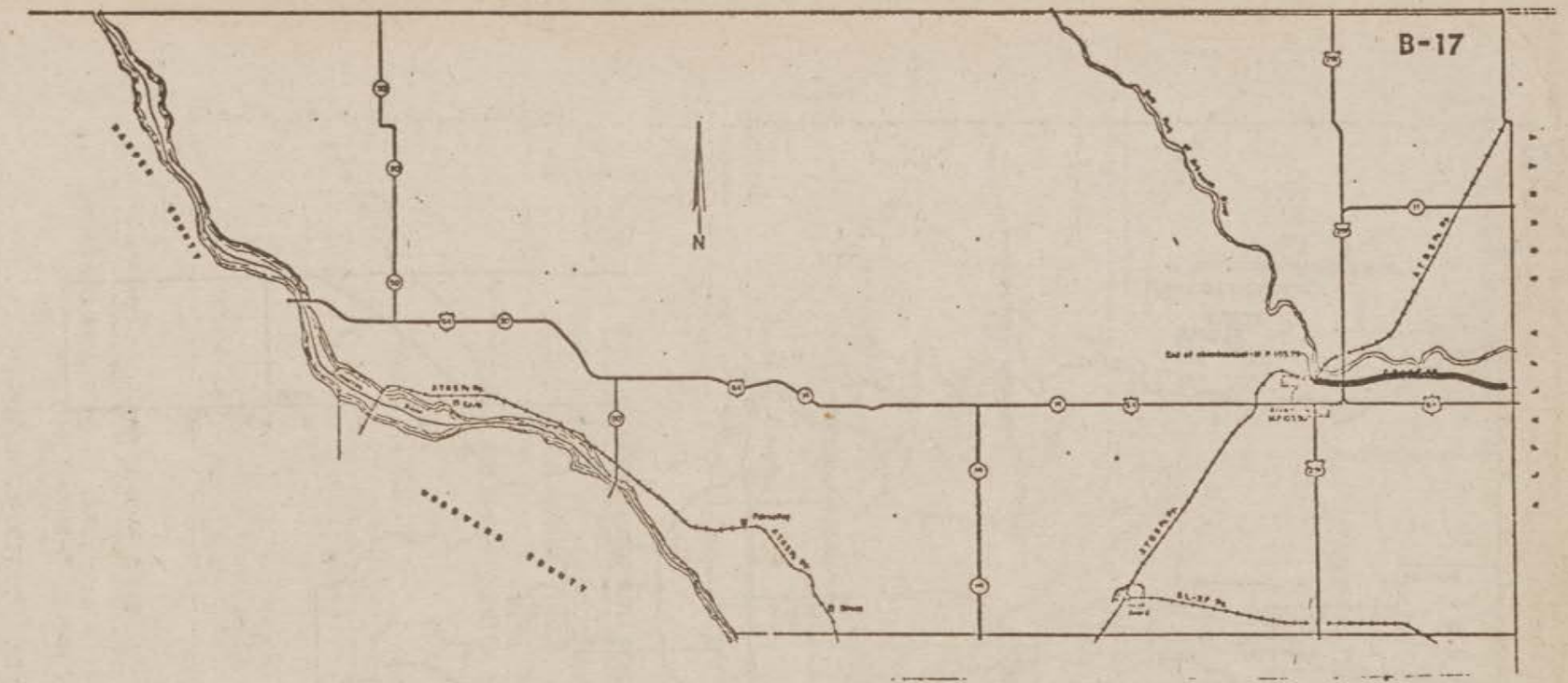
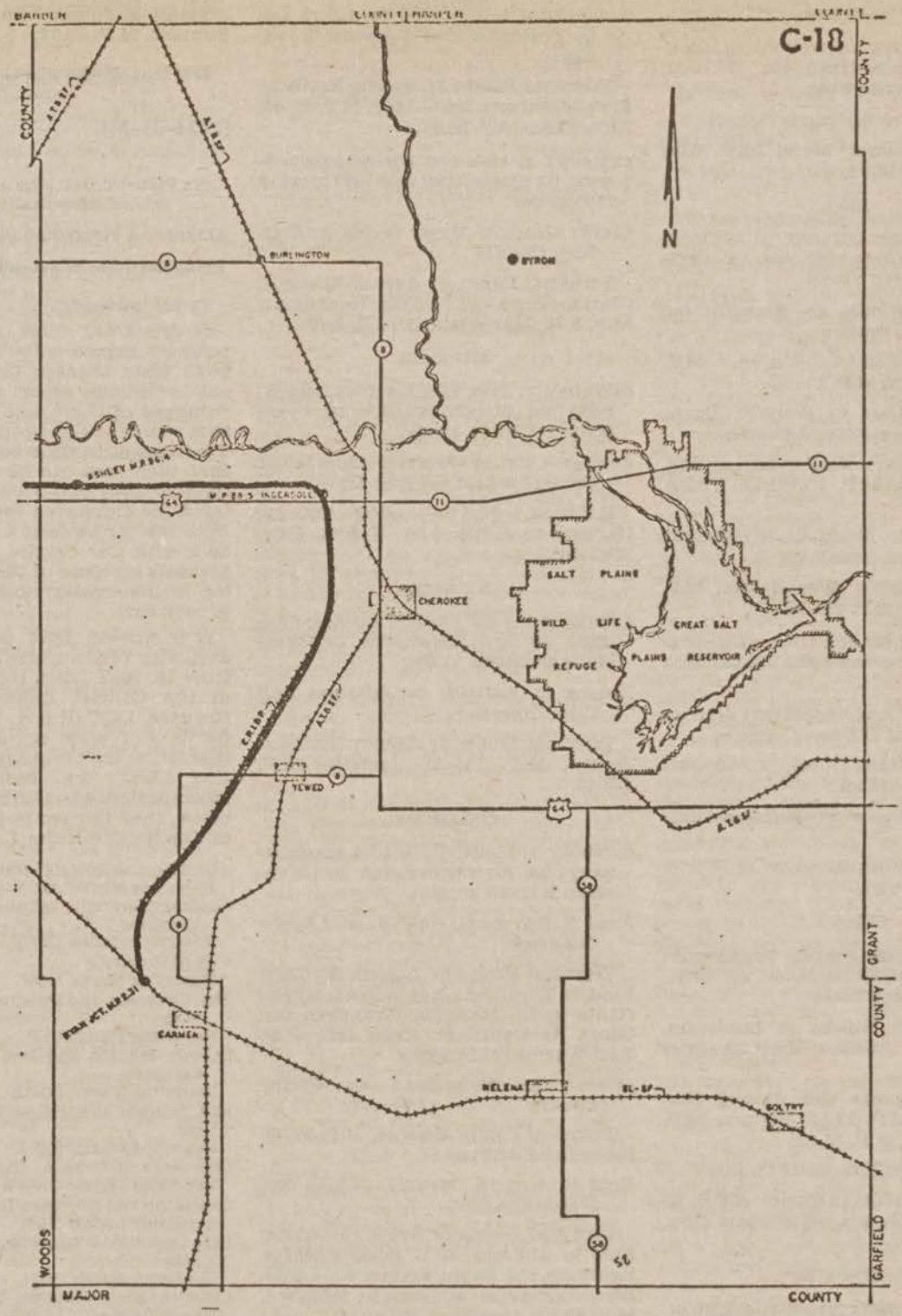
TEXAS
Bryson
THE ROCK
STATE OF OKLAHOMA
• Population Exceeding 5,000



CHICAGO, ROCK ISLAND & PACIFIC RAILROAD COMPANY

LINE SUBJECT TO ABANDONMENT OR DISCONTINUANCE OF OPERATION WITHIN THREE YEARS

WOODS COUNTY, OKLAHOMA



CHICAGO, ROCK ISLAND & PACIFIC RAILROAD COMPANY

LINE SUBJECT TO ABANDONMENT OR DISCONTINUANCE OF OPERATION WITHIN THREE YEARS

ALFALFA COUNTY, OKLAHOMA

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. 0.00; Des Arc, M.P. 14.98.

IOWA

CATEGORY 1: LINES SUBJECT TO ABANDONMENT OR DISCONTINUANCE OF OPERATION WITHIN 3 YEARS

Woden to Titonka in Kossuth and Hancock Counties

Terminal Points: Woden, M.P. 166.70; Titonka, M.P. 172.99.

Keokuk to Eldon in Wapello, Davis, Lee and Van Buren Counties

Terminal Points and/or Agency Stations: Keokuk, M.P. 3.20; Eldon, M.P. 63.90.

Washington to Keota in Washington and Keokuk Counties

Terminal Points: Washington, M.P. 248.20; Keota, M.P. 263.65.

CATEGORY 3: LINES FOR WHICH ABANDONMENT OR DISCONTINUANCE APPLICATION IS PENDING

Royal to (but not including) Hartley in Clay and O'Brien Counties

Terminal Points: Royal, M.P. 502.42; Hartley, M.P. 515.39.

Hancock to Avoca in Pottawattamie 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 and Agency Stations: Troy, M.P. 13.50; Horton, M.P. 40.80; Topeka, M.P. 85.30.

Kansas City in Wyandotte County

Central Industrial District: E.P.S. 83 + 80.6 to E.P.S. 0 + 00, Kansas City, Missouri.

MINNESOTA

CATEGORY 1: LINES SUBJECT TO ABANDONMENT OR DISCONTINUANCE OF OPERATION WITHIN 3 YEARS

Worthington to Lismore in Nobles County

Terminal Points or Agency Stations: Worthington, M.P. 254.70; Lismore, M.P. 275.77.

Rake, Iowa (State line) to Albert Lea in Faribault and Freeborn Counties

Terminal Points or Agency Stations: Iowa-Minnesota State Line, M.P. 51.48; Albert Lea, M.P. 82.47.

CATEGORY 3: LINE FOR WHICH ABANDONMENT OR DISCONTINUANCE APPLICATION IS PENDING

Clarks Grove to Maple Island in Freeborn County

Terminal Points or Agency Stations: Clarks Grove, M.P. 0.00; Hollandale, M.P. 6.70; Maple Island, M.P. 8.70.

MISSOURI

CATEGORY 1: LINE SUBJECT TO ABANDONMENT OR DISCONTINUANCE OF OPERATION WITHIN 3 YEARS

Kansas City in Jackson County, in Central Industrial District

E.P.S. 83 + 80.6 (Wyandotte County, Kansas) to E.P.S. 0.00, Kansas City, Missouri.

NEBRASKA

CATEGORY 1: LINE SUBJECT TO ABANDONMENT OR DISCONTINUANCE OF OPERATION WITHIN 3 YEARS

Jansen to Beatrice in Jefferson and Gage Counties

Terminal Points or Agency Stations: Jansen, M.P. 148.20; Beatrice, M.P. 128.43.

OKLAHOMA

CATEGORY 1: LINES SUBJECT TO ABANDONMENT OR DISCONTINUANCE OF OPERATION WITHIN 3 YEARS

Enid to Warren in Garfield and Major Counties

Terminal Points or Agency Stations: Enid to Ryan Jct., 3.44 miles trackage rights on St. Louis-San Francisco and Santa Fe Railroads; Ryan Jct., M.P. 2.31; Warren, M.P. 24.00.

Okeene to Homestead in Blaine County

Terminal Points: Okeene, M.P. 37.30; Homestead, M.P. 42.80.

Enid to Alva in Garfield, Alfalfa and Woods Counties

Terminal Points or Agency Stations: Enid to Augusta, 39.21 miles trackage rights on the Santa Fe and St. Louis-San Francisco Railroads; Augusta, M.P. 72.17; Alva, M.P. 103.79.

TEXAS

CATEGORY 1: LINE SUBJECT TO ABANDONMENT OR DISCONTINUANCE OF OPERATION WITHIN 3 YEARS

Pringle to Stinnett in Hutchinson County

Terminal Points: Pringle, M.P. 66.47; Stinnett, M.P. 56.82.

[FR Doc. 79-6539 Filed 3-8-79; 8:45 am]

[7035-01-M]

[Ex Parte No. 241, 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 below own numerous 50-ft. plain 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, Placeveille & Lake Tahoe Railroad Company
Reporting Marks: CPLT
City of Prineville
Reporting Marks: COP
The Clarendon and Pittsford Railroad Company
Reporting Marks: CLP
Duluth, Missabe and Iron Range Railway Company
Reporting Marks: DMIR
East Camden & Highland Railroad Company
Reporting Marks: EACH
Genessee and Wyoming Railroad Company
Reporting Marks: GNWR
Greenville and Northern Railway Company
Reporting Marks: GRN
Lake Superior & Ishpeming Railroad Company
Reporting Marks: LSI
Lenawee County Railroad Company, Inc.
Reporting Marks: LCRC
Louisiana Midland Railway Company
Reporting Marks: LOAM
Louisville and Wadley Railway Company
Reporting Marks: LW
Louisville, New Albany & Corydon Railroad Company
Reporting Marks: LNAC
Manufacturers Railway Company
Reporting Marks: MRS

Middletown and New Jersey Railway Company, Inc.
Reporting Marks: MNJ
XXX[1]
New Orleans Public Belt Railroad
Reporting Marks: NOPB
Oregon & Northwestern Railroad Co.
Reporting Marks: ONW
Oregon, Pacific and Eastern Railway Company
Reporting Marks: OPE
Pearl River Valley Railroad Company
Reporting Marks: PRV
Peninsula Terminal Company
Reporting Marks: PT
Raritan River Rail Road Company
Reporting Marks: RR
Sacramento Northern Railway
Reporting Marks: SN
St. Lawrence Railroad
Reporting Marks: NSL
Sierra Railroad Company
Reporting Marks: SERA
Terminal Railway, Alabama State Docks
Reporting Marks: TASD
The Texas Mexican Railway Company
Reporting Marks: TM
Tidewater Southern Railway Company
Reporting Marks: TS
Toledo, Peoria & Western Railroad Company
Reporting Marks: TPW
Vermont Railway, Inc.
Reporting Marks: VTR
WCTU Railway Company
Reporting Marks: WCTR
Youngstown & Southern Railway Company
Reporting Marks: YS
Yreka Western Railroad Company
Reporting Marks: YW

Effective February 15, 1979, and continuing in effect until further order of this Commission.

Issued at Washington, D.C., February 12, 1979.

INTERSTATE COMMERCE COMMISSION,
JOEL E. BURNS,
Agent.

[FR Doc. 79-7204 Filed 3-8-79; 8:45 am]

[1] XXX Missouri-Kansas-Texas Railroad Company deleted.

[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 cancellation or postponements of hearings in which they are interested.

CORRECTION [1]

MC 128527 (Sub-20), May Trucking Company, now assigned for hearing March 19, 1979 (3 days), instead of May 19, 1979, at Portland, Oregon, in a hearing room to be later designated.

H. G. HOMME, Jr.,
Secretary.

[FR Doc. 79-7198 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 cancellation or postponements of hearings in which they are interested.

MC 42846 (Sub-6F), Debolt Somerset Bus Company, now assigned for hearing on March 12, 1979, at Greensburg, Pennsylvania, and will be held in Mountain View Inn, U.S. Highway 30 (East of Greensburg).
MC 114211 (Sub-370F), Warren Transport, Inc., now assigned March 13, 1979, at Chicago, Illinois, is canceled and transferred to Modified Procedure.
MC 115826 (Sub-299F), W. J. Digby, Inc., now assigned April 11, 1979, at Dallas, Texas, is canceled and reassigned April 11, 1979 (3 days), at Amarillo, Texas, in a hearing room to be later designated.
MC 125433 (Sub-160F), F-B Trick Line Company, now assigned March 12, 1979, at San Francisco, California, is canceled transfered to Modified Procedure.
MC 145059 (Sub-3F), Spinelli Bros. Trucking, Inc., now assigned March 14, 1979, at Philadelphia, Pennsylvania, is canceled transferred to Modified Procedure.
MC 51146 (Sub-598F), Schneider Transport, Inc., now assigned for hearing on March 22, 1979, at Chicago, Illinois, and will be held in Room 349, 230 South Dearborn Street.
MC 123048 (Sub-406F), Diamond Transportation System, Inc., now assigned for hearing on March 21, 1979, at Chicago, Illinois, and will be held in Room 349, 230 South Dearborn Street.
MC 119765 (Sub-53F), Eight Way Express, Inc., now assigned for hearing on March 20, 1979, at Chicago, Illinois, and will be held in Room 349, 230 South Dearborn Street.
MC 117604 (Sub-11), Early Rival Motor Express, Inc., now assigned for hearing on March 19, 1979, at Atlanta, Georgia, and will be held in American Motor Hotel, 160 Spring Street, NW.

H. G. HOMME, Jr.,
Secretary.

[FR Doc. 79-7199 Filed 3-8-79; 8:45 am]

[1] This notice corrects hearing date for No. MC 128527 Sub-20.

[7035-01-M]

[Ex Parte No. 241, Rule 19, Exemption No. 159]

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 car owners in accordance with Car Service Rules 1 and 2. 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 regardless of the provisions of Car Service Rules 1 and 2.

(b) This exemption is applicable to general service freight cars bearing reporting marks assigned to railroads listed 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 the following mechanical designations:

Plain Boxcars: "XM", "XMI"
Gondola Cars: "GA", "GB", "GD", "GH", "GS", "GT"
Hopper Cars: "HFA", "HK", "HM", "HMA", "HT", "HTA"
Flat Cars: "FM", less than 200,000 lb. capacity

It is further ordered,

(c) This exemption shall not apply to cars of Mexican or Canadian ownership or to cars subject to Interstate Commerce Commission or Association of American Railroads' Orders requiring return of cars to owners.

Effective 12:01 a.m. February 20, 1979.

Expires March 15, 1979.

Issued at Washington, D.C., February 16, 1979.

INTERSTATE COMMERCE COMMISSION,
JOEL E. BURNS,
Agent.

[FR Doc. 79-7197 Filed 3-8-79; 8:45 am]

[7035-01-M]

[Service Order No. 1344, I.C.C. Order No. 22, Amdt. No. 3]

CHICAGO, MILWAUKEE, ST. PAUL & PACIFIC RAILROAD CO.

Rerouting Traffic

Upon further consideration of I.C.C. Order No. 22, and good cause appearing therefor:

It is ordered,

I.C.C. Order No. 22 is amended by substituting the following paragraph (g) for paragraph (g) thereof:

(g) *Expiration date.* This order shall expire at 11:59 p.m., March 9, 1979, unless otherwise modified, changed or suspended.

Effective date. This amendment shall become effective at 11:59 p.m., February 23, 1979.

This amendment 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. A copy of this amendment shall be filed with the Director, Office of the Federal Register.

Issued at Washington, D.C., February 23, 1979.

INTERSTATE COMMERCE COMMISSION,
JOEL E. BURNS,
Agent.

[FR Doc. 79-7201 Filed 3-8-79; 8:45 am]

[7035-01-M]

Ex Parte No. 241, Rule 19, Revised Exemption No. 155-A]

MANDATORY CAR SERVICE RULES

Exemption

To: *all railroads.*

Upon further consideration of Exemption No. 155 issued January 19, 1979.

It is ordered, That, under authority vested in me by Car Service Rule 19, Revised Exemption No. 155 to the Mandatory Car Service Rules ordered in Ex Parte No. 241 is vacated and set aside.

This order shall become effective 12:01 a.m., February 20, 1979.

Issued at Washington, D.C., February 16, 1979.

INTERSTATE COMMERCE COMMISSION,
JOEL E. BURNS,
Agent.

[FR Doc. 79-7202 Filed 3-8-79; 8:45 am]

[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, 312(b), and 410(g) of the Interstate Commerce Act.

Each application (except as otherwise specifically noted) contains a statement by applicants that there will be no significant effect on the equality 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 seasonably to file a protest will be construed as a waiver of opposition and participation in the proceeding. A protest must be served upon applicants' representative(s), or applicants (if no such representative is named), and the protestant must certify that such service has been made.

Unless otherwise specified, the signed original and six copies of the protest shall be filed with the Commission. All protests must specify with particularity the factual basis, and the section of the Act, or the applicable rule governing the proposed transfer which protestant believes would preclude approval of the application. If the protest contains a request for oral hearing, the request shall be supported by an explanation as to why the evidence sought to be presented cannot reasonably be submitted through the use of affidavits.

The operating rights set forth below are in synopses form, but are deemed sufficient to place interested persons on notice of the proposed transfer.

FD 28956, filed February 7, 1979. Transferee: WASHINGTON BOAT LINES, INC., 2140 Pennsylvania Avenue, N.W., Washington, D.C. 20037. Transferor: WILSON LINE OF WASHINGTON, INC., (Charles A. Docter, Esq., Trustee in Bankruptcy), 1707 H Street, N.W. (Suite 801); Washington, D.C. 20006. Representative: Robert R. Redmon, 1800 Massachusetts Avenue, N.W., Suite 512, Washington, D.C. 20036. By decision entered March 2, 1979, the Commission, Motor Carrier Board authorized the transfer to transferee of the operating rights set forth in Certificate No. W-1124 (Sub No. 4), served January 25, 1962, as follows: Operation, as a common carrier, in interstate and foreign commerce, by self propelled vessels, in the transportation of passengers from Washington, D.C. to Mt. Vernon, Virginia, and Marshall Hall, Maryland, and return, and on cruises on the Potomac River out of Washington, D.C. and Alexandria, Virginia. Transferee presently holds no authority from this Commission.

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 210a(a) of the Interstate Commerce Act provided for under the provisions of 49 CFR 1131.3. These rules provide that an original and six (6) copies of protests to an application may be filed with the field official named in the FEDERAL REGISTER publication no later than the 15th calendar day after the date the notice of the filing of the application is published in the FEDERAL REGISTER. One copy of the protest must be served on the applicant, or its authorized representative, if any, and the protestant must certify that such service has been made. The protest must identify the operating authority upon which it is predicated, specifying the "MC" docket and "Sub" number and quoting the particular portion of authority upon which it relies. Also, the protestant shall specify the service it can and will provide and the amount and type of equipment it will make available for use in connection with the service contemplated by the TA application. The weight accorded a protest shall be governed by the completeness and pertinence of the protestant's information.

Except as otherwise specifically noted, each applicant states that there will be no significant effect on the quality of the human environment resulting from approval of its application.

A copy of the application is on file, and can be examined at the Office of the Secretary, Interstate Commerce Commission, Washington, D.C., and also in the ICC Field Office to which protests are to be transmitted.

NOTE.—All applications seek authority to operate as a common carrier over irregular routes except as otherwise noted.

MOTOR CARRIERS OF PROPERTY

MC 111 (Sub-14TA), filed February 1, 1979. Applicant: VIGEANT MOTOR FREIGHT, INC., 6 Claflin Street, Boston, Mass. 02127. Representative: Joseph R. Siegelbaum, 17 Academy Street, Newark, NJ 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 authority. Supporting shipper(s): 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 730 (Sub-429TA), filed February 2,1979. Applicant: PACIFIC INTERMOUNTAIN EXPRESS CO., 25 N. Via Monte, Walnut Creek, CA 94595. Representative: Edgar E. Reddick (same address as applicant). Common carrier: regular routes: *Railway 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 offroute point in connection with carrier's authorized regular route nationwide operations, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): 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 94105.

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 Storm Lake, IA to points in CT, DE, FL, GA, IL, IN, KY, LA, ME, MA, MD, MI, MO, MS, NE, NH, NJ, NY, NC, OH, OK, PA, RI, SC, TX, VT, VA, WV, and DC restricted to traffic originating at the named origin for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Hygrade Food Products Corporation, P.O. Box 4771, Detroit, Michigan 48212. Send protests to: Vernon V. Coble, District Supervisor, Interstate Commerce Commission, 600 Federal Building, 911 Walnut Street, Kansas City, Missouri 64106.

MC 2900 (Sub-356TA), 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 facilities of the Dana Corporation at or near Edgerton, WI, and Syracuse, IN, restricted to the transportation of shipments originating at the named origin and destined to named destinations, for 180 days. Supporting shipper(s): Parish Division, Dana Corp., P.O. Box 1422, Reading, PA 19603. Send protests to: G. H. Fauss, Jr., DS, ICC, Box 35008, 400 West Bay Street, Jacksonville, FL 32202.

MC 4405 (Sub-589TA), filed February 2, 1979. Applicant: DEALERS TRANSIT, INC., P.O. Box 236, 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, IN, IA, MI, MN, MS, NC, OH, SC, TN, VA, WI, KY, and DC, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Culpepper Lumber Company, Inc., P.O. Box 218, Dearing, GA 30808. Send protests to: Connie Stanley, Transportation Assistant, Interstate Commerce Commisson, 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) Between plantsites of Wheeling-Pittsburgh Steel Corporation at Canfield, Martins Ferry, Mingo Junction, Steubenville and Yorkville, OH; Beech Bottom, Benwood Follansbee and Wheeling, WV; and Allenport and Monessen, PA.; restricted to shipments originating at or destined to the above-named facilities. (2) From plantsite 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 shipper(s): Wheeling-Pittsburgh Steel Corporation, P. O. Box 118, Pittsburgh, PA 15230. Send Protests to: J. A. Niggemyer 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: Beery & 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, Classes A 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 carrier's 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 shipper(s): Paoli Chair Company, P.O. Box 30, 524 E. Third St., Paoli, IN 47454. Send protests to: I.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 180 days. An underlying ETA has been granted. Supporting shipper(s): Midwest Steel Division, National Steel Corp., Route 12, Portage, IN 46368. 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 shipper(s): 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, 58 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 Shipper(s): National Can Corporation, 8101 West Higgins Road, Chicago, Illinois 60631. Send protests to: Vernon V. Coble, District Supervisor, Interstate Commerce Commission, 600 Federal Building, 911 Walnut Street, Kansas City, Missouri 64106.

MC 35807 (Sub-92TA), filed January 29, 1979. Applicant: WELLS FARGO ARMORED SERVICE CORPORA-

TION, P.O. Box 4313, Atlanta, Georgia 30302. Representative: Steven J. Thatcher, P.O. Box 4313, Atlanta, Georgia 30302. *Coin, Currency & securities* between New Orleans, LA and points in LA, for 180 days. An underlying ETA seeks 90 day authority. Supporting Shipper(s): Federal Reserve Bank of Atlanta, 104 Marietta Street, N.W., Atlanta, Georgia 30033. Send protests to: Sara K. Davis, T/A, ICC, 1252 W. Peachtree St., N.W., Atlanta, Georgia 30309.

MC 41404 (Sub-155TA), filed January 31, 1979. Applicant: ARGO-COLLIER TRUCK LINES CORPORATION, P.O. Drawer 440, Fulton Highway, Martin, TN 38237. Representative: Mark L. Horne (same as applicant). *Foodstuffs* (except in bulk) from the facilities or utilized by J. H. Filbert, Inc., in Fulton, Clayton, DeKalb, Cobb, and Douglas Counties, GA to points in AL, IL, IN, KY, LA, MS, NC, SC, and TN, for 180 days. Supporting Shipper(s): J. H. Filbert, Inc., 3701 Southwestern Boulevard, Baltimore, MD 21229. 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 48441 (Sub-30TA), filed January 23, 1979. Applicant: R.M.E. Inc., P.O. Box 418, Streator, IL 61364. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 Eleventh Street, N.W., Washington, D.C. 20001. (1) *Commodities dealt in by wholesale, retail and chain grocery stores and food business houses 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., Checkerboard Square, St. Louis, MO 63188. Supporting Shipper(s): TA Annie Booker, 219 S. Dearborn St. Rm. 1386, Chicago, IL 60604.

MC 51146 (Sub-676TA), filed February 1, 1979. Applicant: SCHNEIDER TRANSPORT, INC., P.O. Box 2298, Green Bay, WI 54306. Representative: John R. Patterson, 2480 E. Commercial Blvd., Ft. Lauderdale, FL 33308. *Plastic articles* (except in bulk) from the facilities of Mobil Chemical Co., Plastics Div. at Frankfort 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: Gail Daugherty, 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 2, 1979. Applicant: RICE TRUCK LINES, P.O. Box 2644, Great Falls, MT 59403. Representative: Ray F. Koby, P.O. Box 2567, Great Falls, MT 59403. *Fuel oil*, in bulk, from Farmington, NM to the facilities of CF&I Steel Corp. located at or near Pueblo, CO, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Parish Oil, Inc., 4739 Utica St., Suite 206, Metairie, LA 70002. Send protests to: Paul J. Labane, DS, ICC, 2602 First Avenue North, Billings, MT 59101.

MC 53965 (Sub-146TA), filed February 5, 1979. Applicant: GRAVES TRUCK LINE, INC., 2130 South Ohio, Salina, KS 67401. Representative: William B. Barker, 641 Harrison St., 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, 61 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 Commercial Zone to pts. in KS, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): John Morrell & Co., 208 S. LaSalle St., Chicago, IL 60604. Send protests to: Thomas P. O'Hara, D/S, ICC 256 Federal Bldg. & U.S. Courthouse, Topeka, KS 66683.

MC 55896 (Sub-111TA), filed February 2, 1979. Applicant: R-W SERVICE SYSTEM, INC., 20225 Goddard Rd., Taylor, MI 48180. Representative: Edwin M. Snyder, 22375 Haggerty Rd., P.O. Box 400, Northville, MI 48167. *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, MI, OH, PA, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Allen Canning Company, P.O. Box 250, 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 59457 (Sub-42TA), filed February 1, 1979. Applicant: SORENSEN TRANSPORTATION CO., INC., 6 Old Amity Road, Bethany, Connecticut 06525. Representative: Gerald A. Joseloff, 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, New York, NY; 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 Atlanta, GA to Charlotte, NC, for 180 days. Supporting Shipper(s): Time, Incorporated, Time & Life Building, Rockefeller Center, New York, NY 10020. Send protests to: J. D. Perry Jr., DS, ICC, 135 High Street, Hartford, CT 06103.

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 22567, Jackson, MS 39204. *Common carrier:* Regular and irregular routes: *General commodities* (except those of unusual value, Classes A and B explosives, commodities in bulk, commodities requiring special equipment, and household goods as defined by the Commission) (1) 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 south of and including Senatobia, MS; and (2) between Memphis, TN, on the one hand, 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 Winona, MS, then over U.S. Hwy 82 to the MS-AL State line (except Starkville, Columbus and Macon, MS). NOTE: Applicant 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 which 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 73688 (Sub-84TA), filed February 2, 1979. Applicant: SOUTHERN TRUCKING CORPORATION, P.O. Box 7195, 1500 Orenda Avenue, Memphis, TN 38107. Representative: Robert E. Tate, P.O. Box 517, Evergreen, AL 36401. (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, filters, materials, supplies, and equipment* as are used in the manufacture, sale, and distribution of the commodities named in Part 1 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. Restricted in Parts I and II above to shipments originating at or destined to the facilities of Quaker State Oil Refining Corporation located 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 85970 (Sub-17TA), filed January 4, 1979. Applicant: SARTAIN TRUCK LINE, INC., 1625 Hornbrook Street, Dyersburg, TN 38107. Representative: Mr. William H. Pendleton (same address as applicant). Authority sought to operate as a *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 subs thereunder. Applicant further intends to interline with other carriers at Memphis, 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 500, 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 95540 (Sub-1073TA), filed February 2, 1979. Applicant: WATKINS MOTOR LINES, INC., 1144 West Griffin Road, P.O. Box 1636, Lakeland, FL 33802. Representative: Benjy W. Fincher (same address as applicant). *Meats, meat products, meat by-products* and *articles distributed by meat packinghouses*, as described in Section A of Appendix I to the Report in Descriptions in Motor Carrier Certificates 61 MCC 209 and 766 (except hides and commodities in bulk) from Huron, SD to points in AL, FL, GA, MS, NC, SC, and TN for 180 days. Supporting shipper(s): Armour Fresh Meat Company, 111 W. Clarendon, Greyhound Tower, Phoenix, AZ 85077. Send protests to: Donna M. Jones, Transportation Assistant, Interstate Commerce Commission, BOp, Monterey Building, Suite 101, 8410 N.W. 53rd Terrace, Miami, FL 33166.

MC 96607 (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 may be examined at the office listed below and Headquarters. Send protests to: Shirley M. Holmes, T/A, ICC, 858 Federal Bldg., Seattle, WA 98174.

MC 100666 (Sub-429TA), filed February 2, 1979. Applicant: MELTON TRUCK LINES, INC., P.O. Box 7666, Shreveport, LA 71107. Representative: Wilburn L. Williamson, Suite 615-East, The Oil Center, 2601 Northwest 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 OK, NM, and TX, 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 20598, Dallas, TX. Send protests to: Connie A. Guillory, ICC, T-9038 Federal Bldg., 701 Loyola Ave., New Orleans, LA 70113.

MC 102567 (Sub-217TA), Applicant: McNAIR TRANSPORT, INC., 4295 Meadow Lane—P.O. Drawer 5357, Bossier City, LA 71111. Representative: Joe C. Day, 13403 N.W. Fwy., 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, NC, OH, PA, TN, WV, TX, and WI, for 180 days. Applicant has filed an underlying ETA seeking up to 90 days. Supporting shipper(s): Ethyl Corporation, 451 Florida Blvd., Baton Rouge, LA 70801. Send protests to: Connie A. Guillory, I.C.C., T-9038 Federal Bldg., 701 Loyola Ave., New Orleans, LA 70113.

MC 103798 (Sub-28TA), filed January 2, 1979. Applicant: MARTEN TRANSPORT, LTD., Route 3, Mondovi, WI 54755. Representative: Robert S. Lee, 1000 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)(6) 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 Transp. Asst., ICC, 414 Federal Building & U.S. Court House, 110 South 4th Street, Minneapolis, MN 55401.

MC 106401 (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), used in the manufacturing and distribution of canned goods from points in AL, FL, GA, NC, SC, TN, VA, and the District of Columbia, to the facilities owned or utilized by Campbell Soup Co., at or near Maxton, NC, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Campbell Soup Company, Maxton, NC. 28364. SEND PROTESTS TO: Terrell Price DS, 800 Briar Creek Road, Room CC516, Mart Office Building, Charlotte, NC 28205.

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 Memphis, TN, to Ft. Smith, AR, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Transbulk, Inc., Suite 407, 4646 Poplar St., Memphis, TN 38117. Send protests to: Alan Tarrant, D/S, 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 30050. Representative: Alan E. Serby, Fifth Floor, Lenox Towers, South, 3390 Peachtree Road, N.E., Atlanta, Georgia 30326. *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-

town, PA, and points in their respective commercial zones, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Lee Dog Food Co., P.O. Box 205, La Grange, KY 40031. Send protests to: Sara K. Davis, T/A, ICC, 1252 W. Peachtree St., NW, Room 300, Atlanta, Georgia 30309.

MC 107515 (Sub-1204TA), filed February 1, 1979. Applicant: REFRIGERATED TRANSPORT CO., INC., P.O. Box 308, Forest Park, Georgia 30050. Representative: Alan E. Serby, Fifth Floor, Lenox Towers, South, 3390 Peachtree Road, N.E., Atlanta, Georgia 30326. *Such commodities as are dealt in by drugstores, grocery, and food business houses (except commodities in bulk),* from the facilities of Warner-Lambert Company and its divisions and subsidiaries at or near Rockford, IL, to the facilities of Warner-Lambert Company and its divisions 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 Plaines, NJ 07950. Send protests to: Sara K. Davis, T/A, ICC, 1252 West Peachtree St., NW, Room 300, Atlanta, Georgia 30309.

MC 107743 (Sub-53TA), filed November 21, 1978, and published in the FR issue of January 10, 1979, and republished as corrected this issue. Applicant: SYSTEM TRANSPORT, INC., E. 11707 Montgomery, P.O. Box 3456 TA, Spokane, WA 99220. Representative: James W. Hightower, 136 Wynnewood Professional Bldg., Dallas, TX 75224. *Drilling mud, clay, gilsonite and lignite,* (except in bulk), from MT, ND, SD, NV, WY, to TX, OK, OR, WS, ID, CA, IL, IN, MO, PA, OH, WI, MI, and IA, for 180 days. Supporting shipper(s): Dresser Industries, Inc., P.O. Box 6504, Houston, TX. Send protests to: Hugh H. Chaffee DS, ICC, 858 Federal Bldg., Seattle, WA 98174. The purpose of this republication is to correct the proper authority sought.

MC 110144 (Sub-20TA), filed December 26, 1978. Applicant: JACK C. ROBINSON, d/b/a ROBINSON FREIGHT LINES, 3600 Raper Mill Road, P.O. Box 10234, Knoxville, TN 37921. Representative: Warren A. Goff, 2008 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 special equipment. (a) Between Knoxville and Bristol, TN via U.S. Hwy. 11-W, serving all intermediate points between Surgionsville and Bristol, including Surgoinsville and Kingsport; (b) Between Knoxville and Bristol, TN, via U.S. Hwy. 11-E, serving all intermediate points between Johnson City and Bristol, including Johnson City and Bristol; (c) Between Knoxville and Bristol, TN, via Interstate Hwy. 81; (d) Between Kingsport and Erwin, TN, via U.S. Hwy. 23 serving all intermediate points; (e) Between Elizabethton and Bristol, TN, via U.S. Hwy. 19-E and U.S. Hwy 19, serving all intermediate points; (f) Between Elizabethton and Johnson City, TN, via U.S. Hwy. 321, serving all intermediate points; (G) Between Bristol and Kingsport, TN, via TN Hwy. 126, serving all intermediate points; (h) Between Blountville, TN and the intersection of U.S. Hwy. 23 and TN Hwy. 75, via TN Hwy. 75, serving all intermediate points; (i) Between Blountville and Bluff City, TN, via TN Hwy. 37, serving all intermediate points; (j) Between Chattanooga and Knoxville, TN over U.S. Hwy. 11 and Interstate Hwy. 75, serving no intermediate points; (k) Between Knoxville and Memphis, TN over Interstate Hwy. 40, serving the intermediate point of Nashville, TN, restricted against the handling of traffic originating at, destined to or interlined at Memphis, TN. NOTE.—Applicant desires to tack his Sub 7 authority at Chattanooga in order to perform a through service to Memphis, TN; to tack his Sub 9 and Sub 15 authority in order to reach the applied for routes at Knoxville from points authorized in Roane, Loudon and Blount counties therein, to tack Sub 14 at Chattanooga to perform through services to and from points in Polk County, TN; and to tack his Sub 19 authority at Knoxville in order to serve points on his route to Sneedville, TN. Applicant desires to interline with other carriers at all gateways for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): There are approximately (48) 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: Glenda Kuss Transp. Asst., ICC, Suite A-422-U.S. Court House, 801 Broadway, Nashville, TN 37203.

MC 110420 (Sub-797TA), filed February 6, 1979. Applicant: QUALITY CARRIERS, INC., P.O. Box 186, Pleasant Prairie, WI 53158. Representative: John R. Sims, Jr., 915 Pennsylvania Bldg., 425-13th St. NW., Washington, DC 20004. *Liquid chocolate products, in bulk, in tank vehicles,* from the facilities of M & M Mars, a division of Mars, Inc. at or near Chicago, IL, Elizabethtown, PA and Waco, TX to the facilities of M & M Mars, a division of Mars, Inc. at or near Cleveland, TN, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): M & M Mars, Div. of Mars, Inc., High St., Hackettstown, NJ 07840. Send protests to: Gail Daugherty, Transportation Asst., Interstate Commerce Commission, Bureau of Operations, U.S. Federal Building & Courthouse, 517 East Wisconsin Avenue, Room 619, Milwaukee, Wisconsin 53202.

MC 110988 (Sub-380TA), filed February 6, 1979. Applicant: SCHNEIDER TANK LINES, INC., 4321 W. College Ave., Appleton, WI 54911. Representative: John R. Patterson, 2480 E. Commercial Blvd., Ft. Lauderdale, FL 33308. *Chemicals, acids, and cleaning compounds* from Minneapolis-St. Paul, MN to points in IA, MN, ND, SD, & WI, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Klenzade Products, Div. of Economics Lab., Inc., Osborn Bldg., St. Paul, MN 55102. Send protests to: Gail Daugherty, Transportation Asst., Interstate Commerce Commission, Bureau of Operations, U.S. Federal Building & Courthouse, 517 East Wisconsin Avenue, Room 619, Milwaukee, Wisconsin 53202.

MC 113325 (Sub-156TA), filed February 1, 1979. Applicant: SLAY TRANSPORTATION COMPANY, INC., 2001 S. Seventh St., St. Louis, MO. 63104. Representative: T. M. Tahan (same). *Sweeteners,* in bulk, from the facilities of Industrial Sugars, Inc. at or near St. Louis, MO to all points in KY, TN, AR, IA, OH, IN, KS, IL and MO, for 180 days. Supporting Shipper(s): Industrial Sugars, 180 E. Broad St., Columbus, OH 43215. Send protests to: P. E. Binder, ADS, ICC, Rm 1465, 210 N. 12th St., St. Louis, MO 63101.

MC 113666 (Sub-148TA), filed February 1, 1979. Applicant: FREEPORT TRANSPORT, INC., 1200 Butler Road, Freeport, PA 16229. Representative: Daniel R. Smetanick (same as applicant). *Zinc, zinc oxide, zinc dust, lead sheet, metallic cadmium, zinc dross, zinc residue, zinc skimmings, and materials, equipment and supplies used in the production of zinc and zinc oxide,* between Josephtown, PA, on the one hand, and, on the other, points in the United States (except AK and HI) 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: John J. England, District Supervisor, Interstate Commerce Commission, 2111 Federal Building, 1000 Liberty Avenue, Pittsburgh, PA 15222.

MC 114194 (Sub-211TA), filed February 5, 1979. Applicant: KREIDER TRUCK SERVICE, INC., 8003 Collinsville Road, East St. Louis, Illinois 62201. Representative: Donald D. Metzler (same as above). *Bulk soybean*

meal, from Lafayette, IN, to the States of Michigan, New York, Ohio, and Pennsylvania., for 180 days. Supporting shipper(s): Ralston Purina Company, Checkerboard Square, St. Louis, MO. 63188. Send protests to: Charles D. Little, District 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 Axminister Dr., Fenton, MO 63026. Representative: David A. Cherry, P.O. Box 1540, Edmond, OK 73034. *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 63119. 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 36401. Representative: Robert E. Tate, (same address as applicant). (1) *Zinc oxide, zinc dust, zinc slabs and zinc dross* (except commodities in bulk in tank vehicles) from the facilities of St. Joe Zinc Company, at Josephtown, Potter Township, Beaver County, PA, to points in GA, FL, AL, MS, LA, TX and TN; and (2) *materials and supplies used in the manufacture, installation and distribution of zinc oxide, zinc dust, zinc slabs and zinc dross* (except commodities in bulk in tank vehicles), from points in GA, FL, AL, MS, LA, TX, and TN, to the facilities of St. Joe Zinc Company, at Josephtown, Potter Township, Beaver County, PA, for 180 days. 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 115331 (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 Corp., Fiberglas Tower, Toledo, OH 43659. Send protests to: P.E. Binder, ADS, ICC, Rm 1465, 210 N. 12th St., St. Louis, MO 63102.

MC 115331 (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; and (2) *Materials and supplies* used or useful in the production, distribution and sales of the commodities in (1) above (except in bulk), from Chicago, Kankakee, Plainfield and Streator, IL; Marion, LaPorte, Indianapolis, Dunkirk and Gas City, IN; Atlanta, GA; Kansas City, KS; Jackson, Columbus and Mineral Wells, MS; Columbus and Mt. Vernon, OH; Tulsa and Muskogee, OK 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: P. E. BINDER, DS, 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, Suite 12, 1587 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 day authority. Supporting Shipper(s): Rmax, Inc., 13524 Welch Road, Dallas, Texas 75340. Send protests to: Sara K. Davis, T/A, Interstate Commerce Commission, 1252 W. Peachtree Street, N.W., Room 300, Atlanta, Georgia 30030.

MC 115651 (Sub-54TA), filed January 8, 1979. Applicant: KANEY TRANSPORTATION, INC., 7222 Cunningham Road, Rockford, IL 61102. Representative: Robert D. Higgins (same address as applicant). *Sand in bulk*, from LaSalle County, IL and Berien County, MI., to AL, AR, CT, DE, FL, GA, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MS, MO, NE, NH, NJ, NY, NC, ND, OH, OK, PA, RI, SC, SD, TN, TX, VT, VA, WV, and WI, for 180 days. Supporting shipper(s): J. J. Stefanec, Traffic Manager, Manley Bros., P.O. Box 538, Chesterton, IN 46304. Send protests to: Lois M. Stahl, Transp. Asst., ICC, 219 S. Dearborn Street, Room 1386, Chicago, IL. 60604.

MC 115826 (Sub-387TA), filed February 1, 1979. Applicant: W. J. DIGBY, INC., 6015 East 58th Ave., Commerce City, CO 80022. Representative: Howard Gore (same address as above). *Carpet and carpet padding*, from Los Angeles, CA to points in OR, WA and AZ, for 180 days. Supporting Shipper(s): General Felt Industries, Inc., Park 80 Plaza West-One, Saddle Brook, NJ 07662. Send protests to: District Supervisor Herbert C. Ruoff, 492 U.S. Customs House, 721 19th Street, Denver, CO 80202.

MC 115826 (Sub-388TA), 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*, from Omaha, NE to points in CA, 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, Cherokee and Des Moines, IA to points in CO, for 180 days. RESTRICTED to transportation originating at the above named origins and destined to named destinations. Supporting Shipper(s): Wilson Foods Corporation, 4545 Lincoln Blvd., Oklahoma City, OK 73105. Send protests to: District Supervisor Herbert C. Ruoff, 492 U.S. Customs House, 721 19th Street, Denver, CO 80202.

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 Fort Worth, TX to points in AL, AR, FL, GA, LA, and MS, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Collier Industries, Div. of Wilsey Foods, Inc., 915 East 9th St., Ft. Worth, TX 76102. Send protests to: Glenda Kuss, TA, ICC, Suite A-422, U.S. Court House, 801 Broadway, Nashville, TN 37203.

MC 115931 (Sub-80TA), filed February 1, 1979. Applicant: BEE LINE TRANSPORTATION, INC., P.O. Box 3987, Missoula, MT 59806. Representative: William Grimshaw (same address as applicant). *Pre-cut and knocked down log homes and hardware and accessories used in the erection thereof* from Ravalli County, MT to points in the U.S. including AK but excluding MT and HI, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Alpine Log Homes, Inc., Box 85, Victor, MT 59875. Send protests to: Paul J. Labane, D/S, ICC,

2602 First Avenue North, Billings, MT 59101.

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 Chemical, division of Borden, 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: LEAVITTS FREIGHT SERVICE, INC., 3855 Marcola Road, Springfield, OR 97477. Representative: David C. White, 2400 S.W. Fourth Avenue, Portland, OR 97201. *Contract carrier*—irregular routes; *Treated poles* from points in Washington and Yamhill Counties, OR to points in CA and NV, under contract with North Pacific Lumber Company, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): North Pacific Lumber Company, P.O. Box 3915, Portland, OR 97208. Send protests to: A. E. Odoms, DS, ICC, 114 Pioneer Courthouse, Portland, OR 97204.

MC 117820 (Sub-27TA), filed February 2, 1979. Applicant: AURELIA TRUCKING CO., 2121 Petit St., Port Huron, MI 48060. Representative: Robert D. Schuler, 100 West Long Lake Rd., Suite 102, Bloomfield Hills, MI 48013. *Candy and confectionary items, dessert preparations, N.O.I., gumball machines and stands, and related advertising and promotional material,* (except in bulk), in vehicles equipped with mechanical refrigeration, from the facilities of Leaf Confectionary, Inc. in Chicago, IL to points in DE, DC, CT, MA, MD, MI, NJ, NY, OH, PA, RI, VA, and WV. Restricted to traffic originating at the named origin and destined to the named destinations, for 180 days. Supporting shipper(s): Leaf Confectionary, Inc., 1155 N. Cicero, Chicago, IL 60651. Send protests to: Tim Quinn, DS, ICC, 604 Federal Building and U.S. Courthouse, 231 W. Lafayette Blvd., Detroit, MI 48226.

MC 117820 (Sub-28TA), filed February 2, 1979. Applicant: AURELIA TRUCKING CO., 2121 Petit St., Port Huron, MI 48060. Representative: Robert D. Schuler, 100 West Long Lake Rd., Suite 102, Bloomfield Hills, MI 48013. *Fruit juices,* (except in bulk), from the facilities of Orchard Grove Company at or near Lansing, MI to points in the Chicago, IL commercial zone, restricted to traffic originating at the named origin and destined to the named destination, for 180 days. An underlying ETA seeks 90 days authority. 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 117883 (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, 5514-B Federal Building, 550 Main St., Cincinnati, OH 45202.

MC 118806 (Sub-67TA), filed December 26, 1978. Applicant: ARNOLD BROS. TRANSPORT, LTD., 851 Lagimodiere Blvd., Winnipeg, Manitoba, Canada R2J 3K4. Representative: Bernard J. Kempare, 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, ports of entry on the International Boundary Line between 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): Deere & Company, John Deere Road, Moline, IL 61265. Send protests to: Ronald R. Mau DS, ICC, Room 268 Federal Building and U.S. Post Office, 657 2nd Avenue North, Fargo, ND 58102.

MC 119399 (Sub-91TA), filed February 2, 1979. Applicant: CONTRACT FREIGHTERS, INC., P.O. Box 1375, Joplin, MO 64801. Representative: Wilburn L. Williamson, 2601 Northwest Expressway, Oklahoma City, OK 73112. *Cheese,* from points in MN and WI to the facilities of L. D. Schreiber Cheese Co., Inc., in Barry, Jasper, Lawrence and Newton Counties, MO for 180 days. Supporting Shipper(s): L. D. Schreiber Cheese Co., Green Bay, WI 54305. Send protests to: DS John V. Barry, ICC, 600 Federal Bldg., 911 Walnut, Kansas City, MO 64106.

MC 119493 (Sub-254TA), filed January 5, 1978. Applicant: MONKEM COMPANY, INC., P.O. Box 1196, Joplin, MO 64801. Representative: Thomas D. Boone (same address as applicant). (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 points in and east of ND, SD, NE, CO, OK, and TX, except those in ME, MA, NH, VT, RI, and CT; (2) *Petroleum, petroleum products, vehicle body sealer and/or sound deadener compounds, filters 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, OK, PA, RI, SC, VA, and WV., to points in Warren County, MS., restricted in parts I and II to shipments originating at or destined to facilities of Quaker State Oil Refining Corp., located in Warren County, MS, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Quaker State Oil Refining Corporation, Oil City, PA 16301. Send protests to: John V. Barry DS, Room 600, 911 Walnut, Kansas City, MO 64106.

MC 119767 (Sub-347TA), filed January 3, 1979. Applicant: BEAVER TRANSPORT CO., P.O. Box 186, 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 Bldg., Cleveland, OH 44115. Send protests to: Gail Daugherty Transp. Asst., ICC, U.S. Federal Building & Courthouse, 517 East Wisconsin Avenue, Room 619, Milwaukee, WI 53202.

MC 119912 (Sub-2TA), filed February 6, 1979. Applicant: SUNRISE TRANSPORTATION, INC., 9850 East Highway 120, Manteca, CA 95336. Representative: Thomas M. Loughran, 100 Bush Street, 21st Floor, San Francisco, CA 94104. *Lime,* in bulk, in tank or hopper type vehicles, from Arrowlime, NV and Nelson, AZ to points in CA in or north of San Luis Obispo, Kern and Inyo Counties, for 180 days.

An underlying ETA seeks 90 days authority. Supporting shipper(s): Central Contra Costa Sanitary District, POB 5266 Walnut Creek, CA 94596 and The Flintkote Lime Products Co. A Div. of The Flintkote 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 120098 (Sub-32TA), filed December 29, 1978. Applicant: UINTAH FREIGHTWAYS, 1030 South Redwood Road, Salt Lake City, UT 84104. Representative: Robert L. Bloomquist, 1030 South Redwood Road, Salt Lake City, UT 84104. Authority sought to operate as a *common carrier,* by motor vehicle, over regular routes, transporting: *General commodities,* except commodities of unusual value, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment and classes A and B explosives, Between Vernal, UT, and Denver, CO; from Vernal, UT, over U.S. Highway 40 to Denver, CO, and return, serving all intermediate points between Vernal, UT, and Craig, CO; Between Baggs, WY, and Denver, CO: from Baggs, WY, over Wyoming Highway 789 to junction I-80, then over I-80 to Cheyenne, WY, then over I-25 to Denver, CO, and return over the same route. Between Price, UT, and Denver, CO; from Price, UT, over U.S. Highway 50/6 to Grand Junction, CO, then over U.S. Highway 6 (I-70) to Denver, CO, and return over the same route. Applicant requests authority to interline at Denver, Grand Junction, and Craig, CO, and to tack with its present authority at Vernal and Price, UT, and Baggs, WY, and authority to serve the commercial zones of all authorized service points, for 180 days. SUPPORTING SHIPPER(S): There are approximately (36) 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: L. D. Helfer DS, ICC, 5301 Federal Building, Salt Lake City, UT 84138.

MC 121626 (Sub-10TA), filed February 1, 1979. Applicant: BAYVIEW TRUCKING, INC., 7080 Florin-Perkins Road, Sacramento, CA 95828. Representative: Ann M. Pougiales, 100 Bush Street, 21st Floor, San Francisco, CA 94104. *Inedible meats, meat products, and meat by-products* from the facilities of Consolidated Pet Foods, Inc., at or near Amarillo, TX to the facilities of Kal Kan Foods, Inc., at or near Vernon, CA, for 180 days. An underlying ETA seeks 90 days authority. Supporting Shipper(s): Kal 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 136501 (Sub-5TA), filed December 28, 1978. Applicant: CARDOSI CONTRACT REFRIGERATED EXPRESS, INC., 5885 Jetway Street, Arlington, TN 38002. 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 the Kroeger Co., at or near Cincinnati, Springdale, Woodlawn, Blue Ash, Columbus, and Whitehall, OH, on the one hand, and, on the other, points in the states of OH, IN, IL, MO, AR, TX, TN, KY, GA, VA, WV, MI, PA, and FL, under a continuing contract or contracts, with the Kroeger 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 Kroeger Co., 1014 Vine Street, Cincinnati, OH 45201. SEND PROTESTS TO: Mr. Floyd A. Johnson DS, ICC, 100 North Main Building, Suite 2006, 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, 180 North LaSalle Street, 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 or near Menomonie, Vesper, Cameron, Eau Claire and Wisconsin Rapids, WI., 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, Everett McKinley Dirksen Bldg., 219 S. Dearborn, St., Room 1386, Chicago, IL 60604.

MC 143289 (Sub-6TA), filed December 19, 1978. Applicant: FEDERATED TRANSPORT SYSTEMS, 800 South McGarry Street, Los Angeles, CA 90021. Representative: Lucy Kennard Bell, of Daniel M. Shaparo Law Offices, 9701 Wilshire Blvd., Suite 829, Los Angeles, CA 90212. Authority sought to operate as a *contract carrier,* by motor vehicle, over irregular routes, transporting: *Adhesive cements; boot and shoe findings, including counters, heels, pads, shanks,* soles, taps, welting (rubber, plastic or foam); *Fabric,* fireproofed, oiled or waterproofed; *Fabric,* friction (coated or processed with soft gum, unvulcanized rubber or other sticky coating); *Plastic articles,* in barrels, boxes or crates; *Plastic film or sheeting,* printed or not printed, in flat sheets or in rolls; *Rubber* (elastic) bands; *Tape,* insulating, friction or electrical (cloth, plastic or rubber), from Canton, MA., to points and places in California, Tucson, Arizona, Chicago, Illinois; and St. Louis, MO., under a continuing contract or contracts, with Plymouth Rubber Company, Inc., located in Canton, MA., for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Plymouth Rubber Company, Inc., Revere Street, Canton, MA. SEND PROTESTS TO: Irene Carlos Transp. Asst., ICC, Room 1321 Federal Building, 300 North Los Angeles Street, Los Angeles, CA 90012.

MC 145435 (Sub-2TA), 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 Visalia and Los Angeles, CA., on the one hand, to points in OR, WA, UT, CO, MO, IL, WI, IN, MI, OH, PA, NY, NJ, CO, 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, Visalia, CA 83277. 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, 666 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): 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, 2020 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, TN, 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 2006, 100 North Main Street, Memphis, TN 38103.

By the Commission.

H. G. Homme, Jr.,
Secretary.

[FR Doc. 79-7203 Filed 3-8-79; 8:45 am]

sunshine act meetings

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409), 5 U.S.C. 552b(e)(3).

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[6335-01-M]

1

COMMISSION 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:

I. Approval of Agenda.
II. Approval of minutes from last meeting.
III. 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 minorities in the Armed Forces.
2. Letter to OCR Director Tatel re higher education desegration.
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.
IV. Report on civil rights developments in the Western Region.
V. State Advisory Committee Re-Charters: (a) Colorado, (b) Delaware, (c) Indiana, (d) Kansas, (e) Maine, and (f) New Hampshire.
VI. Review of *Shapp.* v. *Casey* litigation.
VII. Review of Sears complaint.
VIII. Request from Asian Pacific Coalition for re-scheduling of May consultation.

CONTACT PERSON FOR MORE INFORMATION:

Barbara Brooks, Public Affairs Unit, 254-6697.

[S-471-79 Filed 3-7-79; 3:59 pm]

[6351-01-M]

2

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.

[S-463-79 Filed 3-7-79; 10:39 am]

[6570-06-M]

3

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. 20506.

STATUS: Part will be open to the public and part will be closed to the public.

MATTERS TO BE CONSIDERED:

OPEN TO THE PUBLIC

1. Internal procedures for handling matters brought before EEOC for coordination under Executive Order 12067.
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 1612.13.

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.

[S-461-79 Filed 3-7-79; 9:58 am]

[6715-01-M]

4

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:

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.

PORTIONS CLOSED TO THE PUBLIC (FOLLOWING OPEN SESSION)

Audits and Audit Policy. Compliance. Personnel. Litigation. Labor Management Relations.

PERSONS TO CONTACT FOR INFORMATION:

Mr. Fred S. Eiland, Public Information Officer, telephone 202-523-4065.

MARJORIE W. EMMONS,
Secretary to the Commission.

[S-470-79 Filed 3-7-79; 3:26 pm]

[6740-02-M]

5

FEDERAL ENERGY REGULATORY COMMISSION.

TIME AND DATE: 2 p.m., March 7, 1979.

PLACE: 825 North Capitol Street NE., Washington, D.C. 20426, Room 9306.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

(1) Institution of a formal private investigation.
(2) Proceedings relating to an investigation.

CONTACT PERSON FOR MORE INFORMATION:

Kenneth F. Plumb, Secretary, telephone 202-275-4166.

[S-466-79 Filed 3-7-79; 3:12 pm]

[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.
CP-9. CP74-147, *et al.*, Michigan Wisconsin Pipe Line Company *et al.*

KENNETH F. PLUMB,
Secretary.

[S-469-79 Filed 3-7-79; 3:12 pm]

[6730-01-M]

7

FEDERAL MARITIME COMMISSION.

TIME AND DATE: 10 a.m., March 14, 1979.

PLACE: Room 12126, 1100 L Street NW., Washington, D.C. 20573.

STATUS: Parts 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

1. Docket No. 78-57: Financial Responsibility for Water Pollution Outer Continental Shelf—Proposed final rules.
2. Proposed elimination of financial reporting by carriers of persons in the domestic offshore trades.
3. Docket Nos. 75-57 and 76-43: Matson Navigation Company—Proposed Rate Increases in the United States Pacific Coast/Hawaii Domestic Offshore Trade—Petitions for Reconsideration of the Final Decisions.
4. Docket No. 77-18: Seatrain Gitmo, Inc.—Rates on Government Cargo—No. 77-38: Sea-Land Service, Inc.—Rates on Government Cargo—Consideration of the Record.

PORTIONS CLOSED TO THE PUBLIC

1. Order to Show Cause on sixteen conferences which are in noncompliance with General Order 7.
2. Docket No. 74-44: Agreement Between Puerto Rico Maritime Shipping Authority and Puerto Rico Marine Management, Inc./Puerto Rico Marine Operating Company, Inc.—Petition for reconsideration.

CONTACT PERSON FOR MORE INFORMATION:

Francis C. Hurney, Secretary, 202-523-5725.

[S-460-79 Filed 3-7-79; 9:41 am]

[6770-01-M]

8

[FCSC 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:

Date, 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. Requests for information, or advance notices of intention to observe a meeting, may be directed to: Executive Director, Foreign Claims Settlement Commission, 1111-20th Street, NW., Washington, D.C. 20579: (202) 653-6155.

Dated at Washington, D.C. on February 28, 1979.

FRANCIS T. MASTERSON,
Executive Director.

[S-459-79 Filed 3-7-79; 9:41 am]

7590-01-M]

9

NUCLEAR REGULATORY COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 44 FR 12331.

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: Reappointment of ACRS Member

THURSDAY, MARCH 8; 3:30 P.M.

2. Discussion of Export Matter (Approximately 1½ hours—Closed-Exemption 1) RESCHEDULED from 2/23/79.

CONTACT PERSON FOR MORE INFORMATION:

Walter Magee, 202-634-1410.

ROGER M. TWEED,
Office of the Secretary.

[S-467-79 Filed 3-7-79; 3:12 pm]

[7590-01-M]

10

NUCLEAR REGULATORY COMMISSION.

TIME AND DATE: March 13, 1979.

PLACE: Commissioners' Conference Room, 1717 H St., N.W., Washington, D.C.

STATUS: Open/Closed.

MATTERS TO BE CONSIDERED:

TUESDAY, MARCH 13; 9:30 A.M.

1. Discussion of Report to Congress: Means for Improving State Participation in the Federal Nuclear Waste Management Programs. (Approximately 1½ hours—Public meeting)
2. Affirmation Session. (Approximately 10 minutes—Public meeting): Extension of Interim Rule in S-3; Order in Offshore Power Systems.

TUESDAY, MARCH 13; 1:30 P.M.

1. Meeting on Bailly to Consider Handling of Petitions on Short Pilings (Approximately 1 hour—Closed-Exemption 10) (Postponed from 3/3/79)
2. Discussion of Personnel Matter (Approximately 2 hours)—Closed-Exemption 6)

CONTACT PERSON FOR MORE INFORMATION:

Walter Magee, (202) 634-1410.

Dated: March 6, 1979.

ROGER M. TWEED,
Office of the Secretary.

[S-468-79 Filed 3-7-79; 3:12 p.m.]

[7715-01-M]

11

POSTAL RATE COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 44 FR 12149, March 5, 1979.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE CLOSED MEETING: March 8, 1979, 8:30 a.m.

CHANGES IN THE MEETING: Meeting date and time changed to March 14, 1979, 8:30 a.m.

Meeting remains closed pursuant to 5 U.S.C. 552b(c)(2)(6).

CONTACT PERSON FOR MORE INFORMATION:

Ned Callan, Information Officer, Postal Rate Commission, Room 500, 2000 L St., NW., Washington, D.C. 20268, Telephone (202)-254-5614.

[S-465-79 Filed 3-79; 1:21 pm]

[8010-01-M]

12

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.

DATES PREVIOUSLY ANNOUNCED: February 26 and 27, 1979.

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.

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 containes 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 response to the Office of Management and Budget's request for its comments concerning certain legislative proposals for limiting conglomerate mergers. For further information, please contact Donald C. Langevoort at (202) 755-4829.

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) 376-3561.

The following additional items will be considered at a closed meeting scheduled for Wednesday, March 7, 1979 immediately following the 10:00 a.m. open meeting.

Institution of injunctive action.

Litigation matters.

Chairman Williams and Commissioners Loomis, Evans, and Karmel determined that Commission business required the above changes and that no earlier notice thereof was possible.

MARCH 5, 1979.

[S-462-79 Filed 3-7-79; 10:36 am]

[3810-70-M]

13

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES.

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.—TOUR, LIBRARY

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, 202/295-2111.

H. E. LOFDAHL,
Deputy Director, Correspondence and Directives, Washington Headquarters Services, Department of Defense.

MARCH 7, 1979.

[S-464-79 Filed 3-7-71; 11:20 am]

Federal Register

FRIDAY, MARCH 9, 1979

PART II

DEPARTMENT OF LABOR

Employment and Training Administration

■

COMPREHENSIVE EMPLOYMENT AND TRAINING ACT

Regulations Under Part A of Title IV of The Act

[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 comment 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 30, 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:

1. Part 680 is proposed 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.
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 Earnings disregard.
680.116 Supervisory personnel.
680.117 Academic credit.
680.118 Substitution for Title II programs.
680.119 Common general provisions.
680.120 Review by the RA; redistribution.

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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 Planning 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. 801 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

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. 436(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 IIB, but services to youth under Title IIB shall not be reduced because of the availability of YETP funds (sec. 436(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. 436(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. 436(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 education 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. 436(b)).

(2) The youth council may be either an entirely 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. 436(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 programs 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. 436(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. 436(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 proposd 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.

(2) *Results and benefits.* Describe the benefits that will accrue to YETP participants and include:

(i) the quantifiable performance and placement goals for each program activity.

(ii) the quantifiable performance and placement goals for each target group identified in the analysis of need.

(iii) 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.).

(iv) any non-quantifiable goals or outcomes expected from participation in the YETP program.

(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 based organizations, the apprenticeship system, other CETA youth programs, and other programs for youth.

(B) Describe or attach a copy of the agreement that describes arrangements 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, operation, 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.*

§680.6 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, direct 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 minorities and women.

(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 youths participating in career employment experience need such participation in order to continue their education (sec. 436).

(c) *Special component.* A prime sponsor may design a special component using up to 10 percent of its YETP 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. 435). This special component shall:

(1) Have and follow a structured experimental design;

(2) Establish and use comparison groups;

(3) Provide for followup on participants; and

(4) Provide in the Annual Narrative Report a followup on the experimental outcomes.

§ 680.7 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. 433(d)(1)) pursuant to written agreements between them and local educational agencies (LEA's)

(b) Agreements may be between the prime sponsor and one or more local educational agencies 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:

(1) Provide a description of the activities and services to be provided to eligible participants;

(2) Detail the responsibility 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.

(d) *Additional Provisions.* Additional provisions are required in those agreements which specifically provide for career employment experience opportunities. These include:

(1) Assurances that participating youth will be provided constructive work experience, which will improve their ability to make career decisions and which will provide them with basic work skills needed for regular employment or self-employment;

(2) Assurances that job information, counseling, guidance, and placement services will be made available to participating youth and that funds provided under the agreement will be available to, and will be utilized by, the local educational agency or agencies to the extent necessary to pay the cost of school-based counselors to carry out the provisions of this in-school program;

(3) Assurances that jobs provided under this program will be certified by the participating educational agency or institution as relevent to the educational and career goals of the participating youth.

(4) Assurances that the prime sponsor will advise participating youth of the availability of other employment and training resources in the local community to assist such youth in obtaining employment or self-employment;

(5) An assurance that career employment experience opportunities provided will be certified by a school-based counselor as being relevant to the career and educational program for the youth being provided those opportunities.

(e) In order to carry out the purposes of the LEA agreement, LEA's and prime sponsors, where appropriate, are encouraged to enter into subagreements, grants or contracts with post-secondary schools, State accredited profit and nonprofit educational institutions, public employment service agencies, and CBO's which have demonstrated effectiveness, in serving youth, particularly those who are economically disadvantaged.

(f) An LEA agreement may be a new agreement or a certification that the existing agreement remains the same or that it is revised as described in attachments to the certification. The certification and/or revisions shall be included as part of the YETP annual plan subpart. If an agreement is not reached within 60 days, the RA shall initiate the reallocation process as described in § 680.15.

§ 680.8 Eligibility for participation.

(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, except: (i) during periods when school is not in session, and (ii) where employment is undertaken in cooperation with school-related programs awarding academic credit for work experience; or

(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. 443(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(c) (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) Conseling, 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/or

(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 participant benefits, wages and allowances as provided in § 676.26, 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 Standard Act. Fourteen and fifteen-year olds, however, may be paid the rate set forth in section 14(b) of the Fair Labor Standard Act; or

(2) The applicable State or local minimum wage, including exceptions for the wage rates of 14 and 15-year olds.

(3) The prevailing wage for a job which is substantially the same as existing jobs of the same employer, except that, the employer may pay less than its prevailing wage, but not less than the minimum wage, if:

(i) The employer, the prime sponsor, and the appropriate collective bargaining agent, when a collective bargaining agreement is affected, agrees in writing to a lesser wage;

(ii) There is job restructuring. In order to accomplish job restructuring, the prime sponsor, employer, and the appropriate collective bargaining agent shall enter into an agreement concerning the restructuring. If, after agreeing to the restructured job, the agent, employer, or prime sponsor disagree over the wages to be paid for the restructured job, the parties shall resolve such dispute at the local level within 30 days. If, after 30 days, an agreement has not been reached, they shall either agree to negotiate in good faith with the RA to resolve the disagreement or select other jobs. If negotiations with the RA do not result in resolution within the 30 days, the RA shall set the wage rate; or

(iii) The employer creates new jobs. If disputes arise regarding whether the jobs are new to the employer, the prime sponsor, appropriate collective bargaining agent, and employer

should attempt to resolve the issue within 30 days after the agent has been informed of those jobs. If no agreement can be reached within that time frame, they shall either agree to negotiate in good faith with the RA to resolve the disagreement, or select other jobs. If negotiations with the RA do not result in a resolution within 30 days, the RA shall make a determination as to whether or not the jobs are new to the employer; or

(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 employer, 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 to prescribe an appropriate ratio of journeymen to such participating 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 assignments, 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 sponsors, 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 provisions of § 676.73 (a) of this title apply to all activities funded under YETP (sec. 443).

(b) The maintenance of effort provisions for public service employment programs described in § 676.73 (b) and (c) of this title, shall apply to work experience activities under YETP.

§ 680.13 Substitution for Title II programs.

Programs funded under YETP shall be supplementary 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 covered under LEA 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 circumstances beyond the control of the prime sponsor and LEA, for example, work stoppages. If the RA has initiated reallocation procedures, the RA shall mediate the dispute during the 30 day comment 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 appropriate 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 implementing 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 recorded 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 sponsor shall, at the end of each fiscal year and on a date established by the Secretary, submit an Annual Narrative Report. The report will include an assessment of the sponsor's performance and the accomplishments of the program.

§ 680.18 Governor's Statewide Youth Services Program.

(a) *Activities and services.* The Governor shall use the funds allocated under section 433 of the Act to provide statewide youth services such as the following:

(1) Expanded and experimental programs in apprenticeship arrangements, in conjunction with businesses, labor unions, State or Federal apprenticeship 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 occupational information for prime sponsors and local educational agencies without reimbursements;

(4) Fostering cooperative efforts between State and local institutions, including (i) occupational and career guidance and counseling, as well as placement services for in-school and out-of-school youth; and (ii) coordination of statewide activities carried out under the Career Education Incentive Act to improve the quality of education and enhance career opportunities for students by relating education to their employment aspirations (sec. 433(c)).

(5) Funding employment and training programs as defined in § 680.6 for eligible youth who are under the supervision of the State.

(b) *Eligibility for participation.* Individuals participating in the Governor'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 plan. (2) The provisions for pooling of administrative costs shall be optional for the Governor's youth services plan.

(d) *Governor's statewide youth services 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:

(i) *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 expected results and benefits to be derived by each target group that will be served.

(iii) *Approach.*—(A) *Program activities and services.* Identify each activity, including any experimental, demonstration, or model program, to be supported under this plan and include:

(1) The service deliverers and the activities they will provide;

(2) The target group to be served by each activity;

(3) The duration of each activity; and

(4) If training is one of the activities, the skill(s) to be learned.

(B) *Program coordination and linkage.* Describe the coordination and program linkages, if not elsewhere described, with programs under Title II, Special Governor's grant; 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; SESAs; and State, local or post-secondary institutions including vocational education agencies.

(iv) *Management and administration.* (A) Provide the organizational chart and staffing pattern for the plan, if not included in the master plan.

(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 (YPPS) and a Youth Budget Information Summary (YBIS).

(v) 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.

(vi) The assurances and certifications for the Governor's youth services plan and detailed instructions for completing the requirements of the plan are contained in the *Forms Preparation Handbook.*

(e) *Procedures for comment, modification and approval of Governor's youth services plan.*

(1) In developing 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 references to local agencies shall mean representatives of State agencies who represent statewide concerns.

(2) In submitting the Governor's youth service plan, the procedures specified in § 676.12 (a), (b) and (d) and § 677.33(a)(3) 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 Youth 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 20 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 §§ 676.6 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, by 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 mehtods 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)).

(C) Pursuant to the requirements for YETP, 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 YETP 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 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 YCCIP program.

(5) *Assurances and certifications.* The Assurances and certifications and detailed instructions 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 or geographic areas 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 project applicants, 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 notice 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, if applicable, 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

(3) Describe the expected benefits to accrue to participants, e.g., skills to be obtained, other positive terminations anticipated, academic credits to be earned, etc;

(d) *Job titles, description and wages.* (1) The principal job titles, job descriptions, and hourly wages to be paid. If job restructuring is to occur, a description of the methods of the analysis to be used, the expected results, the methods for obtaining concurrence of appropriate collective bargaining agents, when a collective bargaining agreement is affected, and the relevant expertise of personnel who performed the restructuring; and

(2) The participation of appropriate collective bargaining agents, if a collective bargaining agreement will be affected, with regard to job classifications and wage rates;

(e) *Administration.* A description of the project applicant's organization (including type of organization, purpose of organization), experience in operating employment and training programs and/or providing public services, and a description of the accounting and financial management procedures and/or arrangements; and

(f) *Budget.* The budget should include totals for the following line items:

(1) Direct program costs;

(2) Costs of participant wages and fringe benefits;

(3) Costs of wages and fringe benefits of worksite supervisors;

(4) Costs of job-related training;

(5) Costs of materials, supplies and equipment used by participants on the job; and

(6) 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 tangible output and measurable benefits which will accrue to the community;

(2) Provide benefits to participants in terms of work habits, skills, apprenticeable skills, and attainment of academic credit, where applicable;

(3) Be labor intensive;

(4) Assure an adequate level of supervision, taking into account the complexity of the jobs to be created;

(5) Describe or assure adequate qualifications for supervisors in terms of necessary skills and experience;

(6) Assure that projects shall permit in-school youths employed in the projects to coordinate their jobs with classroom instruction and, to the extent feasible, permit such youths to receive academic credit for their participation in the program (sec. 427(b)); and

(7) Assure that any person hired to supervise youth, shall not impede the promotional rights of existing employees.

(c) *Process.* Project applications from neighborhood and community-based organizations of demonstrated local effectiveness in providing employment and training services to youth shall be considered before applications from other project applicants are considered. Where it can be documented that a neighborhood or community-based organization does not have the administrative capability to run a project, or its project application does not meet the project review criteria established by the prime sponsor, then project applications from other than neighborhood and community-based organizations may be considered; *Provided,* the same criteria are used.

(d) *Review.* Program agents shall review the project applications submitted to them, approve or disapprove them, and submit all project applications to the prime sponsor, indicating their approval or disapproval.

(e) The prime sponsor shall review those project applications received, including those submitted by any program agent(s). When reviewing those submitted by a program agent, the prime sponsor shall give due consideration to project applications approved by the program agent.

(f) After review, the prime sponsor shall submit all project applications to the youth and planning councils for comment and recommendations (sec. 426(c)).

(g) After review of any comments and/or recommendations of the planning and youth councils, the prime sponsor shall approve or disapprove the project applications. The prime sponsor, however, shall not disapprove a project application recommended for approval by the councils unless it has first considered any comments and recommendations made by the planning and youth councils and unless it has provided the councils with a written statement of its reasons for disapproval (sec. 426(c)(2)).

(h) In cases of disapproval, the prime sponsor shall inform the project applicant in writing of its disapproval. It shall also indicate the reasons for the disapproval.

§ 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 limitation 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; or

(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(f)).

(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).

§ 680.115 Earnings disregard.

Wages received by any youth under YCCIP 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 YCCIP 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. 445(a)). If academic credit is not given for work experience in YCCIP 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 YCCIP 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, benifits, and working conditions under YETP shall apply to YCCIP 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.

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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 1 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 schoolyear, 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 or 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 disadvantged 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. 416(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 yearround 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 CETA 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 § 675.4 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

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 (none 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.* (i) 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 sponsors may propose to administer an Entitlement Project under 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 participating youth, separately calculated for each of the program activities listed below. To the extent possible, actual funding levels and numbers of youth served should be provided for Fiscal Year 1977 and planned figures for Fiscal Year 1978. Where applicable, the number of youth being served in each category should be broken out between in-school and out-of-school participants:

(i) Classroom training;

(ii) On-the-job training;

(iii) Public Service employment;

(iv) Work experience; and

(v) Summer Youth program.

(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.

(f) *Innovative Approaches.*—(1) *General.* (i) 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 economically disadvantaged youth between the ages of 19 and 25 who have not received their high school diploma or equivalent;

(D) Inclusion of occupational and career counseling, outreach, career exploration, and on-the-job training as part of the employment entitlement;

(E) Inclusion of 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 of 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.

(g) *Project Organization and Administration.*—(1) *General.* (1) 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 responsiblity for program operations, including coordinating participant recruitment, work site development, operational 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 management agency 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.

(h) *Recruitment*—(1) *General.* The "Entitlement" concept can only be meaningfully tested if eligible youth are aware of the program. Therefore, prime sponsors shall 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)(L)).

(i) *Work-Site Development—T1(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 extend 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 are 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 structered, 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; (Sec 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 agent) 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 work assignment.

(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(e)(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

sponsor. At a minimum, the application should include written statements from school officials indicating their agreement to:

(i) Assist in participant (including dropout) recruitment and eligibility determinations;

(ii) Cooperate in the ongoing monitoring of enrollment and academic and attendance requirements; and

(iii) 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 area agencies which offer high school equivalency programs and provide agreements comparable to those described above for school systems.

(l) *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) Sec. 418(a)(4)(D) of the Act also requires that prime sponsors consult and work with a number of other local institutions and organizations in planning and implementing Entitlement Projects, including law enforcement and judicial agencies, youth groups, State and local public assistance agencies, community-based 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.

(m) *Date 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 participant,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 management purposes, but which differ from the regular reports on program and financial performance required by the CETA regulations for other 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) Work site expenses;
(A) Equipment; and
(B) Supplies;
(vii) Training; and
(viii) Services

§ 680.308 Selection of final applicants.

(a) *Pre-Application review criteria.* (1) 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 § 680.307;

(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 education, 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 cost structure; and

(viii) Commitment and ability to satisfy the data needs required by the research and demonstration character of the Entitlement program;

(2) The following criteria shall be used to evaluate all pre-applications but shall have greater importance for Tier I pre-applications:

(i) Estimated rate of eligible youth participation within the proposed Entitlement Area; and

(ii) Capability of proposed local worksites to provide employment and training opportunities of sufficient quantity and quality to satisfy the objectives of the Entitlement program;

(3) The following criteria shall be used to evaluate all pre-applications but shall have greater importance for Tier II pre-applications:

(i) The extent to which quality work sites are proposed which include new and different job classifications, occupations, or restructured jobs; and

(ii) The quality and feasibility of proposed innovative approaches such as those listed in Section 418(b) of the Act.

(b) Each ETA regional office shall review pre-applications submitted by prime sponsors in its region, particularly those parts of the pre-applications which deal with managerial and administrative capability and fiscal and operational effectiveness. In making this review, each regional office shall take into account the prime sponsor's past performances with respect to other CETA programs.

(c) After regional office review, the Assistant Secretary for Employment and Training may make use of an impartial Review Panel to review each pre-application and the comments of the regional offices in accordance with the criteria set forth in paragraph (a) of this section, and to make recommendations to the Assistant Secretary for Employment and Training.

(d) The Assistant Secretary will review all the pre-applications and shall select final applicants based on the criteria set forth in paragraph (a) of this section taking into account any Review Panel recommendations and/or regional office comments. The Assistant Secretary shall select final applicants from areas with different 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 a variety of different locations and circumstances (Sec. 418(a)(1)). Pre-applicants not selected shall be notified in writing of their nonselection, the reasons therefor, and that further docu-

mentation on their nonselection will be made available to them on written request.

§ 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 sumbit 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, if any 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 reverification 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 and 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 used 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 managment 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 wage agreements entered into pursuant to § 680.319(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 other 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 requirement 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-metropolitian 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.

(1) *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.

(3) *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 payroll, 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.

(4) *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.

(5) *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 § 675.4 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; and

(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

(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 § 675.5(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 have refused a job or 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;

(4) Maintain a cooperative relationship with local business, union and community group interests;

(5) Provide monitorable attendance and productivity standards, and capable on-site supervision; and

(6) Be developed and committed in such numbers and in such a way 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.

(ii) No additional payments shall be provided by the Entitlement program to any such for-profit organization.

(2) 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)(ii).

(3) 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. 79-6838 Filed 3-8-79; 8:45 am]

federal register

FRIDAY, MARCH 9, 1979

PART III

DEPARTMENT OF LABOR

Employment Standards Administration

■

MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION

General Wage Determination Decisions

[4510-27-M]

DEPARTMENT OF LABOR

Employment Standards Administration, Wage and Hour Division

MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION

General Wage Detemination Decisions

General Wage Determination Decisions of the Secretary of Labor specify, in accordance with applicable law and on the basis of information available to the Department of Labor from its study of local wage conditions and from other sources, the basic hourly wage rates and fringe benefit payments which are determined to be prevailing for the described classes of laborers and mechanics employed in construction activity of the character and in localities specified therein.

The determinations in these decisions of such prevailing rates and fringe benefits have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's Order No. 24-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of Part 1 of Subtitle A of Title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates, (37 FR 21138) and of Secretary of Labor's Orders 12-71 and 15-71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in effective date as prescribed in that section, because the necessity to issue construction industry wage determination frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General Wage Determination Decisions are effective from their date of publication in the FEDERAL REGISTER without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision together with any modifications issued subsequent to its publication date shall be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR, Part 5. The wage rates contained therein shall be minimum paid under such contract by contractors and subcontractors on the work.

MODIFICATIONS AND SUPERSEDEAS DECISIONS TO GENERAL WAGE DETERMINATION DECISIONS

Modifications and Supersedeas Decisions to General Wage Determination Decisions are based upon information obtained concerning changes in prevailing hourly wage rates and fringe benefit payments since the decisions were issued.

The determinations of prevailing rates and fringe benefits made in the Modifications and Supersedeas Decisions have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's Order No. 224-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of Part 1 of Subtitle A of Title 29 Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secreatary of Labor's Orders 13-71 and 15-71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in foregoing General Wage Determination Decisions, as hereby modified, and/or superseded shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged in contract work of the character and in the localities described therein.

Modifications and Supersedeas Decisions are effective from their date of publication in the FEDERAL REGISTER without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5.

Any person, organization, or governmental agency having an interest in the wages determined as prevailing is encouraged to submit wage rate information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Office of Government Contract Wage Standards, Division of Wage Determinations, Washington, D.C. 20210. The cause for not utilizing the rulemaking procedures prescribed in 5 U.S.C. 553 has been set forth in the original General Wage Determination Decision.

MODIFICATIONS TO GENERAL WAGE DETERMINATION DECISIONS

The numbers of the decisions being modified and their dates of publication in the FEDERAL REGISTER are listed with each State.

Alabama:	
AL79-1001	Jan. 26, 1979
AL79-1015	Feb. 2, 1979
Arizona—AZ79-5100	Feb. 9, 1979
Delaware—DE78-3080	Nov. 3, 1978
District of Columbia—DC78-3098	Dec. 15, 1978
Florida—FL75.1080	Sept. 5, 1975
Illinois—IL78-2140	Nov. 13, 1978
Louisiana—LA79-4001; LA79-4002	Jan. 5, 1979
Nevada—NV78-5129	Oct. 27, 1978
New Jersey:	
NJ78-3009	Apr. 21, 1978
NJ78-3047	June 16, 1978
North Carolina—NC75-1078	Sept. 5, 1975
Pennsylvania—PA78-3054	Aug. 11, 1978
Puerto Rico:	
PR78-3019	Mar. 31, 1978
PR78-3092; PR78-3093	Nov. 3, 1978
Washington—WA78-5133	Dec. 29, 1978

SUPERSEDEAS DECISION TO GENERAL WAGE DETERMINATION DECISIONS

The numbers of the decisions being superseded and their dates of publication in the FEDERAL REGISTER are listed with each State. Supersedeas Decision numbers are in parentheses following the numbers of the decisions being superseded.

Alabama—AL78-1076(AL79-1043)	Sept. 22, 1978
Arizona—AZ78-5116(AZ79-5104)	July 28, 1978
Florida—GA78-1015(GA79-1042)	Mar. 10, 1978
Georgia—GA78-1015(GA79-1042)	Mar. 10, 1978
Indiana—IN76-2005(IN79-2007)	Jan. 23, 1976
Nevada:	
NV78-5010(NV79-5107)	Mar. 10, 1978
NV78-5018(NV79-5102)	Mar. 17, 1978
North Carolina—GA78-1015(GA79-1042)	Mar. 10, 1978
Pennsylvania—PA77-3078(PA79-3003)	June 4, 1977
South Carolina:	
GA78-1015(GA79-1042)	Mar. 10, 1978
SC76-1008(SC79-1037)	Jan. 9, 1976
SC78-1040(SC79-1045)	Apr. 14, 1978

CACELLATION OF 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 Construction 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 Cos., Texas, dated February 18, 1977 in 42 FR 10270; TX78-4029—Armstrong, Carson, Castro, Childress, Collingsworth, Dallam, Deaf Smith, Donley, Gray, Hansford, Hartley, Hempshill, 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 1685; TX79-4015—Tarrant County, Texas, dated January 5, 1979 in 44 FR 1686.

Signed at Washington, D.C. this 2nd day of March 1979.

DOROTHY P. COME,
Assistant Administrator,
Wage and Hour Division.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DECISION #AL79-1001 - Mod. #1 (44 FR 5601 - January 26, 1979) Statewide Alabama					
CHANGE:					
Electricians:					
Zone 1	$11.45a				
Zone 3	11.45a				
FOOTNOTE:					
a. Plus fringe benefits of $.55 Health and Welfare, 3%+.40 Pension and .5% apprentice training					
DECISION #AL79-1015 - Mod. #1 (44-FR-6863 - February 2, 1979) Madison County, Alabama					
CHANGE:					
Laborers:					
Laborers, mason tenders	$ 5.55	.35	.50		
Air tool op. (jackhammer, vibrator), mortar mixer	5.80	.35	.50		

DECISION #AZ79-5100 - Mod. #2
(43 FR 8482 - February 9, 1979)
Statewide Arizona

Change:	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Elevator Constructors	$13.85	.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		.11
Northern Area	14.43	1.34	2.47		.11
Painters:					
Tucson and Yuma Areas:					
Zone A: 0-30 miles from Stone and Congress in Tucson and from the County Courthouse in Yuma:					
Brush	9.71	.67	.40		.06
Spray and Sandblasters	10.21	.67	.40		.06
Paperhangers	9.84	.67	.40		.06
Swing Stage, under 40 ft.:					
Brush	10.01	.67	.40		.06
Spray	10.51	.67	.40		.06
Swing Stage, over 40 ft.:					
Brush	10.46	.67	.40		.06
Spray	10.96	.67	.40		.06
Structural Steel and Tanks:					
Brush	10.71	.67	.40		.06
Spray and Sandblasters	11.21	.67	.40		.06
Zone B: 31-40 miles from Stone and Congress in Tucson and from the County Courthouse in Yuma:					
Brush	10.46	.67	.40		.06
Spray and Sandblasters	10.96	.67	.40		.06
Paperhangers	10.59	.67	.40		.06
Swing Stage, under 40 ft.:					
Brush	10.76	.67	.40		.06
Spray	11.26	.67	.40		.06

DECISION #AZ79-5100 (Cont'd):

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change (Cont'd):					
Painters (Cont'd):					
Tucson and Yuma Areas (Cont'd):					
Zone B (Cont'd):					
Swing Stage, over 40 ft.:					
Brush	$11.21	.67	.40		.06
Spray	11.71	.67	.40		.06
Structural Steel and Tanks:					
Brush	11.46	.67	.40		.06
Spray and Sandblaster	11.96	.67	.40		.06
Zone C: 41-50 miles from Stone and Congress in Tucson and from the County Courthouse in Yuma:					
Brush	11.21	.67	.40		.06
Sprav	11.71	.67	.40		.06
Paperhangers	11.34	.67	.40		.06
Swing Stage, under ft.:					
Brush	11.51	.67	.40		.06
Spray	12.01	.67	.40		.06
Swing Stage, over 40 ft.:					
Brush	11.96	.67	.40		.06
Spray	12.46	.67	.40		.06
Structural Steel and Tanks:					
Brush	12.21	.67	.40		.06
Spray and Sandblasters	12.71	.67	.40		.06
Zone D: 51 miles and over from Stone and Congress in Tucson and from the County Courthouse in Yuma:					
Brush	11.71	.67	.40		.06
Spray	12.21	.67	.40		.06
Paperhangers	11.84	.67	.40		.06
Swing Stage, under 40 ft.:					
Brush	12.01	.67	.40		.06
Spray	12.51	.67	.40		.06

DECISION #AZ79-5100 (Cont'd):

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change (Cont'd):					
Painters (Cont'd):					
Tucson and Yuma Areas (Cont'd):					
Zone D (Cont'd):					
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	13.21	.67	.40		.06

DECISION NO. DE78-3080 - Mod. #2
(42 FR 51567 - November 3, 1978)
State of Delaware

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Add:					
Line Construction (Railroad Only)	10.82	.45	3%	a	.75%
Linemen	10.82	.45	3%	a	.75%
"A" Equipment Operator	9.47	.45	3%	a	.75%
"B" Equipment Operator					

a. Paid Holidays include New Year's Day, Declaration Day, Independence Day, Labor Day, Thanksgiving Day, Christmas Day and Good Friday.

DECISION #DC78-3098 - Mod. #2
(43 FR 58723 - December 15, 1978)
District of Columbia, Maryland - Montgomery & Prince Georges Counties, and D. C. Training School; Virginia - Independent City of Alexandria and Arlington

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change:					
Electricians	11.70	.70	3%+.80		.13
Paving and Incidental Grading (District of Coulumbia only)					
Asphalt Shoveler	7.30	.32	.35		
Asphalt Raker	7.50	.32	.35		
Asphalt Tamper	7.40	.32	.35		
Cement Masons	7.75	.32	.35		
Concrete Saw Operators	7.50	.32	.35		
Concrete Shoveler	7.40	.32	.35		
Form Setter	7.75	.32	.35		
Laborer:					
Laborers	7.25	.32	.35		
Jackhammer	7.45	.32	.35		
Hand Burner Operator	7.40	.32	.35		
Power Equipment Operators:					
Concrete Spreader Operator, Finishing Machine, Roller, (rough), Compressor, Rubber-tired Loader (1½ cu. yds., or less), Asphalt Plant Mixer Loader Operator Tracks (2½ cu. yds. or less), Burner Planer, Bulldozer, Mechanic or Welder, Rubber Tired Loader (over 1½ cu. yds.)	7.50	.27	.35		
Asphalt Spreader, Hydraulic Backhoe (½ cu. yd., or less) Asphalt Plant Engineer, Asphalt Roller Operator, Concrete Breaker (machine)	7.70	.27	.45		
Crane Operator, Concrete Paving Operator	7.75	.27	.35		
Shovel Operator	7.90	.27	.35		
Gradall Operator (1½ cu. yds. or less), Motor Grader, Operator Tracks (over 2½ cu. yds	8.00	.27	.35		
G-1000 Gradall Operator (over 1½ cu. yds.)	8.65	.27	.35		
	8.90	.27	.35		

DECISION #DC78-3098 - Mod. #2

Paving and Incidential Grading (District of Coulumbia only)	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change: (Cont'd)					
Power Broom, Oiler	7.40	.27	.35		
Sand Setter	7.70	.27	.35		
Truck Drivers:					
Truck Drivers (standard)	7.25	.27	.35		
Tandem	7.37	.27	.35		
Tractor trailer (capable of moving heavy equipment)	7.50	.27	.35		

DECISION #FL75-1080 - Mod. #4
(43 FR 40165 - September 5, 1975)
Alachua, Bradford, Calhoun, Citrus, Columbia, Dixie, Franklin, Gadsden, Gilchrist, Hamilton Hernando, Holmes, Jackson, Jefferson, Lake, Lafayette, Leon Levy, Liberty, Madison, Marion, Pasco, Putnam, Sumter, Suwannee, Taylor, Union, Wakulla, and Washington Counties, Florida

Change:
Mod. #3 to read:
Decision #FL75-1080-Mod. #3
(43 FR 41358 - Sept 5, 1975)

Decision #IL78-2140-Mod. #1
(43 FR 52641 November 13, 1978)
Ford, Grundy, Iroquois, Kankakee, LaSalle, Livingston, McLean, Marshall, Putnum, and Woodford Counties, Illinois

Add:
Power Equipment Operators:
Ford and Iroquios Counties:

ILL-1-PEO-1-2-3

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS I	$12.40	.55	.75		.08
CLASS II	12.30	.55	.75		.08
CLASS III	12.10	.55	.75		.08
CLASS IV	8.00	.55	.75		.08

POWER EQUIPMENT OPERATORS:

CLASS I - Master Mechanic

CLASS II - Utility Operator

CLASS III - Power Cranes, Draglines, Derricks, Shovels, Gradalls, Mechanics, Concrete Mixers with Skip, Tournamixer, Two Drum Machine, One Drum Hoists with tower or Boom, Cableways, Tower Machines, Motor Patrol, Boom Tractor, Boom or Winch Truck, Winch or Hydraulic Boom Truck, Truck Crane, Tournapull, Tractor Operating Scoops, Bulldozer, Push Tractor, Asphalt Planer, Finishing Machine on Asphalt, Large Rollers on Earth, Rollers on Asphalt Mix, Ross Carriers or similar Machine, Gravel Processing Machine, Asphalt Plant Engineer, Paver Operator, Farm Tractor w/half yard Bucket and/or Backhoe Attachment, Dredging Equipment or Dredge Engineer or Dredge Operator, Central Mix Plant Engineer, CMI 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, Hydro Crane, Standard or Dinkey Locomotives, Scoopmobiles, Euclid Loader, Soil Cement Machine, Back Filler, Elevating Machine, Power Blade, Drilling Machines, incl. Well Testing, Caissons, Shaft or any similar type drilling machines, Motor Driven Paint Machine, Pipe Cleaning Machine, Pipe Wrapping Machine, Pipe Bending Machine, Apsco Paver, Boring Machine, (Head Equipment Greaser), Barber-Greene Loaders, Formless Paver, (Well Point System), Concrete Spreader, Hydra Ax, Resco Concrete Saw, Marine Scoops, Brush Mulcher, Brush Burner, Mesh Placer, 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, Straw Blower, Power Sub Grader, Bull Float, Finishing Machine, Self-Propelled Pavement Breaker (Backhoe attached), Lull (or similar type machine), Two Air Compressors, Compressors hooked in Manifold, Overhead Crane, Chip Spreader, Mud Cat, Sull-Air

(Decision #IL78-2140 - Mod. #1 Cont.)

CLASS IV - Concrete Mixers without Skips, Rock Crusher, Ditching Machine under 6', 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, Mud Jack, Gunite Machine, House Elevators when used for hoisting Material, Engine Tenders, Fireman, Wagon Drill, Plex Plane, Conveyor, Siphons and Pulsometer, Switchman, Fireman on Pain Pots, Fireman on Asphalt Plants, Distributor Operator on Trucks, Tampers, Self-Propelled Power Broom, Striping Machine (motor driven), Form Tamper, Seaman Tiller, Bulk Cement Plant Equipment Greaser, Deck hands, Truck Crane, Oiler Driver, Cement Blimps, Form Grader, Temporary Heat, Throttle Valve, Farm Tractor

DECISION #LA79-4001 - Mod. #3 (44 FR 1634 - January 5, 1979) Statewide Louisiana	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change:					
Carpenters (Building Construction):					
Zone 10 - Carpenters & soft floor layers	$10.00	.60	.35		.05
Millwrights	10.90	.60	.35		.05
Piledrivermen	10.50	.60	.35		.05
Electricians:					
Zone 4 - Electricians	12.30	.70	3%		2/10%
Cable splicers	12.55	.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	.745	.56	4%+a+b	.025
Helpers	70%JR	.745	.56	4%+a+b	.025
Helpers (Prob.)	50%JR				
Zone 2 - Mechanics	10.025	.895	.69	4%+a+b	.035
Helpers	70%JR	.895	.69	4%+a+b	.035
Helpers (Prob.)	50%JR				
Line construction:					
Zone 4:					
Linemen, equipment operators	12.30	.70	3%		
Cable splicers	12.55	.70	3%		
Groundmen	50%JR	.70	3%		
Zone 5:					
Linemen & equipment operators	12.35		3%		1/2%
Cable splicers	12.60		3%		1/2%
Groundmen	60%JR		3%		1/2%

DECISION #LA79-4002 - Mod. #2 (44 FR 1650 - January 5, 1979) Bossier, Caddo & Calcasieu Pars., Louisiana					
Change:					
Elevator constructors:					
Bossier & Caddo Parishes:					
Mechanics	10.025	.895	.69	4%+a+b	.035
Helpers	70%JR	.895	.69	4%+a+b	.035
Helpers (Prob.)	50%JR				
Calcasieu Parish:					
Mechanics	10.27	.745	.56	4%+a+b	.025
Helpers	70%JR	.745	.56	4%+a+b	.025
Helpers (Prob.)	50%JR				

DECISION #NV78-5129 - Mod. #5 (43 FR 50344 - October 27, 1978) Washoe County, Nevada	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change:					
Elevator Constructors	$16.37	.895	.69	3% + a	.03
Elevator Constructors' Helpers	11.46	.895	.69	3% + a	.03
Elevator Constructors' Helpers (Prob.)	8.185				
Painters:					
Brush and Roller	13.43	.70	.75		.02
Brush - swing stage, up to 40 ft.; Brush - steel; Sandblaster	13.70	.70	.75		.02
Spray; Taper; Paperhangers	13.95	.70	.75		.02
Spray - swing stage, up to 40 ft.; Spray - steel	14.20	.70	.75		.02
Roofers	12.85	.85	1.00		.05

DECISION #NJ78-3009 - Mod. #8 (42 FR 17223 - April 21, 1978) Bergen, Essex, Hudson, Hunterdon, Middlesex, Morris, Passaic, Somerset, Sussex, Union, and Warren Counties, New Jersey					
Add:					
Line Construction (Railroad Only):					
Linemen	10.74	7%	7%		3/4%
Line Equipment Operator	10.22	7%	7%		3/4%
Groundmen	6.68	7%	7%		3/4%
Omit:					
Hunterdon, Middlesex, Somerset, Union (up to Woods Ave. south of Cranford) and Warren Counties from Zone 1 for Truck Drivers					
Add:					
Truck Drivers:					
Zone 3 Hunterdon, Middlesex, Somerset, Union (up to Woods Ave. south of Crandford), and Warren Counties (Classification Definitions are as listed on page 30 of the above referenced decision.)					
Group 1	9.12	.88	.975	j+k	
Group 2	9.35	.88	.975	j+k	
Group 3	9.40	.88	.975	j+k	
Group 4	9.50	.88	.975	j+k	
Group 5	9.60	.88	.975	j+k	

MODIFICATIONS P. 11

DECISION #NJ78-3047 - Mod. #5
(43 FR 26235 - June 16, 1978)
Atlanctic, Burlington, Camden, Cape May, Cumberland, Gloucester, Mercer, Monmouth, Ocean, and Salem Counties, New Jersey

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Add:					
Line Construction - Railroad only Camden, Gloucester, Mercer, Monmouth, Ocean and Salem Counties:					
Lineman	10.74	7%	7%		3/4%
Line Equipment Operator	10.22	7%	7%		3/4%
Groundman	6.68	7%	7%		3/4%
Change:					
Truck Drivers:					
Zone 3					
Group 1	9.12	.88	.975	p+q	
Group 2	9.35	.88	.975	p+q	
Group 3	9.40	.88	.975	p+q	
Group 4	9.50	.88	.975	p+q	
Group 5	9.60	.88	.975	p+q	

DECISION #NC75-1078 - Mod. #2
(40 FR 41367 - September 5, 1975)
Statewide, North Carolina

Change:					
Laborers:					
Laborers	$2.90				
Mod. #2 as published on February 16, 1979 in 44 FR 10218 to read: Mod. #1					

MODIFICATIONS P. 12

DECISION #PA78-3054 - Mod. # 2
(43 FR 35868 - August 11, 1978)
Bucks, Chester, Delaware, Montgomery and Philadelphia Counties, Pennsylvania

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ADD:					
Line Construction (Railroad only Railroad only)					
Linemen	$10.94	.45	3%	a	.75%
"A" equipment operator	10.94	.45	3%	a	.75%
"B" equipment operator	9.57	.45	3%	a	.75%

Footnote:
d. Paid Holidays: New Year's Day, Decoration Day; Independence Day; Labor Day; Thanksgiving Day; Christmas Day and Good Friday.

DECISION NO. PR78-3092 - Mod. #1
(43 FR 51587 - November 3, 1978)
Puerto Rico, Island Wide

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change:					
Laborers:					
Laborers	$ 2.80				
Mortar Mixers	2.80				

DECISION NO. PR78-3019 - Mod. #1
(43 FR 13738 - March 31, 1978)
Puerto Rico, Island Wide

Change:					
Ironworkers, Reinforcing	2.80				
Laborers , Unskilled	2.80				
Painters	2.80				
Truck Drivers	2.80				

DECISION NO. PR78-3093 - Mod. #1
(43 FR 51587 - November 3, 1978)
Puerto Rico, Island Wide

Change:					
Laborers:					
Laborers	2.80				
Air tool Operator	2.80				
Painters	2.80				
Tile Setters	2.80				

DECISION NO. WA78-5133 - Mod.#1
(43 FR 61199 - Dec. 29, 1978)
Statewide Washington

MODIFICATIONS P. 13

CHANGE:

LINE CONSTRUCTION:	BASE ZONE	ZONE 1	ZONE 2	ZONE 3	ZONE 4
Group 1: Cable Splicer, Leadman Pole Sprayer	$13.29	$14.54	$15.29	$16.04	$ 17.29
Group 2: Lineman, Pole Sprayer Heavy Line Equipment man, certified Lineman Welder	12.00	13.25	14.00	14.75	16.00
Group 3: Tree Trimmer	10.84	12.09	12.84	13.59	14.84
Group 4: Line Equipment Man	10.34	11.59	12.34	13.09	14.34
Group 5: Head groundman (chipper), Head Groundman, Powderman, Jackhammer Man	9.04	10.29	11.04	11.79	13.04
Group 6: Groundman, Tree Trimmer Helper	8.50	9.75	10.50	11.25	12.50

FRINGE BENEFITS:	
Health and Welfare	.45
Pensions:	
Groups 1 thru 3	3%+.60
Groups 4 thru 6	3%+.40
Vacation	,10
Apprenticeship Training	1/2%

BASE ZONE - 0 to 3 miles from geographical center of Cities listed below.

Zone 1 - 3 to 20 miles radius
Zone 2 - 20 to 35 miles radius
Zone 3 - 35 to 50 miles radius
Zone 4 - Over 50 miles radius

Base Zone rate is paid when working out of employer's permanent shop.

Spokane	Ellensburg	Astoria	Medford	Corvallis
Tacoma	Ephrata	Baker	Portland	Coeur D' Alene
Walla Walla	Everett	Burns	Pendleton	Kellog
Wenatchee	Kennewick	Bend	Salem	Lewiston
Yakima	Longview	Eugene	Roseburg	Orofino
Wilbur	Olympia	Seattle	Lakeview	The Dalles
Klamath Falls	Bellingham	Umatilla	Sand Point	

SUPERSEDEAS DECISION

STATE: Alabama COUNTIES: Jefferson, Shelby, St Clair and Walker
DECISION NUMBER: AL79-1043 DATE: Date of Publication
Supersedes Decision No.: AL78-1076 dated September 22, 1978 in 43 FR 43153
DESCRIPTION OF WORK: Building Construction Projects (does not include 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	11.61	.45	.80		.05
Boilermakers	9.95	1.05	1.05		.02
Bricklayers:					
Bricklayers; pointers, caulkers; stonemasons	10.35	.40	.50		.13
Cleaners	9.25	.40	.50		.13
Carpenters:					
Carpenters, soft floor layers	9.55	.55	.30		.07
Millwrights	11.25				.07
Piledrivermen	9.75	.55	.30		.07
Cement masons	9.08	.50			.10
Electricians:					
Electricians	11.45	.55	3%+.40		½%
Cable Splicers	11.70	.55	3%+.40		½%
Elevator constructors	9.74	.545	.35	a+b	.02
Glaziers	9.68	.50	.50		.01
Ironworkers	10.00	.60	.815		.06
Lathers	9.48		.10		.01
Linemen:					
Linemen	9.38	.35	3%		½%
Groundmen under one year	4.21	.35	3%		½%
Groundmen one year and over	4.97	.35	3%		½%
Hole and ditch digging equipment, tractor with winch and derrick, truck with winch and derrick	7.97	.35	3%		½%
Tractor with towing machine, truck with winch only	6.57	.35	3%		½%
Truck without winch	5.63	.35	3%		½%
Mable setters	9.55		.50		
Painters:					
Brush (Commercial)	10.05		.70		
Spray; Structural steel	10.55		.70		
Paperhangers	10.20		.70		
Plasterers	9.22	.50			.10
Plumbers and Pipefitters	11.45	.58	.65		.09
Roofers	8.90		.20		.10
Sheet metal workers	10.80	.79	1.07		.09
Sprinkler fitters	10.80	.75	1.00		.08
Terrazzo workers, Tile setters	9.55		.50		
Tile, Marble, Terrazzo finishers	7.50				

AL79-1043- (Cont'd)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Truck Drivers:					
Up to but not including 1½ tons	7.05	.40			
1½ to but not including 3 tons	7.25	.40			
3 tons but not including 5 tons	7.50	.40			
5 tons and over including special equipment	7.65	.40			
Heavy Duty - off the road trucks	7.75	.40			
Welders, rigger, 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 employee who has worked in business more than 5 years. Employer contributes 6% of regular hourly rate to Vacation Pay Credit for employee who has worked in business less than 5 years.

AL79-1043- (Cont'd)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
LABORERS:					
GROUP A	6.80	.35	.40		.03
GROUP B	6.75	.35	.40		.03
GROUP C	6.70	.35	.40		.03
GROUP D	6.65	.35	.40		.03
GROUP E	7.05	.35	.40		.03
GROUP F	7.50	.35	.40		.03
GROUP G	7.40	.35	.40		.03
GROUP H	7.45	.35	.40		.03
GROUP I	7.35	.35	.40		.03
GROUP J	7.20	.35	.40		.03
GROUP K	8.15	.35	.40		.03

GROUP A
Air 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, conc, & clay and muckers

GROUP C
Plasterers' tenders and hod carriers

GROUP D
Mason tenders, building laborers

GROUP E
Burners on demolition, wagon drill operators and tunnel laborers

GROUP F
Powderman

GROUP G
Caisson-driller (10' Dia)

GROUP H
Tunnel miner

GROUP I
Pneumatic concrete gun operator and nozzleman

GROUP J
Chuck tender

GROUP K
Oxagon operator

AL79-1043- (Cont'd)

POWER EQUIPMENT OPERATORS:	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP A	10.04	.40	.30		.10
GROUP B	9.51	.40	.30		.10
GROUP C	8.44	.40	.30		.10
GROUP D	10.74	.40	.30		.10
GROUP E	10.03	.40	.30		.10
GROUP F	8.57	.40	.30		.10

GROUP A

Asphalt plant, boom tractor, bulldozer, cableways, core driller, compressors (2 or more), crane-derrick-dragline, dinky locomotive, dredges, fork lift, front end loader, gradall, heavy duty mechanic, hoist (1 drum or more), mixers, push tractor, scrapers, shovels, 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 tractor, distributors, (bituminous surface), farm tractors, finishing machine, pumps over 4 inches, rollers, welding machine (4 or more)

GROUP C

Air compressor (125 & under), oilers-firemen, conveyor (1) tended by oiler), pumps (under 4 inches), welding machines (3 or under).

GROUP D

ON STEEL ERECTION: Crane, dragline, derrick, hoist, piledriver, winch truck, fork lift, tower cranes, climbing cranes, cherry picker, mechanics, locomotives, tug boat

GROUP E

Tractors, welding machine, gas or diesel driven welding machine (4 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 compresso
125 and under (2 or less), oiler, fireman, small boat

SUPERSEDEAS DECISION

STATE: Arizona COUNTY: Pima
DECISION NUMBER: AZ79-5104 DATE: Date of Publication
Supersedes Decision No. AZ78-5116 dated July 28, 1978, in 43 FR 33014.
DESCRIPTION OF WORK: Residential Projects (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	$ 11.94	.50	$ 1.20		.02
BOILERMAKERS	14.36	1.075	1.00	1.00	.03
BRICKLAYERS; Stonemasons:					
Zone A: 0-15 miles from Tucson	11.22	1.00	.90		.06
Zone B: 15-30 miles from Tucson	11.59	1.00	.90		.06
Zone C: 30-40 miles from Tucson	11.96	1.00	.90		.06
Zone DD 40 miles and over from Tucson	12.72	1.00	.90		.06
CARPENTERS:					
Carpenters; Drywall Applicator	9.785	.845	.955		.025
Piledrivermen; Floor Layers (finish)	10.07	.845	.955		.025
Millwrights	10.20	.845	.955		.025
CEMENT MASONS	10.22	.85	.85		.05
ELECTRICIANS:					
Zone A: 0-16 miles from City Hall in Tucson or Yuma	9.88	.60	3%		1/2%
Zone B: 26-32 miles from City Hall in Tucson or Yuma	10.42	.60	3%		1/2%
Zone C: 32-48 miles from City Hall in Tucson or Yuma	10.96	.60	3%		1/2%
Zone D: 48 miles and over from City Hall in Tucson or Yuma	11.50	.60	3%		1/2%
ELEVATOR CONSTRUCTORS	11.775	.745	.56	3%+a	.025
ELEVATOR CONSTRUCTORS' HELPERS	70%JR	.745	.56	3%+a	.025
ELEVATOR CONSTRUCTORS' HELPERS (PROB.)	50%JR				
GLAZIERS	9.42	.70	.30		.01
IRONWORKERS	12.30	1.34	2.47		.11
LATHERS:					
Zone A: 0-30 miles from Tucson	10.88	.50	.40		
Zone B: 30-40 miles from Tucson	11.38	.50	.40		
Zone C: 40-50 miles from Tucson	11.63	.50	.40		
Zone D: Area outside Zone C	12.38	.50	.40		
MARBLE SETTERS; Terrazzo Workers; Tile Setters	9.42	.70	.75		

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
PAINTERS:					
Zone A: 0-30 miles from Tucson Post Office:					
Brush	$ 9.71	.67	.40		.06
Structural Steel, Brush	10.71	.67	.40		.06
Zone B: 31-40 miles from Tucson Post Office:					
Brush	10.46	.67	.40		.06
Structural Steel, Brush	11.46	.67	.40		.06
Zone C: 41-50 miles from Tucson Post Office:					
Brush	11.21	.67	.40		.06
Structural Steel, Brush	12.21	.67	.40		.06
Zone D: 51 miles and over from Tucson Post Office:					
Brush	11.71	.67	.40		.06
Structural Steel, Brush	12.71	.67	.40		.06
PLASTERERS:					
Zone A: 0-30 miles from Tucson Post Office	8.57	.35	.60		
Zone B: 30-40 miles from Tucson Post Office	9.07	.35	.60		
Zone C: 40-50 miles from Tucson Post Office	9.32	.35	.60		
Zone D: 50 miles and over from Tucson Post Office	10.07	.35	.60		
PLASTERERS' TENDERS	9.16	.85	.85		.10

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
PLUMBERS; Steamfitters:					
FREE ZONE 0-15 miles					
The "Free Zone" - Zone I shall be 15 road miles from the stated base points in Flagstaff, Yuma, Tucson and Douglas. The "Free Zone" from Phoenix shall be 15 miles radius from the stated base point. In addition, all areas within the City limits of Phoenix, Chandler, Scottsdale, Tempe, Glendale, Mesa, Kingman, Havasu City, Prescott, Winslow and Holbrook will be included as Free Zones. Any work contracted for outside of these zones will be determined from the Phoenix and Tucson basing points.	$ 13.24	.75	$ 1.35		.13
Zone 2: 15-30 miles	13.64	.75	1.35		.13
Zone 3: 30-40 miles	14.09	.75	1.35		.13
Zone 4: 40 miles and over	15.59	.75	1.35		.13
ROOFERS:					
Zone A: 0-44 miles from Tucson	9.77	.845	.20		.03
Zone B: over 44 miles from Tucson	11.52	.845	.20		.03
SHEET METAL WORKERS:					
Zone A: 0-22 miles from Tucson	10.30	3%+1.14	1.91		.04
Zone B: 22-45 miles from Tucson	11.25	3%+1.14	1.91		.04
Zone C: Over 45 miles from Tucson	12.80	3%+1.14	1.91		.04
SOFT FLOOR LAYERS	9.25	.38			
SPRINKLER FITTERS	12.29	.65	.95		.08
TERRAZZO WORKERS; TILE SETTERS; MARBLE SETTERS	9.27	.90	.85		

FOOTNOTE:
a. Employer credits 4% basic hourly rate of employee with over 5 years' service, 2% basic hourly rate from 6 months' to 5 years' service to Vacation Fund. 6 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.

LABORERS	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Group 1:	$ 8.36	.92	.98		.10
Group 2:	8.49	.92	.98		.10
Group 3:	8.63	.92	.98		.10
Group 4:	8.74	.92	.98		.10
Group 5:	8.91	.92	.98		.10
Group 6:	9.285	.92	.98		.10
Group 7:	9.915	.92	.98		.10
POWER EQUIPMENT OPERATORS (Except Piledriving and Steel Erection)					
Group 1:	8.93	1.05	1.00		.08
Group 2:	9.30	1.05	1.00		.08
Group 3:	9.76	1.05	1.00		.08
Group 4:	10.29	1.05	1.00		.08
Group 5:	10.82	1.05	1.00		.08
Group 5A:	11.13	1.05	1.00		.08
Group 6:	11.46	1.05	1.00		.08
Group 7:	12.06	1.05	1.00		.08
TRUCK DRIVERS					
Group 1:	8.52	.92	.98		.08
Group 2:	8.65	.92	.98		.08
Group 3:	8.87	.92	.98		.08
Group 4:	9.22	.92	.98		.08
Group 5:	9.38	.92	.98		.08
Group 5A:	9.56	.92	.98		.08
Group 6:	9.70	.92	.98		.08
Group 7:	10.11	.92	.98		.08
Group 8:	10.625	.92	.98		.08
Group 8A:	11.28	.92	.98		.08
Group 8B:	10.97	.92	.98		.08
Group 8C:	9.08	.92	.98		.08

LABORERS

Group 1: All Helpers not herein separately classified; Cesspool Diggers and installers; Chat Box Man; Checker, tool dispatcher; Concrete dump manbelt, pipe and/or hoseman; Dumpman and/or spotter; Fence builder, guard rail builder highway; Form strippers; Labor, general or construction; Landscape gardener and nurseryman; Packing rod steel and pans; Rip rap stoneman; Astro turf layer; Cleanup, Bull gang; Trackman-railroad

Group 2: Cement finisher tender; Concrete curer (impervious membrane); Cutting torch operator; Fine grader (highway, engineering and sewer work only); Kettleman - Tarman; Power type concrete buggy

Group 3: Bander; Chucktender (except tunnel); Creosote tieman; Guinea chaser; Powderman helper; Rip-rap stone paver; Sandblaster (pot tender); Spiker and wrenchers

Group 4: Cement dumpers (Skip-type mixer or handling bulk cement); Chain saw machines (on clearing and grubbing); Concrete vibrating machines; Cribber and shorer (except tunnel); Floor sanders concrete; Hydraulic jacks, and similar mechanical tools not separately classified herein; Operators and tenders of pneumatic and electric tools; Pipe caulker and/or backup man (pipeline); Pipe wrapper; Pneumatic gopher; Rigger/Signalman (pipeline)

Group 5: Air and water wash-out nozzleman; Asphalt rakers and ironers; Driller; Grade setter (pipeline); Hand 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 pipe, underground tile and conduit); Rock slinger; Scaler (using Bos'ns chairs or safety belt); Tampers (mechanical - all types); Precast manhole erector

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 mixerman (gunite); Sandblaster (nozzleman)

Group 7: Concrete road form setter; Gunite nozzleman or rodman; Drillers, Joy Mustang, PR 143, 220 Gardner-Denver, Hydrasonic; Powderman; Scaler (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 helper; 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-moto paver, Slurry seal machine, and similar type equipment; Motor crane driver; Power sweeper operator - self-propelled; Ross 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; Aspahlt plant firemen; Elevator hoist operator (including Tuskey 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; Screed operator; Self-propelled chip spreading machine operator (including Slurry seal machine operator) Stationary pipewrapping and cleaning machine operator; Tugger operator

Group 5: Aggregate plant operator (including crushing, screening and sand plants, etc.); Asphalt plant mixer operator; Beltcrete machine; Boring machines operator; Concrete mechanical tamping, spreading or finishing machine (including Clary, Johnson or similar types); Concrete pumps operator; Concrete batch plant operator, all types and sizes; Conductor, brakeman, or handler; Drilling machine, including water wells; Elevating grader operator - all types and sizes (except as otherwise classified); Field equipment serviceman; Highline cableway signalman; Kolman belt loader operator or similar, with belt width 48" or over; Locomotive engineer (including Dinky - 20 tons wt. and over); Moto-paver and similar type equipment operator; Operating engineer rigger; Pneumatic-tired scraper operator (Turnapull, 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 pavement; Self-propelled compactor, with blade; Skip loader operator - all types with rated capacity over 1½ 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 K.W. or more; Surface heater and planer operator; Traveling Pipewrapping machine operator

POWER EQUIPMENT OPERATORS (Cont'd)
(Except Piledriving and Steel Erection)

Group 5-A: Heavy duty mechanic and/or welder; Pneumatic tired scraper, all sizes and types over 12 cu. yds. up to and including 45 cu. yds. MRC (Turnapull, 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 Mole, 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 MRC; 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 (150 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; Mucking machine operator; Overhead crane operator; Piledriver engineer (portable, stationary or skid rig); Pneumatic-tired scraper operator - all sizes and types (Turnapull, Euclid, Cat, D-W, Hancock and similar equipment over 45 cu. yds., MRC); 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 Gunnert, Zimmerman and similar types); Specialized power digger operator - attached to wheel-type tractor; Tower crane (or simila type) operator; Tractor operator (Pusher, Bulldozer, Scraper (400 net horsepower and over); Tugger 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 MRC 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 Wagons; Manhaul driver

Group 2: Dump or flatrack (2 or 3 axle); Water truck (under 2500 gallons); Buggymobile (1 cu. yd. or less); Tireman; Bus drivers, ambulance driver, self-propelled street sweeper; Warehouseman

Group 3: Dump or flatrack (4 axle); Dumptor or dumpster (less than 7 cu. yds.); Water truck (2500 gallons but less than 4000 gallons)

Group 4: Dumptor 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 8 cu. yds. but less than 10.5 cu. yds.); Rock truck (i.e. Dart, Euclid and other similar type end dumps, single unit less than 16 cu. yds.)

Group 5A: Oil Tanker or Spreader and/or Bootman, Retortman or Leverman

Group 6: Transit mix (over 10.5 cu. yds. but less than 14 cu. yds.); Ross carrier; Fork 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, i.e., Cat, DW 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 Classifications; Rock trucks (Dart, Euclid, or other similar end dump types) 16 cu. yds. and over; Eject-alls; Dumptor 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

SUPERSEDEAS 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 Aucilla River and all tributary Waterways.
DECISION NUMBER: GA79-1042 DATE: Date of Publication
Supersedes Decision No. GA-78-1015 dated March 10, 1978 in 43 FR 10166
DESCRIPTION OF WORK: Dredging Projects

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
HYDRAULIC DREDGES 20" AND OVER					
Leverman	$8.16	.73	.60	a	
Engineer	8.06	.73	.60	a	
Mate	7.17	.73	.60	a	
Welder	7.43	.73	.60	a	
Derrick Operator	7.73	.73	.60	a	
Spill barge operator	7.55	.73	.60	a	
Spider barge operator	7.55	.73	.60	a	
Tug master	7.10	.73	.60	a	
Carpenter	7.68	.73	.60	a	
Tug mate	6.74	.73	.60	a	
Electrician	7.88	.73	.60	a	
Machinist	7.61	.73	.60	a	
Steward	6.09	.73	.60	a	
Oiler & Fireman	5.87	.73	.60	a	
Deckhand & tug deckhand	5.44	.73	.60	a	
Shoreman	5.32	.73	.60	a	
Second cook	5.44	.73	.60	a	
Messman	5.32	.73	.60	a	
HYDRAULIC DREDGES UNDER 20":					
Leverman	7.38	.73	.60	a	
Engineer	6.97	.73	.60	a	
Welder	7.10	.73	.60	a	
Mate	6.23	.73	.60	a	
Oiler and Fireman	5.80	.73	.60	a	
Launchman	5.87	.73	.60	a	
Shoreman	5.32	.73	.60	a	
Spill barge operator	6.41	.73	.60	a	
Spider barge operator	6.41	.73	.60	a	
Deckhand	5.44	.73	.60	a	
CLAMSHELL DREDGES:					
Operator	8.09	.73	.60	a	
Engineer	7.58	.73	.60	a	
Welder	7.32	.73	.60	a	
Mate	7.01	.73	.60	a	
Fireman & Oiler	5.87	.73	.60	a	
Deckhand	5.44	.73	.60	a	
Launchman	5.87	.73	.60	a	
Scowman	5.54	.73	.60	a	

STATE: INDIANA COUNTY: MARION
DECISION NUMBER: IN79-2007 DATE: Date of Publication
Supersedes Decision No. IN76-2005, dated January 23, 1976 in 41 FR 3602
DESCRIPTION OF WORK: Residential Projects (consisting of single family homes and garden type apartments up to and including 4 stories.)

DECISION NO. GA79-1042

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DIPPER DREDGES:					
Operator	8.19	.73	.60	a	
Craneman	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	
Tug master	7.25	.73	.60	a	
Tug mate	6.82	.73	.60	a	
Scowman	5.54	.73	.60	a	
TUGS (TENDING DIPPER & CLAMSHELL DREDGES):					
Tug master	7.25	.73	.60	a	
Tug mate	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	
STEWARD 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	
Messmen & 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	

FOOTNOTE:

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 7% of straight time pay.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
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	9.53				
Graders	9.10				

SUPERSEDEAS DECISION

STATE: Nevada

COUNTY: Clark County (does not include the Nevada Test Site)

DECISION NUMBER: NV78-5102

DATE : Date of Publication

Supersedes Decision No. NV78-5018 dated March 17, 1978, 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	1.075	1.00	1.00	.03
BRICKLAYERS; Stonemasons	12.97	.90	.60		.06
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:					
Carpenters	11.96	.85	1.10	1.00	.10
Floor Layers; Patent Scaffold Erectors; Power Saw Operators	12.11	.85	1.10	1.00	.10
Piledrivermen	12.16	.85	1.10	1.00	.10
Millwrights	12.46	.85	1.10	1.00	.10
Zone 2: Area outside of Zone 1 and not more than 20 miles from the communities described above:					
Carpenters	12.46	.85	1.10	1.00	.10
Floor Layers; Patent Scaffold Erectors; Power Saw Operators	12.61	.85	1.10	1.00	.10
Piledrivermen	12.66	.85	1.10	1.00	.10
Millwrights	12.96	.85	1.10	1.00	.10
Zone 3: Area over 20 miles and not more than 40 miles from the communities described in Zone 1:					
Carpenters	12.71	.85	1.10	1.00	.10
Floor Layers; Patent Scaffold Erectors; Power Saw Operators	12.86	.85	1.10	1.00	.10
Piledrivermen	12.91	.85	1.10	1.00	.10
Millwrights	13.21	.85	1.10	1.00	.10

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CARPENTERS: (Cont'd)					
Zone 4: Area over 40 miles from the communities described in Zone 1:					
Carpenters	$ 13.96	.85	$ 1.10	$ 1.00	.10
Floor Layers; Patent Scaffold Erectors; Power Saw Operators	14.11	.85	1.10	1.00	.10
Piledrivermen	14.16	.85	1.10	1.00	.10
Millwrights	14.46	.85	1.10	1.00	.10
CEMENT MASONS:					
Cement Masons	11.90	1.00	1.00		.08
Cement Floor Finishing Machine; Color Work	12.15	1.00	1.00		.08
DRYWALL INSTALLERS:					
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	12.13	.85	1.10	1.00	.10
Zone 2: Area outside of Zone 1 and not more than 20 miles from the communties described in Zone 1	12.63	.85	1.10	1.00	.10
Zone 3: Area over 20 miles and not more than 40 miles from the communities described in Zone 1	12.88	.85	1.10	1.00	.10
Zone 4: Area over 40 miles from the communities described in Zone 1	14.13	.85	1.10	1.00	.10

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ELECTRICIANS:					
Electricians; Technicians	$ 15.26	.98	3%+1.55		.08
Cable Splicers	15.59	.98	3%+1.55		.08
ELEVATOR CONSTRUCTORS	14.53	.895	.69	3%+a	.03
ELEVATOR CONSTRUCTORS' HELPERS	10.17	.895	.69	3%+a	.03
ELEVATOR CONSTRUCTORS' HELPERS (PROB.)	7.265				
GLAZIERS	9.83	.65	.40		.05
IRONWORKERS:					
Fence Erectors Ornamental; Reinforcing; Structural	11.11	1.29	2.57	1.65	.07
	12.00	1.29	2.57	1.65	.07
LATHERS	10.60	.70	1.00	1.00	.16
MARBLE MASONS	12.97	.90	.60		.06
MARBLE, TERRAZZO, TILE FINISHERS	9.65	.70	.60		
MASON TENDERS	10.82	.66	1.35		
PAINTERS:					
Brush; Roller	13.64	.75	.35		.06
Paperhangers; Spray; Steel; Swing Stage; Sandblasters; Tapers	13.99	.75	.35		.06
PLASTER TENDERS	11.92	.66	1.35		
PLASTERERS	12.18	1.00	1.00		.08
PLUMBERS; Steamfitters	11.53	1.25	2.32	1.85	.08
ROOFERS	14.75	.80			
SHEET METAL WORKERS	14.71	1.14	1.61		.17
SOFT FLOOR LAYERS	13.47	.65			.15
SPRINKLER FITTERS	15.50	.75	1.05		.08
TERRAZZO WORKERS, TILE SETTERS	12.27	.70	.60		.06

FOOTNOTE:

a. Employer contributes 4% basic hourly rate for over 5 years' service and 2% basic hourly rate for 6 months' to 5 years' service as Vacation Pay 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.

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 dumpman; 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 Gardener and Nurseryman; Tarman and Mortarman, Kettleman, Potman and Man applying asphalt, 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 Dumper (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 Wrapper, Pot Tender and Form Man; Making and Caulking of all non-metallic Pipe Joints; Operators and Tenders of pneumatic and electric tools, Vibrating machines, hand propelled trenching machines, impact wrench multiplate and similar mechanical tools not separately classified herein; Operator of cement Grinding Machine; Riprap Stonepaver; Roto-scraper; Sandblaster (pot tender); Scaler; Septic Tank Digger and Installer (lead man); Tank Scaler and Cleaner; Tree Climber, faller, chain saw operator, Pittsburgh Chipper and similar type brush shreeders

Group 3: Gas and Oil Pipeline Wrapper, 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; Scaler (using bos'n chair or safety belt or power tools)

Group 4: Cribber or Shorer, lagging, sheeting, trench bracking, 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 (nozzleman); Steel Headerboard Man

Group 5: Driller (core, diamond or wagon), Joy Driller Model Tw-M-2A, Gardner-Denver Model DH 143 and similar type drills

POWER EQUIPMENT OPERATORS (Except Piledriving and Steel Erection)	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Group 1	$ 11.10	$ 1.10	$ 2.30	.70	.14
Group 2	11.38	1.10	2.30	.70	.14
Group 3	11.67	1.10	2.30	.70	.14
Group 4	11.81	1.10	2.30	.70	.14
Group 5	12.03	1.10	2.30	.70	.14
Group 6	12.14	1.10	2.30	.70	.14
Group 7	12.26	1.10	2.30	.70	.14
Group 8	12.43	1.10	2.30	.70	.14
Group 9	12.56	1.10	2.30	.70	.14

POWER EQUIPMENT OPERATORS
(Except Piledriving and Steel Erection)

Group 1: Brakeman; Compressor Operator; Engineer Oiler; Generator Operator; Heavy Duty Repairman Helper; Pump; Signalman; Switchman

Group 2: Concrete Mixer Operator, skip type; Conveyor Operator; Fireman; Hydrostatic Pump Operator; Oiler Crusher (asphalt or concrete Plant); Plant Operator, generator, pump or compressor; Rotary Drill Helper (oil-field); Skiploader - wheel type up to 3/4 yd. with attachment; Soils Field Technician; Tar Pot Fireman; Temporary Heating Plant Operator; Trenching Machine Oiler; Truck Crane Oiler

Group 3: A-Frame or Winch Truck; Elevator Operator (inside); Equipment Greaser (rack); Ford Ferguson (with dragtype attachments); Helicopter Radioman (ground); Power Concrete Curing Machine; Power Concrete Saw; Power driven Jumbo Form Setter; Ross 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 Hoist; Highline Cableway Signalman; Hydra-hammer-Aero Stomper; 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 5: Asphalt Plant Engineer; Concrete Batch Plant; Backhoe (up to and including 3/4 yds.); Bit Sharpener; Concrete Joint Machine (canal and similar type); Concrete Planer; Deck Engine; Forklift (under 5 ton capacity) Machine Tool; Maginnis Internal Full Slab Vibrator; Mechanical Berm (curb or gutter concrete or asphalt); Mechanical Finisher (concrete-Clary-Johnson-Bidwell or similar); Pavement Breaker; Road Oil Mixing Machine; Roller (asphalt or finish); Rubber-tired Earth Moving Equipment, (single engine, up to and including 25 yds. struck); Self-propelled Tar Pipelining Machine; Slip Form Pump (power-driven hydraulic lifting device for concrete forms); Tugger Hoist (1 drum); Tunnel Locomotive (over 10 and up to and including 30 tons); Stinger Crane (Austin-Western or similar type); Skiploader Crawler and wheel type (over 3/4 yards and up to and including 1½ yards); Tractor-Bulldozer, Tamper, Scraper (single engine, up to 100 HP, Flywheel and similar types, up to and including D-5 and similar types)

Group 6: Asphalt or Concrete Spreading (tamping or finishing); Asphalt Paving Machine (Barber Greene or similar type); BHL Lima Road Pactor or similar; Bridge Crane; Pipe Laying Machine (cast in place); Combination Mixer and Compressor (gunite work); Concrete Pump (truck mounted); Concrete Mixer; Crane (up to and including 25 tons); Crushing Plant; Elevating Grader forklift (over 5 tons); Grade Checker; Gradeall; Grouting Machine; Heading Shield; Heavy Duty Repairman; Hoist (Chicago Boom and similar type); Kolman Belt Loader and similar type; LeTourneau Blob Compactor or similar type; Lif Slab Machine (Vagtborg and similar types); Lift Mobile; Loader-Athey, Euclid Sierra and similar type); Material Hoist; Mucking Machine 1/4 yd. - rubber-tired, rail or track type); Pneumatic Concrete Placing Machine (Hackley-Presswell or similar type); Pneumatic Heading Shield (tunnel); Pumpcrete gun; Rotary Drill (excluding caisson type); Rubber-tired Earth Moving Equipment Operator (single engine - Caterpillar, Euclid, Athey Wagon and similar types with any and all attachments over 25 yards and up to and including 50 cubic yards struck); Rubber-tired Scraper (self-loading - paddle wheel type John Deere, 1040 and similar single unit); Skiploader (Crawler and wheel typ over 1½ yds., up to and including 6½ yds.); Surface Heaters and Planers; Rub ber-tired Earth Moving Equipment, multiple engine (up to and including 25 yd struck); Trenching Machine (over 6 feet depth capacity, manufacturers rating Tower Crane; Tractor Compressor Drill Combination; Tractor (any type larger 100 flywheel HP and over or similar)(Bulldozer, Tamper, Scraper and Push Tra ctor single engine); Tractor (boom attachments); Traveling PIpe Wrapping, Cleaning and Bending; Tunnel Locomotive (over 30 tons); Shovel, Backhoe, Dra line, Clamshell (over 3/4 yd. and up to 5 cu. yds. M.R.C.)

POWER EQUIPMENT OPERATORS (Cont'd)
(Except Piledriving and Steel Erection)

Group 7: Crane (over 25 tons up to and including 100 tons M.R.C.); Derrick Barge, Dual drum mixer; Hoist, stiff legs, guy derrick, or similar type, up to and including 100 tons; Monorail locomotive (diesel, gas or electric); Motor patrol-blade Operator (single engine); Multiple engine tractor operator (Euclid and similar type except Quad 9 cat); Rubber-tired earth moving equipment (single engine over 50 yds. struck); Rubber-tired earth moving equipment (multiple engine, euclid, Caterpillar and similar) (over 25 yds. and up to 50 cu. yds. struck); Tractor loader operator (crawler and wheel type over 6½ yds.); Tower crane repairman; Shovel, backhoe, dragline, clamshell operator (over 5 cu. yds. MRC); 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 derricks or similar types (capable of hoisting 100 tons or more); Mass excavator (less than 750 cu.yds.); Mechanical finishing machine; Mobile form traveler; Motor patrol (multi engine); Pipe mobile machine; Rubber-tired earth moving equipment (multiple engine, Euclid, Caterpillar and similar type over 50 cu. yds. struck); Rubber-tired self loading scraper (paddle wheel-auger type self-loading) (2 or more units); Tandem equipment (2 units only); Tandem tractor (quad 9 or similar type); Tunnel mole boring machine; Rubber-tired Scraper (pushing without push cat, push-pull) (50¢ 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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Group 1	$9.97	.51	.70		
Group 2	10.08	.51	.70		
Group 3	10.13	.51	.70		
Group 4	10.29	.51	.70		
Group 5	10.47	.51	.70		
Group 6	10.97	.51	.70		

TRUCK DRIVERS

Group 1: Dump Trucks (less than 12 yds.); Trucks (legal payload capacity less than 15 tons); Water and fuel trucks (under 2500 gals.); Pickups; Service; Repairman helper; Drivers of busses (on jobsite used for transportation of up to 25 passengers); Teamster 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 gals. Truck driver working on gas and oil pipeline (including winch truck and all sizes of trucks); Truck greaser and trieman; Drivers of busses (on jobsite used for transportation of more than 25 passengers); Bootman

Group 3: Dumpcrete (less than 6½ yds.); Transit-mix (less than 3 yds); 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 gals. but less than 6000 gals.); Dumpcrete (6½ 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 gals. 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 PB and similar-type trucks when performing work within teamster jurisdiction, regardless of types of attachment including power units pulling off highway belly dumps in tandem

SUPERSEDEAS DECISION

STATE: NEVADA

COUNTIES: Nevada Test Site, including Tonopah Test Range in Clark, Lincoln and Nye Counties, Nevada

DECISION NUMBER: NV79-5107

DATE: Date of Publication

Supersedes Decision No. NV78-5010 dated March 10, 1978, in 43 FR 10229

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

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	$ 14.52	$ 1.10	$ 1.30		
BRICKLAYERS	12.97	.90	.60		.06
CARPENTERS:					
Carpenters	12.16	.85	1.10	.80	.06
Floor Layers	12.185	.85	1.10	.80	.06
Millwrights	12.96	.85	1.10	.80	.06
CEMENT MASONS:					
Cement Masons	9.90	1.00	1.00	2.00	.08
Floor Finishing Machine	10.25	1.00	1.00	2.00	.08
ELECTRICIANS:					
Electricians; Equipment Operators; Linemen	14.22	.98	3%+1.55		.05
Cable Splicers	14.55	.98	3%+1.55		.05
Groundman	11.58	.98	3%+1.55		.05
ELEVATOR CONSTRUCTORS:					
Elevator Constructors	14.53	.895	.69	3%+a	.03
Elevator Constructors' Helpers	10.17	.895	.69	3%+a	.03
Elevator Constructors' Helpers (Prob.)	7.265				
IRONWORKERS:					
Reinforcing; Ornamental; Structural	12.01	1.29	2.57	1.65	.07
MASON TENDERS	10.82	.66	1.35		
PAINTERS:					
Brush; Roller	10.76	.75	.65	1.50	.06
Paperhangers; Spray; Steel; Sandblasters; Swing Stage; Tapers; Buffing; Sandblasters, Steel	11.11	.75	.65	1.50	.06
PLUMBERS; Steamfitters	12.63	1.25	2.32	2.00	.08
ROOFERS	14.75	.80			
SHEET METAL WORKERS	12.46	1.14	1.61	1.50	.10
SPRINKLER FITTERS	15.50	.75	1.05		.08

FOOTNOTE

a. Employer contributes 4% basic hourly rate for over 5 years' service and 2% basic hourly rate for 6 months' to 5 years' service as Vacation Pay 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

LABORERS	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Group 1	$ 8.08	.51	$ 1.25	$ 1.25	
Group 2	8.13	.51	1.25	1.25	
Group 3	8.16	.51	1.25	1.25	
Group 4	8.18	.51	1.25	1.25	
Group 5	8.20	.51	1.25	1.25	
Group 6	8.21	.51	1.25	1.25	
Group 7	8.23	.51	1.25	1.25	
Group 8	8.26	.51	1.25	1.25	
Group 9	8.27	.51	1.25	1.25	
Group 10	8.29	.51	1.25	1.25	
Group 11	8.34	.51	1.25	1.25	
Group 12	8.37	.51	1.25	1.25	
Group 13	8.39	.51	1.25	1.25	
Group 14	8.42	.51	1.25	1.25	
Group 15	8.44	.51	1.25	1.25	
Group 16	8.505	.51	1.25	1.25	
Group 17	8.53	.51	1.25	1.25	
Group 18	8.60	.51	1.25	1.25	

LABORERS

Group 1: Laborer - general; Laborer - demolition (cleaning of bricks, lumber, etc.); Dry packing of concrete and filling of form-bolt holes; Flagman, spotter, debris handler and dumpman; Fence builder; Tool attendant (jobsite only); Gas and oil pipeline laborer; Flagman

Group 2: Cutting torch operator (demolition); Tarman and Mortarman

Group 3: Guinea Chaser

Group 4: Fine grader; highway and street paving, airport runways and similar work; Landscape gardener, nurseryman and grounds keeper

Group 5: Laborer - packing rod steel and pans

Group 6: Underground laborer including caisson bellowers (except tunnels)

LABORERS (Cont'd)

Group 7: Chucktender (except tunnels); Scaler; Tank scaler and cleaner

Group 8: Cesspool 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; Buggymobile 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 slinger; 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: Cribber or shorer; Powderman

Group 16: Steel Headerboard Man

Group 17: Driller (Core, Diamond or Wagon), Joy Driller Model TW-M-2A, Gardner-Denver Model DH 143 and similar type drills; Sandblaster (nozzleman)

Group 18: Head Rock Slinger

POWER EQUIPMENT OPERATORS (Except Piledriving and Steel Erection)	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Group 1	$ 10.78	$ 1.10	$ 2.00	.35	.04
Group 2	11.02	1.10	2.00	.35	.04
Group 3	11.26	1.10	2.00	.35	.04
Group 4	11.37	1.10	2.00	.35	.04
Group 5	11.56	1.10	2.00	.35	.04
Group 6	11.66	1.10	2.00	.35	.04
Group 7	10.36	1.10	2.00	.35	
Group 7-A	10.07	1.10	2.00	.35	
Group 7-B	9.96	1.10	2.00	.35	
Group 7-C	9.72	1.10	2.00	.35	

POWER EQUIPMENT OPERATORS
(Except Piledriving and Steel Erection)

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, $0.10 per hour for each additional unit up to 10 units, portable units); Generator, Pump or Compressor Plant; Rotary Drill Helper (oilfield type); Skiploader, wheeltype, Ford, Ferguson, Jeep or similar type, 3/4 yard or less (w/o drag-type attachments); Temporary Heating Plant; Truck Crane Oiler; 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-hammer or similar type equipment; Power Concrete Curing Machine; Power Concrete Saw; Power-driven Jumbo Form Setter; Ross Carrier; Self-propelled Tar Pipe-lining Machine; Stationary Pipe Wrapping and Cleaning Machine; Towblade Operator

POWER EQUIPMENT OPERATORS (Cont'd)
(Except Piledriving and Steel Erection)

Group 4: Asphalt Plant Fireman; Boring Machine; Boxman or Mixer Box (concrete or asphalt plant); Derrickman (oilfield type); Drilling Machine (including water wells); Highline Cableway Signalman; 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 - finish; Asphalt Plant Engineer; Deck Engine; Grade Checker; Heavy Duty Welder; Machine Tool; Pavement Breaker; Pneumatic Heading Shield - tunnel; Road Oil Mixing Machine; Forklift, under five tons; Rubber-tired, heavy duty equipment (Oshkosh, DW, Euclid, LeTourneau, LaPlant-Choate, or similar type equipment with any type attachments); Sliploader, wheeltype, over 3/4 yards, up to and including 1½ 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 Mixer; Concrete Pump or Pumpcrete Gun; Crushing Plant Engineer; Elevating Grader; Heavy Duty Repairman; Highline Cableway; Hoist (Chicago Boom and Mine); Kolman 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 - Hackley-Presswell or similar type; Rotary Drill, excluding caisson type; Skiploader, wheeltype, over 1½ yards.; Surface Heater and Planer; Tractor Loader - crawler type - all types and sizes; Tractor, with boom attachments; Traveling Pipe Wrapping, Cleaning and Bending Machine; Trenching Machine (over 6 ft. depth); Universal equipment (Shovel, Backhoe, Dragline, Clamshell, Derrick, Derrick Barge, Crane, Piledriver and Mucking 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

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
TRUCK DRIVERS:					
Group 1	$ 10.99	.48	$1.12		
Group 2	11.09	.48	1.12		
Group 3	11.14	.48	1.12		
Group 4	11.30	.48	1.12		
Group 5	11.48	.48	1.12		

TRUCK DRIVERS

Group 1: Light duty driver

Group 2: Bootman; Truck Greaser; Light vehicle dispatcher

Group 3: Tireman; Warehouse Clerk

Group 4: Heavy duty driver; Forklift driver; Equipment parts stockroom clerk

Group 5: Extra heavy duty driver

STATE: Pennsylvania COUNTIES: Lawrence & Mercer
DECISION NO.: PA79-3003 DATE: Date of Publication
Supersedes Decision No. PA77-3078 dated June 4, 1977, in 42 FR 32478.
DESCRIPTION OF WORK: Building Erection and Foundation Excavation Projects, (does not include single family homes and garden type apartments up to and including 4 stories)

DECISION NO. PA79-3003

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Asbestos Workers	12.89	.55	1.00		.02
Boilermakers	11.785	7.5%	7%		.01
Bricklayers & Stonemasons:					
Mercer County	11.25	.75	.60		.02
Lawrence County	10.98	.75	.87		.02
Carpenters:					
Lawrence County	11.15	6%	8%	6%	25%
Mercer County	10.74	1.17	1.10		.05
Cement Masons:					
Lawrence County	11.86				
Mercer County	11.32	.68	1.81		
Electricians:					
Lawrence County	12.08	6%	3%	1.00	1½%
Mercer County	11.45	.35	1% +.45		.01
Elevator Constructors	11.99	.745	.56	b+c	.02
Elevator Constructors Helpers	70%JR	.745	.56	b+c	.02
Elevator Constructor's Helpers (prob.)	50%JR				
Glaziers	10.37	.40	.20		.01
Ironworkers, structural, ornamental & reinforcing	12.03	.40	1.30		.07
Laborers:					
Laborers, carryable pumps, west brick buggy or similar, vibrator operators, walk behind fork lift or simlar (non self-propelled) stripper & mover or forms, cement masons, footers, window cleaner, tool room man, all material conveyor (regardless of power used, including starting & stopping)	9.49	.85	.71		
West brick buggy or similar (self-propelled), power wheelbarrows and buggies, walk behind forklift or similar, (self-Propelled) wagon drill runners's helper, (including drill mounted on truck, track					
Laborers' (Cont'd) or similar), blaster's helper, all operators of compacting equipment, pipe layer, burner, jackhammer man concrete buster	9.615	.85	.71		
Hod Carrier, scaffold builder bell and bottom man on furnaces and stacks, mortar mixer, mortar mixing machine (regardless of power used, including starting and stopping) grout machine feeder and pump operators and concrete saw operator, wagon drill operators	9.74	.85	.71		
Gunnite nozzleman	9.99	.85	.71		
Blaster	10.19	.85	.71		
Landscaping:					
Landscape Laborers	6.70	12%	10%		
Skilled Landscape Laborer	6.85	12%	10%		
Landscape Tractor Operator	7.20	12%	10%		
Lead Burners	10.75	.40	.25	a	.01
Line Construction:					
Linemen, dynamite man, heavy equipment operator	11.61	.50	3%		3/8%
Winch truck operator	8.16	.50	3%		3/8%
Groundman	7.80	.50	3%		3/8%
Marble Setters:					
Lawrence County	10.98	.75	.87		.02
Mercer County	12.305				
Marble Setters Helper:					
Lawrence County	7.95		.10		
Mercer County	11.455				
Millwrights:					
Lawrence County	10.26	6%	6%	25%	½%
Mercer County	11.53	1.17	1.10		.05
Painters:					
Commercial:					
Brush & Roller	10.80	.65	1.00		
Spray	11.80	.65	1.00		
Industrial:					
Brush & Roller	11.60	.65	1.00		
Spray	12.60	.65	1.00		

DECISION NO. PA79-3003

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Piledrivermen:					
Lawrence	11.85	5.5%	10%		50%
Mercer County	11.53	1.17	1.10		.05
Plasterers:					
Lawrence County	11.79				
Mercer County: Shenango, Sandy, Lake & Redonia Twps.	11.79				
Remainder of County	10.98	.75	.87		.02
Plumbers & Steamfitters:					
Lawrence	12.39	.71	.71		.05
Mercer County	11.75	.50	.80		.05
Roofers	11.70	.75	.80		.02
Sheet Metal Workers:					
Lawrence	11.60	.95	1.33		.14
Mercer County	11.84	.75	.79		.04
Soft Floor Layers:					
Lawrence County	10.66	6%	6%	.60	5%
Mercer County	10.20	1.17	1.10		.50
Sprinkler Fitters	12.31	.75	1.05		.08
Terrazzo Workers & Tile Setters:					
Lawrence County	10.98	.75	.87		.02
Mercer County	12.305				
Welders - Receive rate of craft					

PAID HOLIDAYS (Where 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 Eve, 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.

DECOSION #PA79-3003

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
POWER EQUIPMENT OPERATORS					
CLASS 1	$12.075	.95	1.00		.09
CLASS 1 - A	12.325	.95	1.00		.09
CLASS 1 - B	12.575	.95	1.00		.09
CLASS 1 - C	12.825	.95	1.00		.09
CLASS 2 -	11.925	.95	1.00		.09
CLASS 3	10.05	.95	1.00		.09
CLASS 3 A	10.55	.95	1.00		.09
CLASS 4	9.40	.95	1.00		.09
CLASS 5	8.35	.95	1.00		.09
CLASS 6	8.65	.95	1.00		.09
CLASS 6 - A	8.75	.95	1.00		.09
CLASS 6 - B	8.90	.95	1.00		.09
CLASS 6 - C	9.65	.95	1.00		.09

CLASSIFICATION DEFINITIONS
POWER EQUIPMENT OPERATORS

CLASS 1 - Austin-Western or similar type Under 25 ton, austin-western or similar type 25 ton or over, auto grader (CMI or similar, backhoe, batch plant when conveyors are used for direct feedling or discharge, batch plant no conveyors for direct feeding or discharge (without oiler), cableway, caisson drill, central mix plant, cranes (excluding overhead)(truck or crawler type), cranes tower (mobile) cranes tower (stationary) (climbing type) use of oiler to be discussed at pre job) cranes tower (climbing type) cranes hydraulic self contained over 18 ton cranes hydraulic self contained - 18 ton or less, derrick traveler (self propelled), derrick (all types)(when assistance required it will be an oiler or apprentice) derrick boats, dragline, dredge, engineer maintenance franki or similar type pile driver, gradall (remote control or otherwise), helicopter (when used for erection purposes), helicopter hoist operators (when used for erection purposes), hi-lift 4 yds. or over, hoist-hod 2 cages up to 10 floors) Chicago Boom Attached hoist (50 ft. or over) (stacks, stoves or furnaces) hoist (slipform jobs hop to or similar type with 180° swing hop to or similar type with 360° swing kocal koehring scooper, metro chip harvester or similar type, mix mobile or similar type (with self-loading attachment), mix mobiling or similar type, mucking machine (tunnel), multiple bowl machines, pipe driver (sonic or similar type) (when assistance required it will be an oiler or apprentice), post driver-guard rail (truck mounted), post driver-guard rail (skid type), pumpkrete - mobile or similar type, quad nine, shovels (all types), slip form paver (CMI or similar), tractors - Boom Mounted (all types), tractors (all types with hydraulic backhoe attached), tug boat, whirley

CLASS 1-A - Austin-Western or similar type under 25 ton with jib, austin-western or similar type 25 ton 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 ton 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), compressor (1) and gunite machine (1) (combination), concrete belt placer, crane - overhead, crushinf & screening plants, drill - davey or similar type drill - core (truck or skid mounted), drill - well & core (truck mounted), elevator (New buildings), euclid loader, excavating equipment (all Other), forklift-lull or similar, grader, grader-elevating, greaser-equipment (head), hi-lift - less than 4 yds., hoist - one drum (4 floors or over), hoist - hod (buildings 4 floors or more), hoist - (2 drums or more in one unit), jumbo operator, locomotive, lift slab machine (hydraulic) mixer - paving, muching machine, pipe cleaning machine, refrigeration plant (used for construction jobs that is, cooling concrete & holding banks), ross 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 (3 within a reasonable distance); generators electric (3) (over) 5 KW up to 20 KW), pumps (1½" discharge or less) (4 to 5 within reasonable distance), pumps (3) (over 1½" 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), paver operator - asphalt (spreader), pumpkrete or similar type (not self-propelled), pumpcrete 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 blasting machine (1), (combination), crane (carry), curb builder (self-propelled), drills-well & horizional truck mounted, forklifts (ridden or self-propessed), hoist one drum (regradless 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), tube finisher (CMI or similar type), tugger, truck, (winch) 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 (1½" discharge or less (2 to 3), pumps (over 1½" 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), huck machine or similar type, mixer concrete (regardless of power used) mixer mortar - over 10 cu. ft. (regardless of power used) pump (over 1½" discharge regardless of power used) spray cure machine (power driven) steam jenny (or similar type) syphon (steam or air) welding machine single (300 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 ladavator, mixer mortar, (10 cubic ft. or under), mulching machine, pin puller (powered) pulverizer, pump - 1½" discharge or less, seeding machine, spreader side delivery, shoulder (attachment) tie tamper (multiple heads) tractor farm (when used for landscaping) water blaster, oiler-truck 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 Oiler - Truck crane 50 ton up to & incl. 100 ton

CLASS 6-C Oiler - Truck crane 100 ton and over

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
TRUCK DRIVERS					
CLASS 1	$9.10	6.5%	5.6%	a	
CLASS 2	9.15	6.5%	5.6%	a	
CLASS 3	9.17	6.5%	5.6%	a	
CLASS 4	9.26	6.5%	5.6%	a	
CLASS 5	9.19	6.5%	5.6%	a	
CLASS 6	9.46	6.5%	5.6%	a	
CLASS 7	9.28	6.5%	5.6%	a	
CLASS 8	9.44	6.5%	5.6%	a	

CLASSIFICATIONS DEFINITIONS

CLASS 1 - Warehouseman, chauffeu and ambulance drive, service truck (pickup, jeep, busses, station wagon,panel truck, escort vehicle, including fuel and water trucks)

CLASS 2 - Dump and flat top (including fuel and water trucks, fork lift in warehouse or job site storage area and single acle trucks with power tailgate); distributor truck over 33,000 lbs. gross weight (oil, tar asphalt products two man operation, bot men)

CLASS 3 - Transit mix, single axle

CLASS 4 - Transit mix, tandem

CLASS 5 - Heavy duty tractor and trailer with high bed, 4 wheels

CLASS 6 - Heavy duty tractor and trailer with low bed, 6 to 16 wheels andpole trailer and wide load

CLASS 7 - 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; euclids or equivalent, tri-axle including mixer, drivers towing equipment

CLASS 8 - WInch truck and form truck

FOOTNOTE:

a. Paid Holidays: New Year's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, Christmas Day and Veterans 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.

SUPERSEDEAS DECISION

STATE: South Carolina COUNTY: Sumter
DECISION NUMBER: SC79-1037 DATE: Date of Publicati
Supersedes Decision No. SC76-1008 dated January 9, 1976 in 41 FR 1699.
DESCRIPTION OF WORK: Building Construction Projects (excluding 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.
BRICKLAYERS	$5.75				
CARPENTERS	5.00				
CEMENT MASONS	4.75				
ELECTRICIANS	4.49				
IRONWORKERS	4.34				
LABORERS	2.90				
PAINTERS	7.25				
PLUMBERS & Pipefitters	5.03				
ROOFERS	3.80				
SHEET METAL WORKERS	3.51				
SPRINKLER FITTERS	8.25	.75	1.05		.08
TRUCK DRIVERS	2.90				
WELDERS - Rate for craft.					
POWER EQUIPMENT OPERATORS:					
Backhoe	3.74				
Bulldozers	5.00				
Cranes, derricks, draglines	5.00				

SUPERSEDEAS DECISION

STATE: South Carolina COUNTIES: See below*
DECISION NUMBER: SC79-1045 DATE: Date of Publication
Supersedes Decision No.: SC78-1040 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

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Air Conditioning Mechanic	8.10				
Bricklayers	6.50				
Carpenters	4.75				
Cement Masons	6.00				
Electricians	6.74				
Elevator Constructors	8.02				
Glaziers	5.85				
Ironworkers	4.51				
Laborers:					
Laborers, unskilled	3.00				
Mortar mixers	3.25				
Pipelayers	3.25				
Lathers	4.56				
Metal building erector	4.00				
Painters	4.89				
Plasterers	5.10				
Plumbers & Pipefitters	5.50				
Roofers	3.92				
Sheet Metal Workers	5.18				
Sprinkler Fitters	7.50				
Tile Setters	5.75				
Truck Drivers	3.51				
Welders - rate for craft.					
POWER EQUIPMENT OPERATORS:					
Backhoe	4.50				
Bulldozer	4.00				
Crane, derricks, draglines	4.50				
Front End Loader	4.50				
Motor Grader	3.50				
Scraper - pans	3.50				
Tractors	4.50				

[FR Doc. 79-6839 Filed 3-8-79; 8:45 am]

federal register

FRIDAY, MARCH 9, 1979

PART IV

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

MEDICAL DEVICES

Administrative Detention Procedures

[4110-03-M]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

[Docket No. 77N-0218]

SUBCHAPTER A—GENERAL

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

SUPCHAPTER H— MEDICAL DEVICES

PART 800—GENERAL

Administrative Detention Procedures

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The agency is issuing a final regulation establishing administrative detention procedures to enable its representatives to detain, for up to 30 calendar days, medical devices intended for human use believed to be adulterated or misbranded. This regulation is required by the Medical Device Amendments of 1976. This regulation is intended to protect the public from adulterated or misbranded devices during the time it takes the agency to determine whether such devices are adulterated or misbranded and to institute and process any proposed legal action.

EFFECTIVE DATE: April 9, 1979.

FOR FURTHER INFORMATION CONTACT:

Bert L. Schrivener, Bureau of Medical Devices (HFK-116), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7304.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of October 7, 1977 (42 FR 54574), the Commissioner of Food and Drugs proposed a regulation relating to the administrative detention of medical devices as a new § 800.55, *Administrative detention* (21 CFR 800.55).

Interested persons were given until December 6, 1977 to comment on the proposed regulation. Twenty-one comments were received.

The Commissioner has made several changes to clarify and simplify the final regulation. For example, the final regulation substitutes the term "authorized FDA representative" for the proposed term "authorized officer or employee of the Food and Drug Administration."

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 device 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 promises to voluntarily suspend shipments are broken, the public may be exposed to violative products, and the agency's 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 devices will voluntarily suspend shipment and adhere to any agreement with FDA to correct any possible violations before further 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 rather than to institute legal or administrative action to compel compliance.

3. Three comments on proposed § 800.55(b) suggested that the person having possession of devices 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. Furthermore, the required opportunity for a regulatory hearing provides a way for the person having possession of detained devices to present information and views to the FDA Regional director within a few days after the detention. The Commissioner has concluded that the procedures in the regulation already are fair, without the additional steps suggested in the comments.

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 limitation 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 these comments. FDA investigators are trained to observe and evaluate the importance of possible misbrand-

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(g)(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 District 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 physicians and other users (possibly even patients).

The Commissioner agrees with the comments. The inspection authority in section 704 of the act extends to establishments where devices are held by users for introduction into interstate commerce or after such introduction. Section 304(g) of the act, in conjunction with section 704, clearly authorizes detention of devices encountered 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. *An article of device * * * Cameron Spitler * * **, 261 F. Supp. 243 (D. Neb. 1966).) 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) requested 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 (HFA-305), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. However, the Commissioner is not adopting 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 requirements would undermine 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) suggested that the detention order state the manner in which the suspected violation can be corrected.

The Commissioner rejects these comments. In many instances, the precise nature of the violation or the extent of the violation may be uncertain at the time the order is issued. Moreover, the investigator may not know how the violation can be corrected or the best way to correct it. If the person who has the detained devices wants to try to correct the suspected violation, that person should present FDA with a plan for eliminating any violative features of the devices. After FDA's investigation has determined the nature of the violation, this information, together with any suggestions the agency has concerning how the violations may be corrected, will be communicated swiftly and informally to the person who has the detained devices if FDA has not already provided this information. When appropriate (i.e., when correction of the violation is feasible), FDA may extend to the person who has the devices an opportunity to correct the violation voluntarily.

11. Manufacturers with several facilities submitted comments on § 800.55(d) arguing that the detention order should state precisely where the detained devices are located.

The Commissioner agrees with the comments and has revised the final regulation accordingly. The detection order contains a specific block for indicating the location (name, address, and zip code) of the detained devices. The Commissioner has changed § 800.55(d)(3) of the final regulation to make the language consistent with that of the detention notice that serves as the detention order.

12. 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 to the shipper of record and the owner of the vehicle or carrier. It was thus obvious that detention of the devices in the custody of a common carrier was contemplated. Moreover, carriers used to transport or hold devices are subject to inspection under section 704 of the act.

Vehicles in which devices are detained may not be moved until the devices are removed from the vehicles. Because proposed § 800.55(h) did not contain a provision covering such removal, the agency has amended § 800.55(h) in the final regulation to allow the removal from vehicles of detained devices upon written approval of an authorized FDA representative. 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. 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).

13. The Commissioner has made minor corrections in § 800.55(d)(3), explaining language appearing on the detention notice form that will be employed as the detention order that will be delivered to the person in whose possession the device is detained, and making the language in the regulation correspond more exactly to the language in this form. The text of section 304(g) of the act and of § 800.55(g) (1) and (2) will appear on the back of the detention notice to provide notice of opportunity for appeal and an informal hearing on a detention order. The back of the notice also will state that any hearing will be conducted in the form of a regulatory hearing in accordance with 21 CFR Part 16—Regulatory Hearing Before the Food and Drug Administration, with several exceptions described in § 800.55(g)(3) of the regulation.

APPROVAL OF THE DETENTION ORDER

14. Comments on proposed § 800.55(e) suggested that an FDA Regional Director or the Director of the Bureau of Medical Devices, rather than the FDA District Director, would be the proper individual to approve a detention order.

The Commissioner rejects these comments because he believes that FDA District Directors, who are in direct contact with the investigators and the circumstances of each case, are the most appropriate individuals to approve detention orders. The House Committee that considered the Medical Device Amendments of 1976 recommended that the FDA District Directors be designated to approve detention orders (House Comm. Report, above, at 47).

15. Four comments on proposed § 800.55(e) suggested that detention orders always be approved in advance in writing by the District Director or other approving official.

The Commissioner rejects these suggestions. While the investigator will often have sufficient time to discuss the proposed detention order with his superiors and obtain advance written approval, it would not be practical or desirable to require an investigator, particularly one in travel status, to return to the district office to secure a written approval of a detention order. Not only would this requirement result in delay and needless expense, it would also present an additional opportunity for the detained devices to be introduced into commerce or otherwise be disposed of. Therefore, no change is made in the final regulation.

16. Four comments on proposed § 800.55(e) suggested that oral approval of detention orders by the FDA District Director be confirmed in writing within a specific time frame. Time frames suggested for confirmation were 24 hours or 3 days.

The Commissioner agrees that oral approval of detention orders should be confirmed by written memorandum within FDA as soon as possible. The final regulation has been changed accordingly.

17. A comment on proposed § 800.55(e) suggested that detention orders be sent by registered mail.

The Commissioner disagrees. It is FDA's intent that detention orders be personally delivered by an FDA representative to the person in control of the device. While mail delivery of the detention order might sometimes be appropriate, personal service is preferable because it permits the investigator to observe the device and therefore better describe it in the order. Moreover, personal delivery does not entail the delay that may occur in mail delivery.

LABELING OR MARKING OF DETAINED DEVICES

18. Several comments on proposed § 800.55(f) suggested a need to instruct persons ordering detention that official FDA detention tags used to identify detained devices must not harm the devices or their packaging.

The Commissioner believes that FDA representatives generally understand the need for care in these situations and that special instruction is unnecessary.

19. FDA has made several minor changes in § 800.55(f) of the final regulation to be consistent with the language appearing on the official FDA tags and to conform to internal FDA administrative procedures regarding the labeling or marking of the detained devices with the tags.

20. Several comments expressed concern that proposed § 800.55(f)(2) and (h) might prohibit the manufacturer from moving the device to a storage location within the same factory to prevent interference with other operations or harm to the device.

The Commissioner agrees with the comment and has revised § 800.55(f)(2) and (h) of the final regulation to allow authorized FDA representatives to approve the movement of detained devices in these situations. FDA will be receptive to any reasonable request to move devices within a plant to store them safely or to prevent interference with plant operations. However, the movement must be for a bona fide purpose and, once moved, the detained devices must remain segregated to preclude their release into commerce during the detention period.

21. One comment on proposed § 800.55(f) suggested that the regulations be changed to require that detained devices not only not be moved, but also that they not be "used."

The Commissioner agrees with 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

22. Comment on proposed § 800.55(g) argued that the 5 days within which to file the appeal should be "working" days rather than calendar days.

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.

23. Several comments on proposed § 800.55(g) objected to the 5-day limitation on filing an appeal. Some comments suggested a longer period, e.g., from 10 days to 2 weeks. Other comments suggested that the appeal be permitted until the detention order expires.

The Commissioner believes that with modern communication systems, a 5-working-day period is adequate time to hold consultations and file an appeal. Therefore, no change is made in the final regulation.

24. 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 suggested change 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(g) (1) and (6) of the final regulation to require that any requested hearing be scheduled no later than 20

calendar days from the date of the detention notice.

25. 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 continue to be detained until FDA terminates the detention or the detention period expires, whichever occurs first.

26. 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 304(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 detained devices "within" the place where they have been detained 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 detained devices, the manufacturer is required to notify the agency immediately of any such movement and of the location of the detained 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 devices immediately and with minimal burden on the manufacturer.

However, permitting movement of detained devices "from" the establishment, with only after-the-fact notification to FDA, could interfere with the accomplishment of any proposed 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 detained devices at the discretion of the manufacturer to movements "within" the establishment where the devices are detained. Proposed paragraph (h)(2) (now paragraph (h)(3)) provides for the FDA to approve in writing, in advance, other movement of detained 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 or encouraging destruction or reconditioning of violative devices, which FDA may take if it determines that the detained devices remain adulterated or misbranded after being put into final form. Because FDA may take these actions against any violative device, the Commissioner has amended proposed paragraph (h)(4) and redesignated it as new paragraph (i) of the final regulations.

29. One comment on proposed § 800.55(h) argued that the manufacturer should always be allowed to choose whether to destroy or dismantle violative devices and use the parts separately.

The Commissioner rejects the comment. The Commissioner believes that the detained devices must not be destroyed or dismantled without FDA's prior written approval. To permit a person having possession of the devices to make a decision of this kind without agency approval would make it impossible to account for the detained devices or their reused parts and could undermine the preparation of appropriate enforcement actions concerning the detained devices. FDA will, however, approve voluntary destruction or dismantling in all cases the agency considers appropriate.

RECORDKEEPING REQUIREMENTS

30. A number of comments were received on proposed § 800.55(i) (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 detained 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 detained 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, published in the FEDERAL REGISTER of July 21, 1978 (43 FR 31508). Accordingly, the recordkeeping requirements will not be an unreasonable burden on industry.

31. Other comments on proposed § 800.55(i) (now § 800.55(k)) suggested that recordkeeping be limited to the detention period or that recordkeeping be discontinued if the detention order is terminated.

The agency believes that recordkeeping often needs to continue after the detention period to document both compliance and conditions of manufacture and to compare information concerning detained devices to information about other shipments of the devices (or similar devices). However, 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.

32. One comment on proposed § 800.55(i) stated that there was no objection to keeping existing records but objected to initiating new records respecting detained devices, on the

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 that led 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 development of agency procedures to protect the public from adulterated or misbranded devices in commerce. FDA believes that, in the long run, recordkeeping may help prevent future occurrences of adulteration or misbranding of the device and may thus reduce product liability claims.

33. Additional comments on proposed § 800.55(i) (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); *Bellis* v. *United States*, 417 U.S. 85 (1974); *United States* v. *Kordel*, 397 U.S. 1, 8 (1970); *Curcio* v. *United States*, 354 U.S. 118, 122 (1957); *United States*, v. *White*, 322 U.S. 694, 699 (1944); *Wilson* v. *United States*, 221 U.S. 361, 382-384 (1911); *Hale* v. *Henkel*, 201 U.S. 43, 74-75 (1906)).

Even for individuals, the privilege against compelled self-incrimination is inapplicable where a recordkeeping requirement is applied to "an essentially noncriminal and regulatory area of inquiry," where self-reporting is the only feasible means of securing the required information, and where the requirement is not applied to "a highly selective group inherently suspect of criminal activities" in "an area permeated with criminal statutes" (*California* v. *Byers*, 402 U.S. 424, 430 (1971); *Marchetti* v. *United States*, 390 U.S. 39 (1968), and companion cases; *Albertson* v. *SACB*, 382 U.S. 70, 79 (1965); *Shapiro* v. *United States*, 335 U.S. 1 (1948)). Even in the rare instance where a recordkeeping requirement under this regulation applies to an individual who was not acting on behalf of a collective entity, it is almost certain under these cases that the requirement would not be regarded as infringing upon the constitutional privilege against compelled self-incrimination. The recordkeeping requirements in § 800.55(k) have predominantly noncriminal, regulatory purposes: to protect the public from products that may cause harm, to determine why manufacturing errors occurred, to help prevent future errors, and to allow accountability and tracing of devices if there is need to locate them after release from detention.

34. A comment on proposed § 800.55(i) (now § 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 comment argued further that consulting laboratories should not be required to keep records or, alternatively, that records requirements for consulting laboratories should be limited to records concerning restricted devices.

The Commissioner rejects the argument that section 704 of the act only authorizes inspection of consulting laboratories that hold restrictive devices. It is true that consulting laboratories are not mentioned in the first sentence in section 704(a) of the act (which authorizes FDA representatives to enter and inspect "any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held"), but they are mentioned in the second sentence in section 704(a) (which specifically authorizes inspection of all things, including records, "[i]n the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs or restricted devices are manufactured, processed, packed, or held"). Because the second sentence in section 704(a) merely elaborates upon the basic inspection authority granted in the first sentence by stating additional requirements that apply "[i]n the case of" certain types of facilities, the Commissioner believes that a consulting laboratory which manufactures, processes, packs, or holds devices, whether restricted or unrestricted, is subject to inspection as an "establishment" under section 704(a). In addition, the legislative history shows that the second sentence in section 704(a) is not a limitation on the first sentence. (See Drug Amendments of 1962, sec. 201(d), 76 Stat. 793, 21 U.S.C. 374 (Historical Note); Senate Comm. on the Judiciary, Drug Industry Act of 1962, S. Rep. No. 1744, 87th Cong., 2d Sess. 13, Pt. 2 at 3 (1962); Conference Report, Drug Amendments of 1962, H.R. Rep. No. 2526, 87th Cong., 2d Sess. 25 (1962).)

Because consulting laboratories are subject to inspection under section 704 of the act, any devices they manufacture, process, pack, or hold are subject to detention under section 304(g) of the act (although such detentions will probably be rare). For this reason, consulting laboratories are subject to the recordkeeping requirements in § 800.55(k) of the final regulation. As noted earlier, these requirements are authorized generally by sections 304(g) and 701(a) of the act and, with respect to device manufacturers, importers, and distributors, also by section 519 of the act. None of these provisions compels FDA to restrict these recordkeeping requirements to records about restricted devices.

Detention Termination

35. Several comments suggested there 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 disagrees 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 Commissioner 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.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 304, 519, 701, 52 Stat. 1044-1045 as amended, 1055-1056 as amended, 90 Stat. 564-565 (21 U.S.C. 334, 360i, 371)) and under authority delegated to the Commissioner (21 CFR 5.1), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

1. In Subchapter A, Part 16 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.

AUTHORITY: Secs. 304, 519, 701, 52 Stat. 1044-1045 as amended, 1055-1056 as amended, 90 Stat. 564-565 (21 U.S.C. 334, 360i, 371).

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 the FDA District Director in whose district the devices are located determines that a greater period is required to seize the devices, to institute injunction proceedings, or to evaluate the need for legal action, in which case the District Director may authorize detention for 10 additional calendar days. The additional 10-calendar-day detention period may be ordered at the time the detention order is issued or at any time thereafter. The entire detention period may not exceed 30 calendar days, except when the detention period is extended under paragraph (g)(6) of this section. An authorized FDA representative may, in accordance with paragraph (j) of this section, terminate a detention before the expiration of the detention period.

(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, operator, or agent in charge of the place where the devices are located. If the owner or the user of the devices is different from the owner, operator, or 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 paragraph (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.

(e) *Approval 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.

(f) *Labeling or marking a detained device.* An FDA representative issuing a detention order under paragraph (d) of this section shall label or mark the devices 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 the tag is punishable by fine or imprisonment or both (section 303 of the 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 201(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 would have 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 detention order under paragraph (d) of this section, rather than the notice under § 16.24(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 should be addressed to the FDA District Director, not to the presiding officer as provided in the second sentence of § 16.24(b) of this chapter.

(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., regional food and drug directors, who preside at hearings under this section.

(4) The presiding officer of a regulatory hearing on an appeal of a detention order, who also shall decide the appeal, shall be a regional food and drug director (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 or revoking 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 20-calendar-day or 30-calendar-day detention period.

(7) If the appellant appeals the 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 until FDA terminates the detention under paragraph (j) of this section or the detention period expires, whichever occurs first.

(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 (j) 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 under this paragraph, the required tags shall accompany the devices during and after movement 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 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.

(Secs. 304, 519, 701, 52 Stat. 1044-1045 as amended, 1055-1056 as amended, 90 Stat. 564-565 (21 U.S.C. 334, 360i, 371).)

Dated: March 1, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-7030 Filed 3-8-79; 8:45 am]

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FRIDAY, MARCH 9, 1979

PART V

DEPARTMENT OF LABOR

Employment and Training Administration

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FY 1979 VETERANS PREFERENCE INDICATORS OF COMPLIANCE LEVELS

[4510-30-M]

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 insure that veteran applicants receive priority service.

EFFECTIVE DATE: April 9, 1979.

FOR FURTHER INFORMATION CONTACT:

Peter Rell, Director, Office of Program Review, U.S. Employment Service, Room 8324, 601 D Street, NW., Washington, D.C. 20213, (202) 376-6914.

SUPPLEMENTARY INFORMATION: The Department published proposed regulations for the FY 1979 compliance levels on October 27, 1978, at 43 FR 50379. 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. Therefore, based on State agency past 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 uniform floor level of 7.5 percent for *job development* and 60.0 percent for *inactivated with some reportable service* to be applied to all States.

2. 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 floor 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 anticipates 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.

3. 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 "referral to training" in view of the different interpretation by State agencies as to what can appropriately be reported for these indicators. One commentor 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 veterans 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)(7). However, the Department considers the comments received pertaining to the 1978 CETA Reauthorization and interpretation of Federal reporting instructions to be persuasive at this time. The emphasis of the 1978 CETA Reauthorization on serving the disadvantaged could limit training opportunities available to 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* floors and 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 commentor 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 adverse impact acceptance of 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 only in the case where a disability rating is based on a determination of unemployability. The VA indicated further that only veterans with a disability rating between 60 and 90 percent would possibly have a rating based on unemployability and that less than 5 percent of all veterans receiving disability payments would have these payments affected by job acceptance. The Department also considers 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 commentors 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 administrative controls to insure that each eligible veteran and each eligible person receives some specific form of employment assistance. In accordance with this provision, the Department has established in 20 CFR 653.221-226, 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(k).

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 several key areas of service to veterans and eligible persons utilizing data available through the Department's ESARS reporting system. The Department drafted the proposed indicators for FY 1979 after analyzing performance data from FY 1977 and FY 1978. The intent was to set the indicators at 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 commentors discusssed the problems involved with the placement preference for recently separated 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 commentor 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 Vietman-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(k)(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 commentor 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.

FEDERAL MONITORING OF STATE AGENCY COMPLIANCE

653.230 Veterans preference indicators of compliance.
653.231 Secretary's annual report to Congress.

AUTHORITY: 38 U.S.C. chapters 41 and 42; Wagner-Peyser Act, as amended, 29 U.S.C. 49 et seq.; sec. 104 of the Emergency Jobs and Unemployment Assistance Act of 1974 Pub. L. 93-567, 88 Stat. 1845.

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. 2001-2008 (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' regulation under 38 U.S.C. 2012(a) at 41 CFR 60-250.33. 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. 2012(a). Section 653.221(a)(7)(i), moreover, goes beyond the requirement of 41 CFR 60-250.33 by requiring State agencies to give priority in referral to qualified disabled veterans and veterans of the Vietnam era with respect to all job openings listed with the State agency's local offices.

(c) This subpart references the Department of Labor's Office of Federal Contract Compliance Programs' regulation under 38 U.S.C. 2012(b) at 41 CFR 60-250.26. 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. 2012 or of the Department's regulations at 41 CFR Part 60-250. 41 CFR 60-259.26 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. 1845, 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 for an outreach 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 the 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 1974 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:

(i) Serving as the principal advisory and coordinating group to the Secretary of Labor on matters affecting veterans;

(ii) Consulting with and providing guidance to the appropriate DOL Agencies and the DOL Program and Budget Review Committee (PBRC) [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;

(iii) Reviewing the operational effectiveness of departmental plans and programs affecting veterans;

(iv) Facilitating DOL executive-level communications on veterans' affairs within the Department and with other governmental agencies, veterans' organizations, labor, management, and the Congress;

(v) Reviewing and suggesting research essential to the implementation of effective departmental programs on behalf of veterans; and

(vi) Coordinating the preparation of any reports to the Congress concerning veterans' affairs which involve the 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 definitive 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.

(ii) Title VI of the Veterans' Education and Employment Assistance Act of 1976 amended 38 U.S.C., Chapter 42, section 2012, by adding a new subsection (c) which states:

> 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, types, and number of positions listed and the number of veterans receiving priority pursuant to subsection (a)(2) of this section.

(2) 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. 2012 for such agencies at 41 CFR Part 60-250.

(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 funds 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 a 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 designated as special disabled veterans 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" shall mean 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)" shall mean 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, in each Department of Labor regional office who serves veterans and eligible persons pursuant to this subpart. The RDVE shall report to, be responsible to, and be under the administrative direction of the DASVE. In addition, the RDVE shall report to, be responsible to, and be under the operational direction of the RA.

"Reportable service" shall mean counseling, job development, referral to a job, referral to training, enrollment in training, referral to supportive services, testing, and placement.

"Special disabled veteran" shall mean a person entitled to disability compensation under laws administered by the Veterans Administration for a disability rated at 30 per centum or more, or a person whose discharge or release from active duty was for a disability incurred or aggravated in line of duty.

"State Director for Veterans' Employment (SDVE)" shall mean a 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 "Veteran 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 (August 5, 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 Employement 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.

[43 FR 9093, Mar. 3, 1978; 43 FR 12855, Mar. 28, 1978]

§ 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 (ETA) regional 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 for, and assist 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 SDVE and other findings regarding State agency compliance with the regulations under this subpart and recommending appropriate corrective action to the RA;

(iii) Assisting other 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 60-250; 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. RDVEs shall compare actual services to veterans by each State agency by comparing the statistics generated by the veterans 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 apropriate, 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 (SVERs).

(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 per 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. Chapter 51 and 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 assisting State agency personnel in carrying out services to veterans and eligible persons and evaluating their performance. Functional supervision shall entail providing technical assistance, making suggestions for improvement of services, helping to plan programs and projects, checking for compliance with ETA regulations affecting veterans helping to correct errors by working with local and State staffs, analyzing work as it affects veterans and eligible persons, training new State agency employees and providing refresher courses for State agency staff, bringing matters which require corrective action to the attention of those State 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. Nor does it authorize and SDVE or ASDVE 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 marts and other special programs to match veterans and eligible persons with appropriate job and job-training opportunities;

(4) Assist in securing and maintaining current information on available employment and training opportunities, using, when feasible, electronic data processing and telecommunications systems, and in matching veteran 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; and

(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 using local office and State agency reports including:

(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.

(10) Compare actual services to veterans and eligible persons against the standards for State agency performance set forth at § 653.221-26.

(11) Conduct periodic onsite reviews 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

§ 653.220 Standards of performance.

Sections 653.221-226 set forth the standards of performance governing services to veterans and eligible persons which must be met by the State employment service agencies.

§ 653.221 Standards of performance governing State agency services.

(a) Each State agency shall assure that all of its local offices, using LVERs and other staff, offer the following services to all veterans and eligible persons:

(1) *Registration.* Local offices shall encourage all veterans and eligible

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 for 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 potential qualifications for work, alternative vocational choices, and occupational requirements to assist them in formulating a plan to achieve their occupational and/or training goals. As appropriate, the counselors shall also provide such applicants with assistance in solving problems relating to the obtaining or holding of jobs.

(4) *Testing.* As appropriate, qualified local office staff shall administer objective aptitude and proficiency 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.

(7) *Job and training referral.* (i) 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) (ii) and (iii) of this section, shall observe the following order of priority in making referrals to the job openings or training opportunity:

(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 38 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 office is a subgrantee or contractor under the Comprehensive Employment and Training Act (CETA) or Title IV of the Social Security Act (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 them. Such programs shall include contact with veterans organizations, Veterans Administration facilities, military bases, military hospitals and other appropriate organizations. The State agency public information program shall develop and disseminate 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 applications 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 applications of disabled veterans.

(c) Local offices shall review veteran 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 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 Part 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, ASDVEs 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-

erans' 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 for 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 evaluating 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 available to be trained, the placing of job orders with the ES by employers who provide VA-approved on-the-job training, the referral of veterans and eligible persons to such job openings, and joint ES-VA programs to aid VA field staff in providing assistance to employers with VA programs. Each State agency should develop a written agreement with its VA counterpart covering areas of mutual concern and delineating each agency's areas of responsibility.

(b) Each State agency shall develop cooperative arrangements with public agencies and other organizations who are sponsors of programs under the Comprehensive Employment and Training Act of 1973 (CETA). State agencies shall make their staffs aware of the fact that, under section 205(c)(5) of the Comprehensive Employment and Training Act, sponsors of public service employment programs under Title II of that Act are required to make special efforts to acquaint veterans with the public service jobs available under Title II of CETA and to coordinate their efforts on behalf of veterans with ES activities under this subpart.

§ 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 658 of this chapter except that, if the complaint relates to the responsibilities of an employer under 38 U.S.C. 2012, 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 §§ 653.221-226 are being met, the ETA shall use the floor levels and the veterans preference indicators of compliance set forth in this section to compare the level of services provided to veterans and eligible persons with the level of services provided to nonveterans.

(b) The term "applicants" as used in this section shall mean individuals who filed or renewed job applications during the fiscal year. To improve statistical comparability, the term "nonveteran" as used in this section shall not include women and persons 19 years of age or younger. The term "veteran" as used in this section, shall include eligible persons. 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 mathematically appearing, according to the veterans preference indicators of compliance, to be doing well, 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 year's 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 Applicant=(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.

	(iv) Placed
	Percent
Region I (Boston):	
Connecticut	14
Maine	24
Massachusetts	19
New Hampshire	24
Rhode Island	24
Vermont	24
Region II (New York):	
New Jersey	22
New York	22
Puerto Rico	23
Virgin Islands	.....
Region III (Philadelphia):	
Delaware	14
District of Columbia	24
Maryland	20
Pennsylvania	19
Virginia	22
West Virginia	23
Region IV (Atlanta):	
Alabama	24
Florida	24
Georgia	24
Kentucky	23
Mississippi	24
North Carolina	23
South Carolina	22
Tennessee	23
Region V (Chicago):	
Illinois	18
Indiana	19
Michigan	16
Minnesota	24
Ohio	18
Wisconsin	24
Region VI (Dallas):	
Arkansas	24
Louisiana	24
New Mexico	24
Oklahoma	24
Texas	24
Region VII (Kansas City):	
Iowa	24
Kansas	24
Missouri	24
Nebraska	24
Region VIII (Denver):	
Colorado	24
Montana	24
North Dakota	24
South Dakota	24
Utah	24
Wyoming	24
Region IX (San Francisco):	
Arizona	24
California	23
Guam	.....
Hawaii	24
Nevada	23
Region X (Seattle):	
Alaska	24
Idaho	24
Oregon	24
Washington	24

(2) Only after a State agency meets three of its four expected levels of accomplishment—one of which must be the floor level for placement—shall the veterans' indicators be applied.

(d) The ETA shall compare the level of State agency services for veterans versus that for nonveterans by examining rates of service rather than the numbers of persons served to compensate for the differing sizes of comparison groups and to avoid the difficulties associated with establishing absolute numbers under varying conditions, time periods and locations. In addition, the two groups, veterans and nonveterans, shall be compared after adjustments for demographic and other appropriate characteristics to make them as comparable as possible within the limitations of available data systems.

(e) ETA shall establish numerical values for the veterans preference indicators of compliance for each Federal fiscal year for:

(1) Veterans versus nonveterans:

(2) Veterans of the Vietnam era versus nonveterans: and

(3) Disabled veterans versus nonveterans.

(f) Veterans preference indicators of compliance for service to all veterans shall be stated as follows:

(1) The ratio of veteran applicants counseled to the total number of veteran applicants shall exceed the ratio of nonveteran applicants counseled to the total number of nonveteran applicants by at least 25 percent.

Veteran's counseled/Veteran applicants ÷ Nonveterans counseled/Nonveteran applicants −1.00=25 percent

(2) The ratio of veteran applicants referred to training to the total number of 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.

Veterans referred to training/Veteran applicants ÷ Nonveterams referred to training/Nonveteran applicants −1.00=(NA FY 1979) percent

(3) The ratio of job development contacts made for veterans to the total number of veteran applicants shall exceed the ratio of job development contacts made for nonveterans to the total number of nonveteran applicants by at least 50 percent.

Job development contacts for veterans/Vereran applicants ÷ Job development contacts for nonveterans/Nonveteran applicants −1.00=50 percent

(4) 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 applicant −1.00=10 percents

(5) 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 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 veterans 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 nonveteran applicants placed in jobs to the total number of nonveteran applicants by at least 15 percent.

Vietnam-era veterans placed/Vietnam-era veteran applicants ÷ Nonveterans placed/Nonveteran applicants −1.00=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 veteran applicants ÷ Nonveterans inactivated with some reportable service/Nonveteran applicants −1.00=20 percent

(h) Veterans preference indicators of compliance for service to disabled veterans are as follows:

(1) The ratio of disabled veteran applicants counseled to the total number of disabled veteran applicants shall exceed the ratio of nonveteran applicants counseled to the total number of nonveteran applicants by at least 100 percent.

Disabled veterans counseled/Disabled veteran applicants ÷ Nonveterans counseled/Nonveteran applicants −1.00=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 (NA FY 1979) percent.

Disabled veterans referred to training/Disabled veteran applicants ÷ Nonveterans referred to training/Nonveteran applicants −1.00= (NA FY 1979) percent

(3) The ratio of job development 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/Disabled veteran applicants ÷ Job development nonveterans/Nonveteran applicants −1.00=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/Disabled veteran applicants ÷ Nonveterans placed/Nonveteran applicants −1.00=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/Disabled veteran applicants ÷ Nonveterans inactivated with some reportable service/Nonveteran applicants −1.00=25 percent

(i) The veterans preference indicator of compliance for State agency action under the mandatory job listing requirements of 38 U.S.C. 2012 shall be: The ratio of the total number of veterans of the Vietnam era and special disabled veterans placed in mandatory listing job openings to total number of individuals placed in mandatory listing job openings shall exceed 7 percent.

(j) Following analysis of the past fiscal year's accomplishments, the numerical value for each of the veterans 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.

(l) 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 LVER in accordance with § 653.224 (b)(2); and

(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.

ERNEST G. GREEN,
Assistant Secretary for Employment and Training.

[FR Doc. 79-7137 Filed 3-8-79; 8:45 am]

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FRIDAY, MARCH 9, 1979
PART VI

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

[4110-92-M]

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 citizen efforts to prevent, identify, and treat 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 activiies have focused primarily on improving the identification and treatment of child 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 efforts to encourage 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 another 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 requirements of 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 will be most helpful if they are presented in the same format and with the same topical areas as the priorities described in this announcement. *No proposals, concept papers, or other forms of application should be submitted at this time.* Any such submissions will be discarded. In order to maintain a procedure fair to everyone, applications will be accepted only in response to the final Program Announcements 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 proprietarial systems which have charge of such institutions do not lend themselves to public monitoring. There is only meager data on the nature, incidence and severity of such maltreatment in residential institutions, and there are no definitive statistics. Yet, there is compelling public responsibility for the public safety and protection of children in institutions.

While the CB/NCCAN does not have legal or regulatory responsibility for residential institutions, it does have responsibilities to provide leadership, technical assistance and information that will improve child protection in such settings. Most institutions are State or privately operated under existing State and local laws and regulations. State and local legislative bodies and regulatory agencies determine and implement enforcement of child abuse and neglect laws and child protection measures governing their operation. However, there is a need for more practical experience or knowledge that States and private operators can look to in formulating and implementing child protective services in residential institutions.

These projects will define, through field research, various approaches to the development and implementation of appropriate policies, regulations and administrative procedures which will support effective prevention, identification, investigation and corrective action of child abuse and neglect in institutional settings.

Background

Approximately 1% of the child population of the United States, or about 754,000 children, are in some form of residential or foster family care. While the number seems relatively small, the public responsibility for these children is great. In many cases, these children are in institutional care because society, acting through public agencies, has determined that their care and nurture cannot be provided by their families and has intervened to provide it in place of families. In other cases, these children are in institutional care because their families have recognized their inability to cope with special physical or emotional handicaps and have chosen or been forced by these circumstances to seek alternative ways to care for their children. In any event, there is strong 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 the number 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 Social Rehabilitation 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 validate 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 initiate 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 make a major effort at raising awareness of institutional employees of their responsibility to report known and suspected cases of child maltreatment.

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, protocols, 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 access to institutions proposed 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 systems; (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 psychiatric 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 taditional 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.

(3) 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 semiannual basis, make annual site visits and 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]

(4) PROJECT TITLE: CHILD PROTECTION AGENCY MANAGEMENT OF PARENTAL SELF-REFERRALS

Number, Cost and Duration

Approximately 8 grants will be awarded for total project periods of two and one-fourth years each. The initial award and subsequent noncompeting continuation awards will be funded at a level of $40,000 to $60,000 each.

Importance and Purpose

Public child protection agencies need to implement effective ways of handling self-referrals, as well as the opportunity and the incentive to make their services, and those of their community, responsive to the needs of voluntary clients.

These projects will seek to improve the effectiveness of child protection agencies through the development of

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 in-take to followup 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 31 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 CB/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 prognosis 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 nonthreatening 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, multicounty, 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 contractural 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 are received by the mandated child protection agency, and (2) coordination and joint management of self-referrals which are received by other agencies or professionals in the community. Methods for improving internal 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-

quate staff or resources needed to develop comprehensive, in-service training components. Recognizing this, Congress amended Pub. L. 93-247 to provide support for the provision of personnel training in the area of child sexual abuse. The purpose of the proposed project is to test the feasibility, lay the groundwork and develop the methodology for the full implementation of training/treatment centers on a regional basis. It will address such questions as: Number of personnel that can be trained per year; effectiveness of various training methods; number of staff and clients needed to maintain training components; and cost-effectiveness of various methods.

Expected Findings

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 treatment 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 CÁRDINAS RAMIREZ,
Commissioner for Children, Youth and Families.

Approved: March 5, 1979.

ARABELLA MARTINEZ,
Assistant Secretary for Human Development Services.

[FR Doc. 79-7060 Filed 3-8-79; 8:45 am]

federal register

FRIDAY, MARCH 9, 1979

PART VII

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

■

PUBLIC TELECOMMUNICATIONS FACILITIES PROGRAM

Planning and Construction Grants

[3510-60-M]

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

[15 CFR Part 2301]

[Docket No. 78-1]

PUBLIC TELECOMMUNICATIONS FACILITIES PROGRAM

Planning and Construction Grants

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The National Telecommunications and Information Administration (NTIA), U.S. Department of Commerce, seeks public comment on proposed rules and policies to govern its administration of grants under the Public Telecommunications Financing Act of 1978 (Pub. L. 95-567, 92 Stat. 2405). The Act authorizes the issuance of planning and construction grants for public telecommunications facilites. This action is required because the Act transferred the former Educational Broadcasting Facilities Program from the Department of Health, Education, and Welfare to NTIA and broadened its application.

DATES: Comments should be submitted on or before April 12, 1979,

ADDRESS: An original and seven copies of comments should be sent to the National Telecommunications and Information Administration, Office of the Chief Counsel, Room 703, 1800 G Street, N.W. Washington, D.C. 20504.

FOR FURTHER INFORMATION CONTACT:

Kenneth Salomon, (202) 395-5616.

SUPPLEMENTARY INFORMATION:

In the matter of Public Telecommunication Facilities Program; *Notice of Proposed Rulemaking;*

1. The National Telecommunications and Information Administration (NTIA), U.S. Department of Commerce (DOC), has before it the *Advance Notice of Proposed Rulemaking* in this proceeding, published on January 3, 1979, 44 FR 897, and comments filed in response to the *Advance Notice.*[1]

2. The *Advance Notice* sought to identify issues to be addressed in the process of developing rules for the issuance of planning and construction grants for public telecommunications facilities under the Public Telecommunication Financing Act of 1978, Pub. L. 95-567, 92 Stat. 2405 (PTFA). That publication was part of our continuing effort to insure and maximize meaningful public participation in the development of the rules. (See Executive Order 12044, *Improving Government Regulations,* 43 FR 12661 (March 24, 1978); and DOC *Request for Public Comment,* 43 FR 23170 (May 30, 1978)). Other efforts consisted of the distributing of approximately 1500 copies of an issues paper to members of the interested public, the industry and trade press, and the convening of a public meeting on December 19, 1978 at which the issues paper and a draft of the *Advance Notice* were discussed and debated by NTIA staff, industry representatives, and members of the interested public.[2]

3. The PTFA modifies the Communications Act of 1934, as amended, 47 U.S.C. § 1 *et seq.* (statutory references are to the Communications Act). In part, the PTFA transfers the Educational Broadcasting Facilities Program (EBFP) from the Department of Health, Education, and Welfare (HEW) to DOC. Substantively, the Act:

(i) Permits for the first time Federal funding for the nonbroadcast distribution of noncommercial educational and cultural radio and television programs and related instructional or informational materials (Sections 390 and 397(14));

(ii) Permits Federal funding for the planning of any project that may be funded under the Act (Section 392(c));

(iii) Provides that not less than 75 percent of appropriated funds "shall be available"[3] for the extension of public telecommunications services to areas not presently receiving such service (Section 393(c)); and

(iv) Requires that "special consideration" be given to applications which would increase minority and women's "ownership of, operation of, and participation in public telecommunications entities" (Section 392 (f)).[4]

4. The *Advance Notice* listed four general categories of issues to be considered in this proceeding:

- 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)(1).) 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 *Advanced 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

[1] The parties filing comments are listed in Appendix A. Some of the parties listed filed comments in response to the issues paper discussed in paragraph 2, *infra.*

[2] The parties attending the meeting are listed in Appendix B. The meeting was recorded and a full transcript, together with the issues paper are included in the public file which is located in Room 703, 1800 G Street, N.W., Washington, D.C. 20504.

[3] We agree with the numerous comments that the phrase "shall be available" for extension does not establish a rigid allocation of the appropriation but, rather, establishes funding priorities between eligible applicants. Thus, if, after funding all approvable extension applications, the 75 percent set aside has not been exhausted, the balance will be utilized to fund other eligible applicants within their order of priority. (See *Advance Notice,* 44 FR at 898.)

[4] Section 393(b)(3) requires that grants be approved which would achieve "the development of public telecommunications facilities owned by, operated by, and available to minorities and women * * *".

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 cultural 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 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. [5] 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 the 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 nonprofit subsidiaries of such groups would be constitutional as long as the 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 conclusion is justified by the Supreme Court's decision in *Tilton* v. *Richardson*, 403 U.S. 672, *reh. denied* 404 U.S. 874 (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 * * * 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 a facility constructed with funds under that program. If, 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. § 754(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 limitation on religious use. (403 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." (Id.).

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 more than an incidental 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 more than 10 years. For such equipment, the period of restricted use must exceed the 10 years required by the Act.[6] (*Tilton, supra*, 403 U.S. at 684.) (See § 2301.27(d) of the proposed Rules.) Comments on how to measure and define the valuable life of PTFP equipment and the other issues raised by this discussion are encouraged.

13. A third issue raised in the comments concerns the eligibility of production facilities such as media art centers. We believe that a central requirement of eligibility is the possession of the means of electronic distribution of public telecommunications services. If an applicant proposes production capability as well, it might receive a higher priority. Therefore, an applicant that is exclusively a production center would not be eligible for PTFP funds. (See generally Sections 397(7)(B) and (12).

PRIORITIES AND SPECIAL CONSIDERATION

14. In Section 393(b) of the Act, Congress set forth objectives which are to govern the review and approval of PTFP applications. There can be no doubt that the paramount priority of the legislation, reflected in the declaration of purpose (Section 390(1)) and the 75 percent set aside (Section 393(c)), is the extension of first public telecommunication services to currently unserved areas of the country.[7] But within that priority and the others listed in Section 393(b) of the Act, various sublevels of priorities exist. To achieve the legislative purpose, while at the same time preserving our flexibility to react to the ever-changing nature of public telecommunications, we have elected in § 2301.20 of the proposed rules to restate the objectives of § 393(b)(1)(4) without elaboration. At the same time, however, we take this opportunity to state priorities that will serve as guiding policy in our administration of the PTFP:

● *Priority I—Provision of Telecommunications Facilities for First Service to a Geographic Area.* Within this first priority, we propose to established three subcategories:

A. *Projects to establish telecommunications facilities which include local origination capacity.* This category includes the activation of new facilities which can provide a full range of radio and/or television programs, including material that is locally produced. Eligible projects include new radio or television broadcast stations, new cable systems, origination facilities to feed existing cable channels, etc.

B. *Projects to extend existing telecommunications delivery systems.* This category includes projects such as increase in tower height and/or power of existing stations; and construction of translators, cable networks and repeater transmitters. No local origination capacity is required.

C. *Projects to establish telecommunications delivery systems without local*

[5] In this regard, we note that applicants proposing construction or acquisition of facilities must, in addition to the PTFP eligibility requirements, first be eligible to receive any necessary FCC authorization. H.R. Rep. No. 95-1774, 95th Cong., 2nd Sess. 24 (1978) (*Conference Report*).

[6] 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. Section 1132e(c).

[7] Message from the President transmitting proposals to amend the Act, House Doc. 95-239, 95th Cong., 2nd Sess. 6 (1978); H.R. Rep. No. 95-1178, 95th Cong., 2nd Sess. 20-21 (1978) (*House Report*); Sen. Rep. No. 95-858, 95th Cong., 2nd Sess. 6-7 (1978) (*Senate Report.*) *See also, A Public Trust: Report of the Carnegie Commission on the Future of Public Broadcasting* 233-43, published January 30, 1979 (*Carnegie Report II*).

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 for which a clear and substantial community need can be demonstrated. Eligible projects include services to identifiable ethnic or linguistic minority audiences; [8] 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 equipment 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 studies 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.

15. If in any one fiscal year, all other approvable applications have been funded and appropriated funds remain, we believe that NTIA possesses the discretionary authority to award grants to eligible applicants where proposals do not clearly fall within any of the listed priorities but whose applications, nevertheless, would further the overall objectives of the Act.

16. It should be emphasized, as elaborated in the next section, that in the evaluation and approval of projects which fall into any of the priority categories, special consideration will be given to applications which would enhance the role of minorities and women in such public telecommunications entities.

THE ROLE OF MINORITIES AND WOMEN

17. In considering this legislation, Congress concluded that one of the characteristics of the public broadcasting [9] is the underrepresentation of minorities and women in the control and management of stations. Further, Congress concluded that public broadcasting programming has not always been responsive to the needs and interests of these groups.[10] To remedy this situation, Congress has mandated that the Secretary of Commerce give "special consideration to applications which would increase minority and women's ownership of, operation of, and participation in public telecommunications entities" (Section 392(f)). We believe that this consideration is a modifier of the priorities listed in Section 393(b). Thus, when faced, for example, with two applications in which all other factors are equal, the application that enhances minority or women's involvement in an entity will be the one that receives the grant.

18. Both at the public meeting and in written comments, several parties pointed out that as a general rule, public telecommunications entities are not "owned" by an individual or group of individuals in the sense of commercial businesses since these entities will either be governmental agencies or subdivisions or nonprofit organizations. (Sections 393 (a)(1) and 397 (6), (7) and (12)). We fully concur with this observation and, therefore, in order to achieve one of the major Presidential and Congressional objectives of this legislation, the expansion opportunities for minorities [11] and women, we will interpret the words "ownership" and "owned" to include the concept of "control" of the entity through the possession or exercise of the normal incidents of ownership.

19. Having reached this conclusion, it is necessary to define what degree of control, operation and participation is needed to trigger Section 392 (f). Many have expressed concern over the need to avoid sham applications in which minorities and women are used merely as fronts in order to obtain special consideration for an application. Some urge that we withhold special consideration unless the governing board of the applicant has a minimum of 51 percent minority and/or women members. While we, too, are concerned that front applications not subvert this section, we believe that adoption of a strict numerical approach would prove to be unduly restrictive, and might preclude the funding of meritorious applications which would further the aims of Sections 392(f) and 393(b)(3) of the Act even though a majority of the governing body is not comprised of minorities and women. Therefore, we propose to accord special consideration where there is actual (*de facto*) or legal (*de jure*) control by women, minorities or a combination of these groups.[12] In applying this standard, we would look at the composition of the governing body of the applicant and the individuals who hold management-level and policy-making positions in the organization. Such an approach, we believe, will assure that entities receiving special consideration will legitimately merit that consideration and will, most importantly, provide an increase in educational, cultural and related program-

[8] See note 13, *infra.*

[9] This characteristic is equally true of commercial broadcasting. NTIA *Petition for Issuance of Policy Statement or Notice of Inquiry* 2-3, filed January 31, 1978 with the FCC. (*NTIA Petition*). *Statement of Policy on Minority Ownership of Broadcasting Facilities,* 68 FCC 2nd 979, 42 RR 2nd 1689 (1978) (*FCC Policy Statement*). See generally *A Formula for Change: The Report of the Task Force on Minorities in broadcasting* (Washington, D.C. 1978) 78, 264 (mimeographed) (*CPB Task Force Report*).

[10] *House Report* at 13; accord *CPB Task Force Report* at 198-99, 233-38; *Carnegie Report II* at 84-5, 207-08, 284-87.

[11] NTIA will adhere to the definition of "minority" contained in the Senate Report in implementing this program. Included in this group of citizens are "American Indians or Alaskan Native; Asian or Pacific Islander; Hispanic; and Blacks, not of Hispanic Origin." *Senate Report* at 11. See also the *Advance Notice,* 44 FR at 897-98 and authority cited therein. We also choose to interpret "participation" to include the holding of management and other positions, especially those dealing with programming decisions and the day-to-day running of the facility. These categories are not exclusive but are designed to reflect our intent that applications that are afforded special consideration are genuine in all respects and will, *in fact,* foster meaningful involvement of women and minorities in public telecommunications entities.

[12] In this regard, we agree with the courts and the FCC that minority ownership and managerial participation are likely to result in programming directed towards these segments of the population. *Garrett Broadcasting Service* v. *FCC,* 515 F. 2nd 1056, 1063 (D.C. Cir. 1975); *TV-9 Inc.* v. *FCC,* 495 F. 2nd 929 (D.C. Cir. 1973); *cert denied,* 419 U.S. 986 (1974); *FCC Policy Statement, NTIA Petition;* and CPB Task Force Report at 282.

ming responsive to the needs of these groups.[13]

20. As we have indicated, we propose to limit the granting of special consideration to situations where minorities and women are in actual or legal control of the applicant. We also believe, however, that applications proposing substantial but less than controlling minority and women board membership also merit favorable consideration. We propose to award a plus to applicants with substantial (*i.e.*, 20 percent or more) minority and women board membership and with women and minorities in full-time managerial positions. Obviously, the greater the percentage and number of directors and managers, the stronger the plus. (See generally, *NTIA Petition* at 15–16.)

21. Having stated this commitment, however, it must also be stressed that applications seeking Section 392(f) consideration must meet the other eligibility requirements of the Act and funding criteria of the Rulemaking. In other words, Section 392(f) does not relieve applicants of the basic background, planning and detail work required to create a public telecommunications entity and prepare a feasible, comprehensive and meaningful application.

22. The special consideration provision also imposes on the Department of Commerce an obligation to take "affirmative steps" to advise minorities and women of PTFP funds and localities where new facilities are needed. Additionally, the Department is directed to provide "such other assistance and information as may be appropriate." The first informative requirement does not appear to present any significant problems. Our initial implementation plan includes presentations to national and regional meetings of groups representing minorities and/or women, advising all pending deferred applicants of Section 392(f), and preparing an information sheet on the PTFP, in general, and the special consideration provision, in particular. This sheet would be sent to the various communications and education trade journals and to publications which address the needs and interests of minorities and women. The assistance requirement, however, is more difficult because of the need to assure equal access to the program by all potential applicants. We contemplate, therefore, that the PTFP staff would be available to discuss and assist all applicants in the technical preparation of an application. This assistance would not reach the merits of comparative position of the application. At the same time, we encourage suggestions on how we can best implement the informative and assistance requirements of the Act, while, at the same time, assuring evenhanded treatment of all applicants.

[13] It must be emphasized, that the goal of the Act is to provide public telecommunications services to the public as a whole. Thus, while the Act does not prevent an applicant from proposing to "target a specific segment of the public for its programming "(*i.e.*, the New York City Black community) this does not mean that the funding priorities of the Act and the goals of public broadcasting are not relevant.

Only after the [Section 393(b)] priorities have been addressed * * * [should] the Secretary of Commerce give serious consideration to extending support to entities proposing to serve specific interests within the public at large. Even then these specific interests must closely fit with the general purposes and objectives of public broadcasting. *Senate Report* at 8-9.

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 applications. In large part it tracks the form and content of the former EBFP regulations and, therefore, no detailed comments are required. Several points are worthy of mention, however. First, applicants will be required to make an affirmative showing of how their proposals will promote the most efficient and economic utilization of Federal funds under this program. This showing, at a minimum, would need to reflect a study and analysis of the economic, cultural and other benefits and detriments of other technological means for providing the same service and a conclusion demonstrating why the method proposed in the application was selected.

24. Second, applicants would be required to give local notice in the proposed community or communities of service of the filing of their applications. This duty is similar to the publication requirements imposed on broadcast applicants by the Federal Communications Commission, 47 CFR 1.580. The content of such a notice would essentially be a reprint of the Federal Register notice of acceptance for filing pursuant to § 2301.11 of the proposed rules. Specifically, the portions of that notice referring to the applicant and the invitation of public comments are to be published. NTIA is proposing this requirement in an effort to maximize effective and meaningful public participation in the administration of the PTFP. We are disbursing public money and, therefore, believe that the public has a legitimate and vital interest in how we administer this program and select grantees.

25. Finally, we are including language in § 2301.13(b) to reflect the Congressional mandate that proposals which require an FCC construction permit, license or other authorization are not eligible for funding under the PTFP unless the entity is eligible to receive the FCC authorization. (*Conference Report* at 24.)

Planning Grants

26. Both at the public meeting and in written comments, several parties raised the issue whether a total dollar amount and time duration should be established for planning grants. Since NTIA has no experience regarding the number of planning grants to be anticipated, the dollar amounts of such grants, and the time entailed in undertaking such a study, we believe that any limits on amount and duration at this point would be arbitrary. We propose, therefore, at least for the first year, to handle these requests on a case-by-case basis taking into account the nature of the application and the total requests for both planning and construction grants. It has also been suggested that different times of the year be specified for filing construction and planning grants. This suggestion appears to have merit. However, because of the time factors involved in this first year of the program, we will not adopt that proposal at this time.

Conditions Relating to Federal Financial Participation

27. The EBFP regulations incorporated by reference most of the administrative and fiscal requirements of HEW's Office of Education contained in 45 CFR Subsection 100a.10 *et seq.* (45 CFR Subsections 153.14–.17 and 153.19–.21). Part of the thrust of these requirements was to assure that transactions utilizing Federal funds would be conducted in a manner designed to provide "maximum open and free competition" (45 CFR 100a.103). To that end, grant recipients were required to follow formal bid procedures.

28. Neither DOC nor NTIA have similar administrative and financial standards which can be incorporated by reference into the proposed regulations. However, we are equally concerned that our grant monies be utilized in an open and free market and in a manner designed to avoid conflicts of interests or noncompetitive practices between grantee officers and employees and prospective contractors. Such procedures will further the goal of assuring that our grants extend delivery of services by the most economical means. The Office of Management and Budget has established procurement standards for grant recipients. These standards are contained in OMB Circulars A-102 and A-110 for governmental grantees and private non-profit grantees, respectively. NTIA proposes to adopt these Circulars. See § 2301.25 of the proposed Rules.

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 for the public losing 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*, 44 FR at 899.) Another possible safeguard, proposed in § 2301.27 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 public telecommunications 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 § 2301.26. 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 applicants 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 57286, published November 1, 1977.) 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.

EQUIPMENT

32. The EBFP regulations listed the requirements and standards by which broadcast equipment and related costs [14] were to be deemed eligible for funding. The rules incorporated an appendix which listed fundable and nonfundable broadcast apparatus and related costs and indicated standards by which eligible equipment was to be judged. (See Appendix A of the EBFP regulations, 42 FR at 57294-295.) Transmitters, translators and antenna systems and certain other equipment had to comply with FCC specifications and performance requirements. In addition, Electronic Industries Association (EIA) standards were incorporated by reference to "serve an benchmarks for determining minimum systems 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 EIA standards. 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 include funding for nonbroadcast technologies, continued reliance on EIA standards for broadcast proposals would make relative judgments of broadcast and nonbroadcast applications difficult. Moreover, there are no industrywide 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.[15] 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 evolving broadcast and nonbroadcast equipment, it appears to be preferable to list categories of ineligible apparatus, rather than list equipment in detail. Finally, it has been suggested that NTIA encourage the formation of an *ad hoc* committee to develop updated standards for both broadcast and nonbroadcast equipment. We recognize that several groups have been working to develop such standards, and we invite comments as to the application of their work to this program.

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 provision 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 contribution. (Section 392(g)(2).) 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 that 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)). It follows, 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 non-

[14] By definition, this program was limited to broadcast applicants and licensees and, therefore, eligible equipment consisted of radio and television broadcast apparatus.

[15] 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 can be accomplished by less than professional quality equipment, the funding request should justify the selection of that equipment.

profit entities (other than religious organizations) and for governmental agencies. Nothing would prevent a grantee from making its facilities available to other noncommercial entities provided that the grantee maintained absolute control of the facilities.

38. In the past, EBFP personnel have been confronted with requests to permit secondary commercial use of noncommercial programs produced or disseminated with funded facilities. As indicated above, EBFP policy precluded such use. In our view, the critical factor to be considered in this area is whether the educational or cultural programming was produced and will be used primarily by the grantee or other noncommercial entities. If that is the case, and the grantee wishes to secure a wider distribution of its program, it may do so only under the following circumstances: after the primary purpose of the program has been satisfied, the program first must be made available to other noncommercial entities and cultural and educational groups.[16] Only after a diligent effort has been made to secure further noncommercial distribution, may residual use of the program by a commercial organization be permitted. Our primary interest here is the most efficient utilization of PTFP-funded facilities to achieve the widest possible distribution of public telecommunications services. However, any money earned through residual use must be employed by the grantee strictly for legitimate station-related purposes and no portion of the proceeds may be credited in any way to the general fund of the grantee's parent institution, if any.

39. Commercial competitors of a grantee would be permitted to file a complaint with NTIA if they believed that the primary use of a program was commercial. Grantees would not be required to obtain prior NTIA clearance for specific distribution arrangements, but they would be cautioned that if they choose to engage in residual distribution, they would do so at their own risk. A finding by the Administrator that the Section 392(a)(4) assurance has been violated would result in revocation of the grant and a repayment demand under Section 393(g)(2) of the Act. NTIA invites comments on this proposal.

40. Section 153.22 of the EBFP regulations contained the applicant's administrative appeal rights. While NTIA continues the principle of administrative reconsideration of adverse decisions, we are proposing a revision of the procedures. Specifically, § 2301.33 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.[17] 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.[18] 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.[19] Broadcast applicants will be required merely to include a copy of their FCC plan rather than complete an additional original section for their applications. Similarly, applicants would be required to assure that they will not discriminate against handicapped persons.

Ex Parte Rules

42. With the publication of this *Notice*, the rulemaking proceeding has become formalized. It is appropriate, therefore, specify the procedural rules governing the proceeding, particularly as to *ex parte* contacts. *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U.S. 402 (1971); *Home Box Office* v. *FCC*, 567 F.2d 9 (D.C. Cir.), *cert. denied* 434 U.S. 829 (1977); *Action for Childrens Television* v. *FCC*, 564 F.2d 458 (D.C. Cir. 1977); *Portland Cement Assoc.* v. *Ruckelshaus*, 486 F.2d 375 (D.C. Cir. 1973), *cert. denied* 417 U.S. 921 (1974); *cert. denied* 423 U.S. 1025, *reh. denied* 423 U.S. 1092 (1976).

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. 78-167, *Policies and Procedures Regarding Ex Parte Communications During Informal Rulemaking Proceedings.*) This objective provides interested parties with an opportunity to contribute 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 guidelines to govern 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[20] with: Office of Chief Counsel,

[16] Heretofore unconventional methods should be considered in addition to traditional broadcast technologies such as video tape distribution and exploration of noncommercial cable TV leased channels.

[17] Neither the Associate Administrator for Applications nor any employee of the Public Telecommunications Facility Division would be members of the Board.

[18] The following FCC rules contain EEO requirements for permittees and licensees: Sections 73.125 (for FM); 73.301 (for AM); 73.599 (for noncommercial educational FM stations); and 73.680 (for television).

[19] Applicants proposing less than five full-time employees need not file an EEO plan, but all applicants must give assurance that equal employment practices will be followed.

[20] While this proceeding relates to a grant program and is, therefore, exempt from the notice and comment requirements of the

Footnotes continued on next page

NTIA/DOC, 1800 G Street, N.W., Washington, D.C. 20504.

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 18, 1979 as the closing date for applications.

Dated: March 6, 1979.

HENRY GELLER,
Administrator, National Telecommunications and Information Administration.

APPENDIX A

American Federation for Blind, Inc., 15 West 16th Street, New York, NY 10011.
American Women in Radio and Television, 1321 Connecticut Avenue, N.W., Washington, DC 20036.
Andrew, Paul, 3 Hancock Avenue, Cambridge, MA 02139.
Archdiocese of San Fransisco, Educational Television Center, 324 Middlefield Road, Menlo Park, CA 94025.
Center for Excellence, Inc., P.O. Box 158, Williamsburg, VA 23185.
City University of New York, Center for Advanced Study in Education, 33 West 42nd Street, New York, NY 10036, (Attn. Dr. Lee Cohen).
City of Valparaiso, Florida, P.O. Box 296, Valparaiso, FL 32580.
Corporation for Public Broadcasting, c/o Verner, Liipfert, Bernhard and McPherson, Suite 1000, 1660 L Street, N.W., Washington, DC 20030.
Federal Communications Commission, Washington, DC 20554.
Florida East Coast Educational Television, Inc., 2908 West Oak Ridge Road, Orlando, FL 32809.
Foundation for Independent Video and Film, Inc., 99 Prince Street, New York, NY 10012.
Global Village, 454 Broome Street, New York, NY 10013.
Goldstein, Michael and Disenhaus, Helen, 1225 Connecticut Avenue, N.W., Washington, DC 20036.
Indiana University at South Bend, Division of Arts and Sciences, 1825 Northside Boulevard, South Bend, IN 46615.
Intercollegiate Broadcasting System, Box 592, Vails Gate, NY 12584.
Iowa Public Broadcasting Network, P.O. Box 1758, Des Moines, IA 50306.
KTSC-TV, 900 West Orman Avenue, Pueblo, CO 81004.
KWSU-AM-TV, Washington State University, Pullman, WA 99163.
Libre Press, Suite 512-514, Brooks Building, Scranton, PA 18503.
McClausand, Robert, 107-15 Jersey Street, Boston, MA 02215.
Media Communications, Inc., Suite 104, Monsanto Building, 6230 Fairview Road, Charlotte, NC 28210.
Minnesota Public Radio, Inc., 400 Sibley Street, Saint Paul, MN 55101.
Montgomery County Intermediate Unit, 400 Penn Street, Lansdale, PA 19446.
National Federation of Community Broadcasters, 1000 11th Street, N.W., Washington, DC 20001.
North Carolina Task Force on Public Telecommunications, 116 West Jones Street, Raleigh, NC 27603.
North Dakota Educational Broadcasting Council, The Prince Hotel, Bismarck, ND 58501.
Public Broadcasting Service, 475 L'Enfant Plaza W, S.W., Washington, DC 20024.
Public Service Satellite Consortium, 4040 Sorrento Valley Blvd., San Diego, CA 92111.
Robertson Associates, Inc., P.O. Box 8077, Port Charlotte, FL 33952.
Rocky Mountain Corporation for Public Broadcasting, 1603 Sigma Chi Road, N.E., Albuquerque, NM 87106.
State of Kansas Public Television Board, Suite 508, 503 Kansas Avenue, Topeka, KS 66603.
University of Alaska, School of Engineering, Fairbanks, AK.
WNET/Thirteen, 356 West 58th Street, New York, NY 10019.
Wilkes College, Wilkes Barre, PA 18766.
Woll, Susan, 39 Brighton Avenue, Allston, MA 02138.

APPENDIX B

Agency from Instructional Television
American Women in Radio and Televison
Association for Educational Communications and Technology
Black Media Coalition
Corporation for Public Broadcasting
Federal Commuunicatons Commission
Joint Council on Educational Telecommunications
National Association of Broadcasters
National Audio-Visual Association
National Cable Television Association
National Citizens Committee for Broadcasting
National Congress of American Indians
National Federation of Community Broadcasters
National Latino Media Coalition
National Public Radio
National Translator Association
Native American Public Broadcasting Consortium
Public Broadcasting Service

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 Assurances.
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 Nondiscrimination.

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 status.
2301.33 Petition for reconsideration.

Footnotes continued from last page

Administrative Procedure Act (5 U.S.C. Section 553(a)(2)), nevertheless, NTIA has opted to provide the public with the opportunity to participate. Both Executive Order 12044 and DOC's 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 in succeeding fiscal years if an approved application for those funds has been submitted by an applicant in the current fiscal year. Because Pub. L. 95-567 was not enacted until November 2, 1978 and NTIA was required to institute this proceeding and design an application form, it has been necessary to expedite the rulemaking to allow sufficient time for the submission and processing of applications before the end of the fiscal year on September 30th. As a result, reply time to both the *Advance Notice* and the *Notice* had to be shorter than we would otherwise have wished. However, NTIA is making every effort to give the public opportunities for meaningful input into the formulation of our regulations, *i.e.*, the issues paper, public meeting and the *Advance Notice* were mailed to interested parties and the trade press. Copies of this *Notice* will be mailed to the same individuals and groups as well as to all who filed comments on the *Advance Notice*. These various steps and the serious time problem have led to our conclusion that this proceeding has been conducted in substantial compliance with Executive Order 12044.

Subpart F—Control and Use of Facilities

Sec.
2301.34 Equipment.
2301.35 Items and costs ineligible for Federal funding.
2301.36 Control and use of facilities.
2301.37 Waiver.

AUTHORITY: Pub. 95-567, 92 Stat. 2405 (47 U.S.C. 390-394).

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 public telecommunications facilities. They implement the provisions of Part IV of Title III of the Communications Act of 1934, as amended by the Public Telecommunications Financing Act of 1978 (47 U.S.C. Sections 390-94) (Act).

§ 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 1 (Practice and Procedure); 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 Stations); 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:

(1) "Act" means Part IV of Title III of the Communications Act of 1934, as amended (47 U.S.C. Sections 390-94).

(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 "noncommercial educational and cultural radio and television programs" means educational, community service, public service, public affairs and cultural programs of benefit to the area or community to be served by a public telecommunications entity;

(5) The terms "noncommercial educational broadcast station" and "public broadcast station" means a television or radio broadcast station which—

(i) Under the rules and regulations of the Federal Communications Commission in effect on the effective date of enactment of the Public Telecommunications Financing Act, is eligible to be licensed by the Commission as a noncommercial educational radio or television broadcast station and which is owned and operated by a public agency or nonprofit private foundation, corporation, or association; or

(ii) Is owned and operated by a municipality and which transmits only noncommercial programs for educational purposes.

(6) The term "noncommercial telecommunications entity" means any enterprise which—

(i) Is owned and operated by a State, a political or special purpose subdivision of a State, a public agency, or a nonprofit private foundation, corporation or association; and

(ii) Has been organized primarily for the purpose of disseminating audio or video noncommercial educational and cultural programs to the public by means other than a primary television or radio broadcast station, including, but not limited to, coaxial cable, optical fiber, broadcast translators, cassettes, discs, microwave or laser transmission through the atmosphere.

(7) The term "nonprofit" (as applied to any foundation, corporation, or association) means a foundation, corporation, or association, no part of the net earning of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(8) The term "preoperational expenses" means all nonconstruction costs incurred by new telecommunications entities 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 personnel employed by an operating public telecommunications entity.

(9) 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) Disseminates 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 processors and switches, towers, antennas, transmitters, translators, microwave equipment, mobile equipment, satellite communications equipment, instructional television fixed service equipment (ITFS), 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 small 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.

(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 392(a)(1) of the Act and that it 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) (1) 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) PTFP funds and any monies generated through the use of PTFP-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 project 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 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.); and

(j) No otherwise qualified individual shall, solely by reason of handicap, be excluded from the participation in, be denied of benefits of or 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. 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 § 2301.9 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 projected 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 service area and the extent to which there is no duplication of services;

(7) If special consideration is requested under Section 392(f) 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 296A, 1325 G Street, N.W., Washington, D.C. 20005. 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 servied, a notice that it has tendered an application for a Federal grant under the Act, that it has tendered 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 FEDERAL REGISTER 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 in question is assigned jointly to communities in different States, upon the State agency, if any, in each of such States.

(3) 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 b returned to the applicant; *Provided*, That within 30 days of such return, the applicant may file with the Administrator a petition pursuant to § 2301.33.

(b) Applications proposing projects which require authorization from the Federal Communications Commission will not be accpeted for filing by the Administrator until the Federal Communications Commission has accepted the necessary application for filing.

(c) The acceptance of applications for filing, as provided in paragraph (a) of this section, is a procedure designed for making preliminary determinations of eligibility and for providing the opportunity for public comment on applications, as described in § 2301.14. Acceptance of an application for filing does not preclude subsequent return or disapproval of an application if it is found to be not in accordance with the provisions of this part or if the applicant fails to file any additional information requested by the Administrator. Acceptance for filing does not assure that application of being funded; it merely qualifies that application to compete for funding with other applications accepted for filing.

§ 2301.14 Comments on applications.

(a) The Administrator will publish notice in the FEDERAL REGISTER of the acceptance for filing of each application and of the receipt of each amendment which substantially changes the proposed project.

(b) Within 30 calendar days from the date on which notice is published in the FEDERAL REGISTER of the acceptance for filing of an application or a substantial amendment to an application, any interested party may file comments with the Administrator supporting or opposing the application or amendment, setting forth the grounds for support or opposition, accompanied by a certification that a copy of the comments has been mailed to the applicant.

(c) Within 30 calendar days from the last day for filing such comments, the applicant may file a reply to any comments opposing its application or an amendment.

(d) 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 392(a) 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 telecommunicaitons 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.

§ 2301.18 Funding criteria for planning applications.

In order to achieve the objectives of Section 393 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.

§ 2301.19 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 § 2301.7 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 gorunds 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.

(c) If the Administrator awards a grant, the grant award document shall include grant terms and conditions set forth in Subpart D of the Rules and whatever other provisions are required by Federal law or regulations, or may be deemed necessary or desirable for the achievement of the purposes of the program.

Subpart C—Priorities Among Applications and the Role of Minorities and Women

§ 2301.20 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.

§ 2301.21 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

§ 2301.22 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.

(1) The Administrator may provide up to 100 percent of the funds necessary for the planning of a public telecommunications facility which is eligible for construction grant funding.

(2) Two copies of any study conducted in whole or in part with funds provided under this program shall promptly be provided to the Administrator. Copies of studies shall be served on the Public Telecommunications Facilities Division, NTIA, Room 296A, 1325 G Street, N.W., Washington, D.C. 20005.

(b) Construction Grants. A Federal grant award for the construction of a public telecommunications facility shall be an amount determined by the Administrator and set forth in the grant award document, except that such amount shall not exceed 75 percent of the amount determined by the Administrator to be the reasonable and necessary cost of such project.

(c) No part of the grantee's matching share of the eligible project costs may be met with funds supplied by Federal departments and agencies or the Corporation for Public Broadcasting except where the use of such funds to meet a Federal matching requirement is specifically and expressly authorized by Federal statute.

(d) If the actual costs incurred in completing the project are less than the estimated costs which constituted the basis for the Administrator's determination of the Federal grant award, the amount of the final grant shall be that amount of the actual total project cost remaining after deducting the amount of local matching funds used as a basis for the grant award at the time of project approval (including the fair market value of gifts, if any); *Provided,* That in no case shall the final Federal grant exceed the Federal grant award.

§ 2301.23 Payment of Federal grant.

(a) No payments under any award will be made unless and until the recipient complies with all relevant requirements imposed by this part. Additionally, with regard to public telecommunications entities requiring a Federal Communications Commission authorization, no payments will be made until confirmation has been received from the Federal Communications Commission that any necessary authorization has been granted.

(b) After the conditions indicated in Subsection (a) have been satisfied, payment will be made to the grantee in such installments consistent with construction progress, as the Administrator may determine. The Administrator may require as a precondition to any such payments, site visits by representatives of NTIA to determine construction progress.

§ 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 the time of completion of the project and at any other 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 No. 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 title to and control of facilities 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 to the fullest extent possible NTIA's commitment to the nondiscrimination policies of the Federal Government as expressed in the several statutes, Executive Orders and messages 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 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 insure 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 employment opportunity policy and program and enlist their cooperation;

(3) Communicate the equal employment opportunity policy and program and its employment needs to sources of qualified applicants without regard to race, color, national origin, sex or physical handicap and solicit their recruitment assistance on a continuing basis;

(4) Conduct a continuing campaign to exclude every form of prejudice or discrimination based upon race, color, national origin, sex or physical handicap from the applicant's personnel policies and working conditions; and

(5) Conduct 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.

(h) 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 296A, 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 for filing 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)(1) The Director, Public Telecommunications Facilities Division shall make a prompt investigation whenever a compliance review, report, 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 policies of the grantee or other party subject to this Subpart, the circumstances under which the possible noncompliance with this Subpart occurred, and other factors relevant to a determination as to whether there has been a failure to comply with this subpart.

(3) If an invesigation 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 a continuing 10-year 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 as 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 or use of the project apparatus during the reporting period, or describing any change 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 members 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 Administator 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 of the eligible 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 petitioner. If 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 any case 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 public telecommunications facilities are situated to determine the amount of the repayment, and will take the necessary action to secure repayment.

§ 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 programing, 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]

federal register

FRIDAY, MARCH 9, 1979

PART VIII

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

AGENCY: Equal Employment Opportunity Commission.

ACTION: Interim Amendments to Guidelines on Discrimination because of Sex, and Addition of Questions and Answers concerning the Pregnancy Discrimination Act, Pub. L. 95-555, 92 Stat. 2076 (1978).

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 makes clear that discrimination on the basis of pregnancy, childbirth or related medical conditions constitutes unlawful sex discrimination under Title VII. The amendments to the Equal Employment Opportunity Commission's Guidelines on Discrimination Because of Sex bring the Guidelines into conformity with Pub. L. 95-555. The accompanying questions and answers respond to concerns raised by the public about compliance with the Pregnancy Discrimination Act.

EFFECTIVE DATE: March 9, 1979.

ADDRESS: Written comments should be addressed to Marie Wilson, Executive Officer, Executive Secretariat, Equal Employment Opportunity Commission, 2401 E Street, N.W., Washington, D.C. 20506.

FOR FURTHER INFORMATION CONTACT:

Peter C. Robertson, Director, Office of Policy Implementation, Room 4002A, Equal Employment Opportunity Commission, 2401 E Street, N.W., Washington, D.C. 20506, (202) 634-7060.

SUPPLEMENTARY INFORMATION: 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 95-331, 95th Cong., 1st Session (1977) and House of Representatives Report 95-948, 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, 1972) had "rightly implemented the Title VII prohibition of sex discrimination in the 1964 act." H.R. 95-948 at p. 2.

Contrary to the EEOC's Guidelines and rulings by eighteen 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 those modifications.

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 to read 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 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. "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 "abortion" 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 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, 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 existence on October 31, 1978, 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 29, 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 requirements of Executive Order 12044. 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 12067, 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 the Commission may reconsider some of the views expressed below will not in any way excuse failure to comply with the Pregnancy Discrimination Act by the statutory deadlines.

By virtue of the authority vested in it by Section 713 of Title VII of the Civil Rights Act, as amended, 42 U.S.C. § 2000e-12, 78 Stat. 265, the Equal Employment Opportunity Commission hereby amends § 1604.10 and adopts questions and answers concerning the Pregnancy Discrimination Act, Pub. L. 95-555, 92 Stat. 2076 (1978), as an appendix to Part 1604 of Title 29 of the Code of Federal Regulations as set forth below.

Signed at Washington, D.C., this 6th day of March 1979.

E. NORTON,
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 in 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. 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.

(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, 1979 or the expiration of a collective bargaining agreement in effect on October 31, 1978, whichever is later.

(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:

APPENDIX—QUESTIONS AND ANSWERS ON THE PREGNANCY DISCRIMINATION ACT, PUB. L. 95-555, 92 STAT. 2076 (1978)

INTRODUCTION

On October 31, 1978, President Carter signed into law the *Pregnancy Discrimination Act* (Pub. L. 95-955). 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 or on the basis of pregnancy, childbirth or related medical conditions." Therefore, Title VII prohibits discrimination in employment against women affected by pregnancy or related conditions.

The basic principle of the Act is that women affected by pregnancy and related conditions must be treated the same as 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, merely 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 provided must cover expenses for pregnancy-related conditions on the same basis as expenses for other medical conditions. However, health insurance for expenses arising from abortion is not required 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.

Some questions and answers about the *Pregnancy Discrimination Act* follow. Although the questions and answers often use only 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 medical conditions, the Act does not change employee rights arising prior to October 31, 1978, or April 29, 1979. Most employment 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 from failing to accord a woman on pregnancy-related leave the same seniority retention and accrual accorded those on other disability leaves.

2. Q. If an employer had 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 when created.

With respect to all aspects of sick leave policy other than payment of benefits, such as the terms governing retention and accrual of seniority, credit for vacation, and resumption of former job on return from sick leave, equality of treatment was required by Title VII without the Amendment.

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 paid for absences resulting from 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.

4. 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 is required to treat an employee temporarily unable to perform the functions of her job because of her pregnancy-related condition in the same manner as it treats other temporarily disabled employees, whether by providing modified tasks, alternative assignments, disability leaves, leaves without pay, etc. For example, a woman's primary job function may be the operation of a machine, and, incidental to that function, she may carry materials to and from the machine. If other employees temporarily unable to lift are relieved of these functions, pregnant employees also unable to lift must be temporarily relieved of the function.

6. Q. What procedures may an employer use to determine whether to place on leave as unable to work a pregnant employee who claims she is able to work or deny leave to a pregnant employee who claims that she is disabled from work?

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 inability 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 allows its employees to obtain doctor's statements from their personal physicians for absences due to other disabilities or return dates from other disabilities, it must accept doctor's statements 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 perform her job.

9. Q. Must 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's policy concerning the accrual and crediting of 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 reasons as for those absent for other medical reasons.

11. Q. For purposes of calculating such matters as vacations and pay increases, may 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 women 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 provide such 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 disability.

17. Q. If an employer provides benefits to employees on leave, such as installment purchase disability insurance, payment of premiums for health, life or other insurance, continued 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 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 benefits for disabilities 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 the medical expenses of 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 excludes 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. Therefore, whether a plan reimburses the employees on a fixed basis, or a percentage of reasonable and customary charge basis, the same basis should be used for reimbursement of expenses incurred for pregnancy-related conditions. Furthermore, if medical costs for pregnancy-related conditions increase, reevaluation of the reimbursement level should be conducted in the same manner as are cost reevaluations of increases for other medical conditions.

Coverage provided by a health insurance program for other conditions must be provided for pregnancy-related conditions. For example, if a plan provides major medical coverage, pregnancy-related conditions must be so covered. Similarily, if a plan covers the cost of a private room for other conditions, the plan must cover the cost of a private room for pregnancy-related conditions. Finally, where a health insurance plan covers office visits to physicians, pre-natal and post-natal visits must be included in such coverage.

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 proportion of actual costs. If, in addition to the scheduled amount for other procedures, additional costs are paid for, either directly or indirectly, by the employer, such additional payments must also be paid for pregnancy-relate procedures.

25. Q. May an employer impose a different deductible for payment of costs for pregnancy-related medical conditions than for costs of other medical conditions?

A. No. Neither an additional deductible, an increase in the usual deductible, nor a larger deductible can be imposed for coverage for pregnancy-related medical costs, whether as a condition for inclusion of pregnancy-related costs in the policy or for payment of the costs when 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.

26. 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.

27. Q. Can the added cost of bringing benefit plans 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, if that apportionment was nondiscriminatory. If the costs were not apportioned on October 31, 1978, they may not be apportioned in order to come into compliance with the Act. However, in no circumstance may male or female employees be required to pay unequal apportionments on the basis of sex or pregnancy.

28. Q. In order to come into compliance with the Act, may an employer reduce benefits or compensation?

A. In order to come into compliance with the Act, benefits or compensation which an employer was paying on October 31, 1978 cannot be reduced before October 31, 1979 or before the expiration of a collective bargaining agreement in effect on October 31, 1978, whichever is later.

Where an employer has not been in compliance with the Act by the times specified in the Act, and attempts to reduce benefits, or compensation, the employer may be required to remedy its practices in accord with ordinary Title VII remedial principles.

29. Q. Can an employer self-insure benefits for pregnancy-related conditions if it does not self-insure benefits for other medical conditions?

A. Yes, so long as the benefits are the same. In measuring whether benefits are the same, factors other than the dollar coverage paid should be considered. Such factors include the range of choice of physicians and hospitals, and the processing and promptness of payment of claims.

30. Q. Can 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 cost 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.

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federal register

FRIDAY, MARCH 9, 1979

PART IX

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

CLASSIFICATION OF MEDICAL DEVICES

Development of General Provisions; Proposed Rules

[4110-03-M]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR PART 870]

[Docket No. 78N-1406]

CLASSIFICATION OF CARDIOVASCULAR DEVICES

Development of General Provisions

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Agency is proposing general rules applicable to the classification of all cardiovascular devices. 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. In the preamble to this proposal, FDA describes the development of the proposed regulations classifying individual cardiovascular devices, which are being published elsewhere in this issue of 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, 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:

DEVICE CLASSIFICATION SYSTEM

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. 360c), establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories are as follows:

Class I, general controls;

Class II, performance standards; 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 the premarket notification procedure in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807).

RELATED REGULATIONS

In the FEDERAL REGISTER of July 28, 1978 (43 FR 32988), The Commissioner issued final regulations describing the procedures for classifying devices intended for human use. These regulations, which were proposed in the FEDERAL REGISTER of September 13, 1977 (42 FR 46028), supplement the agency's regulations in Part 14 (21 CFR Part 14) governing the use of advisory committees. The agency also issued interim device classification procedures in a notice published in the FEDERAL REGISTER of May 19, 1975 (40 FR 21848).

ACTIVITIES OF PANEL

Anticipating enactment of the amendments, FDA established several advisory committees to make preliminary recommendations on device classification. The Cardiovascular Device Classification Panel (the Panel) was originally chartered on October 15, 1974, as the Panel on Review 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 9, 1975 (40 FR 41829). On August 9, 1976, the Panel and other preamendments device classification panels were rechartered to reflect their new responsibilities under the amendments. The agency directed each panel to reconsider its preamendments classification recommendations in light of the new requirements. In 1976 and 1977, the Panel reviewed all devices that FDA had referred to it to make certain that its recommendations were in accord with the amendments.

Throughout the 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, Rm. 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 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 this 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 26 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) and (d)(1) of the act (21 U.S.C. 360c(c)(2) and (d)(1)).

Published Panel Recommendations

Each published Panel recommendation concerning a cardiovascular device includes the information described below.

1. *Identification.* Both the Panel recommendation and the proposed FDA classification regulation include a brief narrative identification of the device. The identification statement is necessarily broad because it applies to a category or type of device rather than to a specific device. As explained in proposed § 870.1, any manufacturer of a newly offered device who files 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(f) 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 I or class II). It is not practical for FDA to publish an identification of each type of device that is so detailed as to anticipate every product feature that may be relevant in determining whether a new device is substantially equivalent to previous devices classified by the regulation. The Commissioner believes that this problem was recognized in, and addressed by, the premarket notification procedures in section 510(k) of the act. Accordingly, any manufacturer who submits a premarket notification submission should state why the manufacturer believes the device is substantially equivalent to other devices in commercial distribution, as required by § 807.87 (21 CFR 807.87), and whether the device is described in a classification regulation.

2. *Recommended classification.* Each Panel's recommendation describes whether the device is recommended for classification into class I (general controls), class II (performance standards), or class III (premarket approval).

For each device recommended for classification into class I, the Panel considered whether the device should be exempt from any requirements under certain sections of the act: section 510 (21 U.S.C. 360, registration), section 519 (21 U.S.C. 360i, records and reports), and section 520(f) (21 U.S.C. 360j(f), good manufacturing practice requirements). 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.

A 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 particular device meets the statutory criteria for classification into class I, II, or III.

Except in those instances in which FDA's classification proposal differs from the Panel's recommendation, the Commissioner is adopting the Panel's summary of reasons as the agency's statement of the reasons for issuing the regulations, as required by section 517(f) of the act (21 U.S.C. 360g(f)).

The summary of reasons for a recommendation identifies any device that is an implant or a life-supporting or life-sustaining device. The summary of reasons for any implant or life-supporting or life-sustaining device that is not recommended for classification into class III also explains why the Panel determined that classification of the device into class III is not necessary to provide reasonable assurance of its safety and effectiveness. The agency provides a similar explanation in the "Proposed Classification" section of the preamble to any proposal to classify an implant or a life-supporting or life-sustaining device into a class other than class III.

4. *Summary of data on which the recommendation is based.* In many cases, the Panel based its recommendations on 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-

termined that clinical experience and judgment constitute valid scientific evidence for classifying certain devices.

In many cases, FDA sought more data and information concerning the classification of a device than were cited by the Panel. References to these data and information are found in the "Proposed Classification" section of the preambles to individual cardiovascular device regulations. The Commissioner is adopting as the agency's statement of the basis for issuing the regulation under section 517(f) of the act, the Panel's summary of the data on which a recommendation to classify a device is based, together with any additional data and information cited in the preamble to the proposed classification regulation.

5. *Risks to health.* In identifying the risks to health presented by cardiovascular devices, the Panel recognized that few devices are completely free of risk. The Panel listed the risks it considered most significant, especially those that are unique to the individual device. Among the more frequently identified risks, the Panel listed thromboembolism, gaseous or particulate embolism, 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 of 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 can dissect the vessels 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 availabale 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 submission of premarket approval applications for any particular device that is classified by an FDA regulation into class III: the number of devices reviewed by a panel and the priority of a particular device in relation to other class III devices considered by a classification panel. For example, where FDA classifies into class III only a few devices within a Panel's specialty area, FDA may at the same time also publish regulations under section 515(b) of the act requiring premarket approval for many of the class III devices considered by the Panel, regardless of whether of a high or a low priority. Where practical, FDA will publish these section 515(b) regulations during the grace period (30 months) following classification during which a device classified into class III by FDA regulation may lawfully remain on the market without a premarket approval application. The grace period is provided for in section 501(f) of the act (21 U.S.C. 351(f)).

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

Section	Device	Docket No.	Class
870.1025	Arrhythmia detector and alarm	78N-1407	III
870.1100	Blood pressure alarm	78N-1408	II
870.1110	Blood pressure computer	78N-1409	II
870.1120	Blood pressure cuff	78N-1410	II
870.1130	Noninvasive blood pressure measurement system	78N-1411	II
870.1140	Venous blood pressure manometer	78N-1412	II
870.1200	Diagnostic intravascular catheter	78N-1413	II
870.1210	Continuous flush catheter	78N-1414	II
870.1220	Electrode recording catheter and electrode recording probe	78N-1415	II
870.1230	Fiberoptic oximeter catheter	78N-1416	II
870.1240	Flow-directed catheter	78N-1417	II
870.1250	Percutaneous catheter	78N-1418	II
870.1260	pH catheter probe	78N-1419	II
870.1270	Intracavitary phono catheter system	78N-1420	II
870.1280	Steerable catheter	78N-1421	II
870.1290	Steerable catheter control system	78N-1422	II
870.1300	Catheter cannula	78N-1423	II
870.1310	Vessel dilator for percutaneous catheterization	78N-1424	II
870.1320	Catheter guide holder	78N-1425	I
870.1330	Catheter guide wire	78N-1426	II
870.1340	Catheter percutaneous introducer	78N-1427	II
870.1350	Catheter ballon repair kit	78N-1428	III
870.1360	Trace microsphere	78N-1429	III
870.1370	Catheter tip occluder	78N-1430	II
870.1380	Catheter stylet	78N-1431	II
870.1390	Trocar	78N-1432	II
870.1425	Programmable diagnostic computer	78N-1433	II
870.1435	Single-function, preprogrammed diagnostic computer	78N-1434	II
870.1450	Densitometer	78N-1435	II
870.1650	Angiographic injector and syringe	78N-1436	II
870.1660	Indicator injector	78N-1437	II
870.1670	Syringe actuator for injectors	78N-1438	II
870.1750	External programmable pacemaker pulse generator	78N-1439	II
870.1800	Withdrawal-infusion pump	78N-1440	II
870.1875	Stethoscope	78N-1441	II
870.1915	Thermodilution probe	78N-1442	II

Subpart C—Cardiovascular Monitoring Devices

870.2050	Biopotential amplifier and signal conditioner	78N-1443	II
870.2060	Transducer signal amplifier and signal conditioner	78N-1444	II
870.2100	Cardiovascular blood flowmeter	78N-1445	II
870.2120	Extravascular blood flow probe	78N-1446	II
870.2300	Cardiac monitor (including cardiotachometer and rate alarm)	78N-1447	II
870.2310	Apex cardiograph (vibrocardiograph)	78N-1448	II
870.2320	Ballistocardiograph	78N-1449	II
870.2330	Echocardiograph	78N-1450	II
870.2340	Electrocardiograph	78N-1451	II
870.2350	Electrocardiograph lead switching adaptor	78N-1452	II
870.2360	Electrocardiograph electrode	78N-1453	II
870.2370	Electrocardiograph surface electrode tester	78N-1454	II
870.2380	Electrocardiograph conducting media	78N-1455	II
870.2390	Phonocardiograph	78N-1456	II
870.2400	Vectorcardiograph	78N-1457	II
870.2450	Medical cathode-ray tube display	78N-1458	II
870.2600	Signal isolation system	78N-1459	II
870.2620	Line isolation monitor	78N-1460	II
870.2640	Portable leakage current alarm	78N-1461	II
870.2675	Oscillometer	78N-1462	II
870.2700	Oximeter	78N-1463	II
870.2710	Ear oximeter	78N-1464	II
870.2750	Impedance phlebograph	78N-1465	II
870.2770	Impedance plethysmograph	78N-1466	II
870.2780	Hydraulic, pneumatic, and photoelectric plethysmograph	78N-1467	II
870.2800	Medical magnetic tape, recorder	78N-1468	II
870.2810	Paper chart recorder	78N-1469	II
870.2840	Apex cardiographic transducer	78N-1470	II
870.2850	Extravascular blood pressure transducer	78N-1471	II
870.2860	Heart sound transducer	78N-1472	II
870.2870	Catheter tip pressure transducer	78N-1473	II
870.2880	Ultrasonic transducer	78N-1474	II
870.2890	Vessel occlusion transducer	78N-1475	II
870.2900	Patient transducer and electrode cable (including connector)	78N-1476	II
870.2910	Radiofrequency physiological signal transmitters and receivers	78N-1477	II
870.2920	Telephone electrocardiograph transmitters and receivers	78N-1478	II

Subpart D—Cardiovascular Prosthetic Devices

870.3250	Vascular clip	78N-1479	II
870.3260	Vena cava clip	78N-1480	II
870.3300	Peripheral arterial embolization device	78N-1481	III
870.3375	Cardiovascular intravascular filter	78N-1482	III
870.3450	Vascular graft prosthesis of less than 6mm diameter	78N-1483	III
870.3460	Vascular graft prosthesis of 6mm and greater diameter	78N-1484	II
870.3470	Intracardiac patch and pledget made of polypropylene, Teflon, or Dacron	78N-1485	II
870.3535	Intra-aortic balloon and control system	78N-1487	III
870.3545	Ventricular bypass (assist) devices	78N-1488	III
870.3600	External pacemaker pulse generator	78N-1489	III
870.3610	Implantable pacemaker pulse generator	78N-1490	III
870.3620	Pacemaker lead adaptor	78N-1491	III
870.3630	Pacemaker generator function analyzer	78N-1492	II
870.3640	Indirect pacemaker generator function analyzer	78N-1493	II
870.3650	Pacemaker polymeric mesh bag	78N-1494	II
870.3670	Pacemaker charger	78N-1496	II
870.3680	Permanent and temporary pacemaker electrode	78N-1497	III
870.3690	Pacemaker test magnet	78N-1498	II
870.3700	Pacemaker programmer	78N-1499	III
870.3710	Pacemaker repair and replacement materials	78N-1500	III
870.3720	Pacemaker electrode function tester	78N-1501	II
870.3730	Pacemaker service tools	78N-1502	I
870.3800	Annuloplasty ring	78N-1503	III
870.3850	Carotid sinus nerve stimulator	78N-1504	III
870.3925	Replacement heart valve	78N-1505	III
870.3935	Prosthetic heart valve holder	78N-1506	II
870.3945	Prosthetic heart valve sizer	78N-1507	II
870.4075	Endomyocardial biopsy device	78N-1508	II
870.4200	Cardiopulmonary bypass accessory equipment	78N-1509	II
870.4205	Cardiopulmonary bypass bubble detector	78N-1378	II
870.4210	Cardiopulmonary bypass vascular catheter, cannula, and tubing	78N-1510	II
870.4220	Cardiopulmonary bypass heart-lung machine console	78N-1511	II
870.4230	Cardiopulmonary bypass defoamer	78N-1512	III
870.4240	Cardiopulmonary bypass heat exchanger	78N-1513	II
870.4250	Cardiopulmonary bypass temperature controller	78N-1514	II
870.4260	Cardiopulmonary bypass arterial line blood filter	78N-1515	III
870.4270	Cardiopulmonary bypass cardiotomy suction line blood filter	78N-1516	II
870.4280	Cardiopulmonary pre-bypass filter	78N-1517	II
870.4290	Cardiopulmonary bypass fitting, manifold, stopcock and adaptor	78N-1518	II
870.4300	Cardiopulmonary bypass gas control unit	78N-1519	II
870.4310	Cardiopulmonary bypass coronary pressure gauge	78N-1520	II
870.4320	Cardiopulmonary bypass pulsatile flow generator	78N-1521	III
870.4330	Cardiopulmonary bypass on-line blood gas monitor	78N-1522	II
870.4340	Cardiopulmonary bypass level sensing monior and/or control	78N-1523	II
870.4350	Cardiopulmonary bypass oxygenator	78N-1524	III
870.4360	Nonroller type cardiopulmonary bypass blood pump	78N-1525	III
870.4370	Roller-type cardiopulmonary bypass blood pump	78N-1526	II
870.4380	Cardiopulmonary bypass pump speed control	78N-1527	II
870.4390	Cardiopulmonary bypass pump tubing	78N-1528	II
870.4400	Cardiopulmonary bypass blood reservoir	78N-1529	II
870.4410	Cardiopulmonary bypass in-line blood gas sensor	78N-1530	II
870.4420	Cardiopulmonary bypass cardiotomy return sucker	78N-1531	II
870.4430	Cardiopulmonary bypass intracardiac suction control	78N-1532	II
870.4450	Vascular clamp	78N-1533	II
870.4475	Surgical vessel dilator	78N-1534	II
870.4500	Cardiovascular surgical instruments	78N-1535	II
870.4875	Intraluminal artery stripper	78N-1536	II
870.4885	External vein stripper	78N-1537	II
870.5050	Patient care suction apparatus	78N-1538	II
870.5150	Embolectomy catheter	78N-1539	II
870.5175	Septostomy catheter	78N-1540	II
870.5200	External cardiac compressor	78N-1541	III
870.5225	External counterpulsating device	78N-1542	III
870.5300	DC-defibrillator (including paddles)	78N-1543	III
870.5325	Defibrillator tester	78N-1544	II
870.5550	External transcutaneous cardiac pacemaker (noninvasive)	78N-1545	III
870.5800	Compressible limb sleeve	78N-1546	II
870.5900	Thermal regulating system	78N-1547	II
870.5925	Automatic rotating tourniquet	78N-1548	II

DEVICES CONSIDERED BY TWO OR MORE PANELS

Many devices were reviewed by two or more device classification panels. For these devices, FDA will publish each panel's 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 angiographic guide wires and accessories be classifed 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. Bases 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 General Hospital and Personal Use Device Classification Panel recommended that mechanical stethoscopes and DC-powered 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:

Device	Other panel(s)
Flow directed catheter	
Ballon-type cardiovascular catheter	General and Plastic Surgery
Diagnostic intravascular catheter	
Angiographic catheter	Neurological
Cardiovascular catheter	General and Plastic Surgery
Opaque vascular catheter	Radiology
Blood pressure computers	
Internal arterial pressure monitor	General and Plastic Surgery
Atrial cardiac pressure monitor	General and Plastic Surgery
Ventricular cardiac pressure monitor	General and Plastic Surgery
Powered pulmonary artery pressure monitor	General and Plastic Surgery
Indwelling blood pressure monitor	Anesthesiology
Invasive neonatal blood pressure monitor	General Hospital and Personal Use
Single-function, preprogrammed diagnostic computer	
Dye cardiac output monitor	General and Plastic Surgery
Thermal cardiac output monitor	General and Plastic Surgery
Trend cardiac output monitor	General and Plastic Surgery
Blood pressure cuff	
Nonpowered external arterial pressure monitor	General and Plastic Surgery
Inflation cuff	General and Plastic Surgery
Manual cuff inflating air pump	General and Plastic Surgery
Noninvasive blood pressure measurement system	
Nonindwelling blood pressure monitor	Anesthesiology
Powered external arterial pressure monitor	General and Plastic Surgery
Aneroid blood pressure manometer	General and Plastic Surgery
Mercury blood pressure manometer	General and Plastic Surgery
Ultrasonic/doppler neonatal blood pressure monitor	General and Plastic Surgery
Electrocardiograph	
Electrocardiograph monitor	General and Plastic Surgery
Electrocardiograph monitor	Anesthesiology
Cardiovascular blood flowmeter	
Transcutaneous ultrasonic blood flowmeter	Anesthesiology
Flowmeter cardiac output monitor	General and Plastic Surgery
Electromagnetic or Doppler, noninvasive blood flowmeter	Urology
Electrovascular blood flow probe	
Indwelling blood flow transducer	Anesthesiology
Nonindwelling blood flow transducer	Anesthesiology
Cardiac monitor (including cardiotachometer and rate alarm)	
Pulse rate monitor	Anesthesiology
Neonatal heart rate monitor	General Hospital and Personal Use
Impedance plethysmograph	
Impedance plethymography cardiac output monitor	General and Plastic Surgery
Extravascular blood pressure transducer	
Nonindwelling blood pressure transducer monitor	Anesthesiology
Catheter tip pressure transducer	
Indwelling blood pressure transducer monitor	Anesthesiology
Transducer signal amplifier and signal conditioner	
Blood pressure monitor amplifier and associated electronics	Anesthesiology
Paper chart recorder	
Ophthalmic analog and digital recorder	Ophthalmic
Vascular graft prosthesis (6mm and greater diameter)	
Synthetic arterial graft prosthesis (6mm and greater diameter)	General and Plastic Surgery

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:

Device	Other panel(s)
Electrosurgical electrode gel	General and Plastic Surgery
	Neurological
	Anesthesiology
	Dental
Electrosurgical electrode	General and Plastic Surgery
	Neurological
	Anesthesiology
	Dental
	Gastroenterology and Urology
Electrosurgical device	General and Plastic Surgery
	Neurological
	Anesthesiology
	Dental
	Gastroenterology and Urology
Pneumatically powered saw	General and Plastic Surgery
	Orthopedic
	Neurological
	Dental
	Ear, Nose and Throat
Electrically powered saw	General and Plastic Surgery
	Orthopedic
	Neurological

Device	Other panel(s)
Electrically powered saw	Dental Ear, Nose and Throat
Surgical saw blade	General and Plastic Surgery
Medical support stocking	General Hospital and Personal Use Physical Medicine
Biopsy needle	General and Plastic Surgery Gastroenterology and Urology Dental
Infusion pump	General Hospital and Personal Use Gastroenterology and Urology
Long-term vascular catheter	General Hospital and Personal Use General and Plastic Surgery
Sutures	General and Plastic Surgery Dental Ophthalmic

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.

Arterial Graft Prostheses of Animal (Including Human) Origin

At a future date, FDA will publish in the Federal Register a final regulation stating that one cardiovascular device (arterial graft prostheses of animal (including human) origin) is classified into class III (premarket approval) because of transitional provisions of the act, section 520(1) (21 U.S.C. 360j(1)). The transitional provisions classify into class III any device previously regarded by FDA as a new drug. At the time FDA publishes this regulation it will also publish the Panel's recommendations regarding arterial grafts of animal (including human) origin.

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. 360c, 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—CARDIOVASUCLAR DEVICES

Subpart A—General Provisions

Sec.
870.1 *Scope.*

Authority: Secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c and 701(a)).

Subpart A—General Provisions

§ 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 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.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the office of the Hearing Clerk, Food and Drug Administration.

Dated: February 26, 1979.

Joseph P. Hile,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6103 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1407]

MEDICAL DEVICES

Classification of Arrhythmia Detectors and 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 arrhythmia detectors and alarms 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, 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 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 arrythmias 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 apply to specific parts 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 only 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 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 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 the health care team, 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6104 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1408]

MEDICAL DEVICES

Classification of Blood Pressure 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 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:

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 blood pressure alarms:

1. 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.

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 blood pressure alarm 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 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 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 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) 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) 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 § 870.1100 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 pre-set 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6105 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1409]

MEDICAL DEVICES

Classification of Blood Pressure Computers

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 computers into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel, the General and Plastic Surgery 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 classsifying 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, the General and Plastic Surgery Device Classification Panel, the General Hospital and Personal

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 computers:

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 life or 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 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 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 CLASSIFICATION

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. 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 § 870.1110 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, 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. 79-6106 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1410]

MEDICAL DEVICES

Classification of Blood Pressure Cuffs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying blood pressure cuffs 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 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.

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, the General Hospital and Personal Use Device Classification Panel, and the General and Plastic

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 low 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 potentially 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 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. 79-6107 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1411]

MEDICAL DEVICES

Classification of Noninvasive Blood Pressure Measurement 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 noninvasive blood pressure measurement systems into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel the Anesthesiology Device Classification Panel, the General Hospital and Personal Use 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 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, the Anesthesiology Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of nonin-

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-supportng 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 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 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 iatrogenic 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 diagnostic 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.

1. "Standardization of Blood Pressure Readings. Joint Recommendations of the American Heart Association and the Cardiac Society of Great Britain and Ireland," *American Heart Journal* 18:95-101, 1939.

2. Bordley, J., et al., "Recommendations for Human Blood Pressure Determinations by Sphygmomanometers," *Circulation*, 4:503-509, 1951.

3. Kirkendall, W. M., et al., "Recommendations for Human Blood Pressure Determinations by Sphygmomanometers," *Circulation*, 36:980-988, 1967.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), 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 tranducers 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-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. 79-6108 Filed 3-8-79 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1412]

MEDICAL DEVICES

Classification of Venous Blood Pressure Manometers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying venous blood pressure manometers 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 and the recommendation of the General and Plastic Surgery Device Classification Panel that the device be classified into class I. 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 Device Classification 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 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 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 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 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6109 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1413]

MEDICAL DEVICES

Classification of diagnostic intravascular 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 diagnostic intravascular catheters into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel, the General and Plastic Surgery Device Classification Panel, the Neurological Device Classification Panel, and the Radiological 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:

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 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 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 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 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) Misdiagnosis: Inadequate mechanical design with regard to frequency response 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 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.

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 § 870.1200 as follows:

§ 870.1200 Diagnostic intravascular catheter.

(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).

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. 79-6110 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1414]

MEDICAL DEVICES

Classification of Continuous Flush 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 continuous flush catheters into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the 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 Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of continuous flush catheters:

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 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 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 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 potentially 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 can escape into the bloodstream. (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, 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 § 870.1210 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-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. 79-6111 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1415]

MEDICAL DEVICES

Classification of Electrode Recording Catheters and Electrode Recording 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 electrode recording cath-

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, 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 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 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 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 (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 § 870.1120 as follows:

§ 870.1220 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 caridac 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, 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.

Date: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6112 Filed 3-8-79; 8:45 am]

[4110-03-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. 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 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 adequate diagnostic results 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 managing 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) Embolism: 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, 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 § 870.1230 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner, for Regulatory Affairs.

[FR. Doc. 79- 6113 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1417]

MEDICAL DEVICES

Classification of Flow-Directed 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 flow-directed catheters 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 clas-

sifying 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 and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of flow-directed catheters:

1. Identification: A flow-directed catheter is a device that incorporates a gas-filled balloon to help direct the catheter to the desired position.

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 flow-directed 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, that may affect the degree of compatibility. In addition, the material used for the balloon should not be excessively permeable to the filling gas, and the balloon burst strength should meet certain minimum requirements. 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 campatibility 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 potentially debilitating or fatal emboli. (c) Gas embolism: A rupture or a leak in the flow-directed catheter can allow potentially debilitating or fatal gas emboli to escape in the bloodstream.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendations and is proposing that the flow-directed catheter be classified into class II (performance standards). The Commission 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 establih 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, this device will be listed in the Code of Federal Regulations under cardiovascular devices. Although flow-directed 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, 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 § 870.1240 as follows:

§ 870.1240 Flow-directed catheters.

(a) *Identification.* A flow-directed catheter is a device that incorporates a gas-filled ballon to help direct the catheter to the desired position.

(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. 79-6114 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1418]

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.

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 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 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 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. 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 § 870.1250 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6115 Filed 3-8-79; 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. 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 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 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. (d) 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 the pH catheter 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. Although pH catheter 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 (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 § 870.1260 as follows:

§ 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).

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. 79-6116 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1420]

MEDICAL DEVICES

Classification of Intracavitary Phono-Catheter Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposd regulation classifying intracavitary phono-catheter 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 (FHA-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 intracavitary phono-catheter systems:

1. 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 trans-

ducer placed within the heart, blood vessels, or body cavities.

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 intracavitary phono-catheter system be classified into class II (performance standards) because this device is neither life-supporting nor lifesustaining 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 acoustic transducer has performance characteristics such as electrical isolation, accuracy, and stability that should be maintained at an acceptable 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 currrent 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) Embolism: Pieces of the catheter that 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 Panel's recommendation and is proposing that the intracavitary phono-catheter 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 intracavitary phono-catheter systems 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 § 870.1270 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 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. 79-6117 Filed 3-8-79; 8:45 am]

[4110-03-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 (performace 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:

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 Classfication Panel, an FDA advisory committee, made the following recommendation with respect to the classification of steerable catheters:

1. Identification: A steerable catheter is a catheter used for diagnostic and monitoring purposes whose movements are directed by a steering control unit.

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 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. 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 devise 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 haszards 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 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 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, 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 § 870.1280 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR. Doc. 79-6118 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1422]

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 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 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 a 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. If 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 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: 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 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 § 870.1290 as follows:

§ 870.1290 Steerable catheter control system.

(a) *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.

Dated: February 26, 1979.

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.

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 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 this 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6120 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1424]

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 is 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 Caradiovascular 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 to enlarge the opening in the vessel, and which is then removed before sliding the catheter over the guide wire.

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 vessel dilator for percutaneous catheterization be classified into class II because this device is neither life-sustaining nor life-supporting, but is potentialy 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 campatibility, 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 rough, or if the dilator is too stiff, vessel dissection may result. (b) Embolism: Pieces of the dilator which 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 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 catherization 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 then 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.

Dated: February 26, 1979.

JOSEPH P.HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6121 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1425]

MEDICAL DEVICES

Classification of Catheter Guide 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 catheter guide holders into class I (ageneral 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 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 guide holders:

1. Identification: A catheter guide holder is a tube that holds a spring guide during percutaneous terchniques and during storage and sterilization.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the catheter guide holder be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The device is a simple tube which is not life sustaining, life supporting, or implanted and which is not potentially hazardous to life and health when properly used. The Panel believes that the materials currently used in the device are generally acceptable and need no additional control requirements.

4. Summary of data on which the recommendation is based: The Panel members based their recommendation on the lack of potential hazards associated with the inherent properties of the device and on their personal knowledge of, and eperience with, the device.

5. Risks to health: None identified.

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 folllows:

§ 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.

Dated: February 26, 19679.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs

[FR Doc. 79-79-6122 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1426]

MEDICAL DEVICES

Classification of Catheter Guide Wires

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 guide wires into class II (performance standards). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel and the Radiological Device Classification Panel that the device be classified into class II, and the recommendation of the Neur-

ogical Device Classification Panel that the device be classified into class I. 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 Device Classification Panel, the Neurological Device Classification Panel, and the Radiological Device Classification Panel, FDA advisory committees, made the following recommendations with respect to the classification of catheter guide wires:

1. 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.

2. Recommended classification: Class II (performance standards). The Cardiovascular Device Classification Panel and the Radiological Device Classification Panel recommend that establishing a performance standard for this device be a high priority. The Neurological Device Classification Panel recommends Class I (general controls) with no exemptions.

3. Summary of reasons for recommendation: The Cardiovascular Device Classification Panel and the Radiological Device Classification Panel recommend that the catheter guide wire 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 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 classifying the device into class I (general controls).

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 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 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 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 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, 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 § 870.1330 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]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1427]

MEDICAL DEVICES

Classification of Catheter Percutaneous Introducers

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 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-

sifying 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 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) 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 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 reasonalbe 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 catheter percutaneous introducers are used as an accessory device to catheters, this device will be listed along with catheters in the Code of Federal Regulations under cardiovascular diagnostic devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 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 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. 79-6124 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1428]

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 regulation 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 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, 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 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 embolism is 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 do not exist 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 provie 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, and experience 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 thromboemboli. (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 the device presents a potential unreasonable risk of illness or injury because potentially debilitating or fatal gas or particulate emboli are likely to occur when this device is used. 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6125 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1429]

MEDICAL DEVICES

Classification of Trace Microsphere

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying trace microspheres 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, 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 trace microspheres:

1. Identification: A trace microsphere is a radioactively tagged nonbiodegradable particle that is injected into an artery or vein and trapped in the capillary bed for the purpose of studying blood flow within or to an organ.

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 trace microsphere be classified into class III because this implanted 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. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's ability to demonstrate blood flow should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. Materials used in the device should meet a generally accepted satisfactory level of tissue and blood compatibility. The device could cause genetic damage by exposing the patient's reproductive organs to excessive radiation. 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.

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 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 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 the device is purported or represented to be for 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 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 § 870.1360 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 (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. 79-6126 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No.78N-1430]

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 (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, 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 cathether tip occluder 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 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 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) 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(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart B by adding new § 870.1370 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.

Dated: February 26, 1979.

JOSEPH P. 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. 78N-1431]

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 stylets 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 (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 stylets:

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 potential hazards associated with the inherent properties of the device and on their personal knowledge of, and experices 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) Cardiac perforation and vessel dissection: If the stylet is 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.

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 au-

thority delegated to him (21 CFR 5.1), 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 cannual to render it stiff.

(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. Recieved 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. 79-6128 Filed 3-8-79; 8:45 am]

[4110-03-M]

[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 II, and the recommendation of the Neurological Device Classification Panel that the device be classified into class I. 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 Drug proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, 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 backgroud 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 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 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 and that there is sufficient information to establish a standard to provide such assurance. The Neurological Device Classification Panel reviewed needles used to puncture the artery prior to catheterization for cerebral angiograms. These needles are essentially the same device, and serve the same function, as the trocar for cardiovascular catherterization procedures. The Neurological Device Classification Panel believes that the device presents no potential hazard to health and that general controls are sufficient to ensure the safety and effectiveness of 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: Unnecessary damage to vessel: Improper mechanical design of the device can cause unnecessary damage to the vessel during the piercing operation.

PROPOSED CLASSIFICATION

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. 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 § 870.1390 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6129 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No.78-1433]

MEDICAL DEVICES

Classification of Programmable Diagnostic Computers

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. 4-65, 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, and FDA advisory committee, made the following recommendation with respect to the classification of programmable diagnostic computers:

1. Identification: A programmable diagnostic computer is a device that can be programmed to compute various physiologic or blood flow parameters based on the output from one or more electrodes, transducers, or measuring devices; this device includes any associated commercially supplied programs.

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 programmable diagnostic computer be classified into class II bcause 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 and reproducibility, and any limitations on the device's programmed measurements, 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 electric 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 prodedure, 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 programmable 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 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 programmable diagnostic 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. 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 § 870.1425 as follows:

§ 870.1425 Programmable diagnostic computer.

(a) *Identification.* A programmable diagnostic computer is a device that can be programmed to compute various physiologic or blood flow parameters based on the output from one or more electrodes, transducers, or measuring devices; this device includes any associated commercially supplied programs.

(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. 79-6130 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1434]

MEDICAL DEVICES

Classification of Single-Function, Preprogrammed Diagnostic Computers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying single-function, preprogrammed diagnostic computers 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 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, 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 recommend that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panels recommends 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 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 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. 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 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 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. 300c, 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 § 870.1435 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.

(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. 79-6131 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 Devise 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 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 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 physican 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 densitometer 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 effectivess 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, and 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 § 870.1450 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6132 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1436]

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, 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 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 in to 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. Performance characteristics, including accuracy, 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. When the device is synchronized with the 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 blood stream 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 estabish 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, 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 § 870.1650 as follows:

§ 870.1650 Angiographic injector and syringe.

(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, 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. 79-6133 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

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 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 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 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 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 which places the patient at risk unnecessarily.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the indicator injector 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6134 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1438]

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, 6500 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, 301-427-7759.

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 Device 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) signal.

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 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 life or 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.

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. Failure of the device to properly synchronize the injection with the correct time in the cardiac cycle may also lead to cardiac arrythmias. 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 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. 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 § 870.1670 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6135 Filed 3-8-79; 8:45 am]

[4110-03-M]

[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 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:

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 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. Inaccurate rate control or electronic circuit failure could cause improper stimulation rate. (c) Cardiac arrythmias: 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 arrythmias.

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. 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 § 870.1750 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6136 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1440]

MEDICAL DEVICES

Classification of Withdrawal-Infusion Pumps

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying withdrawal-infusion pumps 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:

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 withdrawal-infusion pumps:

1. 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.

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 measurement of fluid volume delivery or withdrawal, 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 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 Panel believes 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, and experience with, the device. In addition, the Panel reviewed the "Final Report: Safety and Performance of Angiographic Injectors and Infusion and Withdrawal Pumps," of June 30, 1977, prepared under contract for FDA by the Utah Biomedical Testing Laboratory. This report cites four types of infusion and withdrawal pumps, including this device. The report states that the performance required of a withdrawal-infusion pump is the delivery (or withdrawal) of fluid to (or from) the patient in an accurate, controllable manner, without inadvertent administration of substances not intended to be delivered (e.g., air or electrical energy). The report shows that standards can be established for these characteristics.

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) Inaccurate administration of drugs: An inaccurate pump speed control can produce an overdosage or underdosage of a drug. (c) Inaccurate determination of the patient's cardiac output: Inaccurate pump speed control can also result in inaccurate determination of cardiac output.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the withdrawal-infusion pump be classified into class II (performance standards). Although the device can be life-supporting, the Commissioner believes that a performance standard is sufficient 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. The Commissioner believes that general controls by themselves are insufficient to control the risks to health of the device. Although withdrawal-infusion pumps are used both 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 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. 79-6137 Filed 3-8-79; 8:45 am]

[1110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1441]

MEDICAL DEVICES

Classification of Stethoscopes

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying stethoscopes 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 and the recommendations of the General Hospital and Personal Use Device Classification Panel and the General and Plastic Surgery Device. Classification Panel that the device be classified into class I (general controls). The effect of classifying a device into class II is to provide for the future development of one or more performace 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, the General Hospital and Personal Use 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 stethoscopes:

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 establishing 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 recommends 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 such assurance. The General and Plastic Surgery Device Classification Panel and the General Hospital and Personal Use Device Classification Panel believe that the device presents no potential hazards to life or health and that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel members based their 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 with regard to frequency response 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 recommendation of the Cardiovascular Device Classification Panel and is proposing that the stethoscope 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. Although stethoscopes have many uses, this device will be listed in the Code of Federal Regulations under cardiovascular devices because cardiovascular uses are the most common.

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 § 870.1875 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 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. 79-6138 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1442]

MEDICAL DEVICES

Classification of Thermodilution 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 thermodilution 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, 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, 301-427-7759.

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 Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of therodilution probes:

1. 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.

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 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 place 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 compatability, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatiblity. This device is attached to the body directed or through a catheter and is used in a clinical environement 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 output, 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 used 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 safely 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: Inadequate design with regard to resistance change in the device or the device's accuracy 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. (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 thromboemboli.

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, 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 § 870.1915 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, 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. 79-6139 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1443]

MEDICAL DEVICES

Classification of Biopotential Amplifier and Signal Conditioners

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying biopotential amplifiers and signal conditioners 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:

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 biopotential amplifiers and signal conditioners:

1. Identification: A biopotential amplifier and signal conditioner is a device used to amplify or condition an electrical signal of biologic origin.

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 biopotential amplifiers and signal 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 the amplification and conditioning are inadequate for accurate and precise measurement of the bioelectric signal, 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. Performance characteristics, including accuracy, stability, frequency response, input impedance, 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 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: Inadequate design with regard to frequency response and accuracy and stability of zero and calibration 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 biopotential amplifier and signal conditioner be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although biopotential amplifiers and signal 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.

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 C and new § 870.2050 as follows:

Subpart C—Cardiovascular Monitoring Devices

§ 870.2050 Biopotential amplifier and signal conditioner.

(a) *Identification.* A biopotential amplifier and signal conditioner is a device used to amplify or condition an electrical signal of biologic origin.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 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. 79-6140 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1444]

MEDICAL DEVICES

Classification of Transducer Signal Amplifiers and Conditioners

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation 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. 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 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 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, reproductibility, 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 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 effectivenes 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, or if the device provides an inadequate frequency response, 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 panels' recommendations and is proposing that the transducer signal amplifier and conditioner be classified into class II (performance standards). The Commissioner believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health. a performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Commissioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. 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.

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 § 870.2060 as follows:

§ 870.2060 Transducer signal amplifier and conditioner.

(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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6141 Filed 3-8-79; 8:45 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 into class II (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 (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 de-

velopment of the proposed regulation. The Cardiovascular Device Classification Panel, the Anesthesiology Device Classification Panel, the Gastroenterology and Urology Device Classification Panel, and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of cardiovascular blood flowmeters:

1. Identification: A cardiovascular blood flowmeter is a device, connected to a flow transducer, that energizes the transducer and processes and displays the blood flow 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 blood flowmeters 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 a flow 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. Although the device releases an acceptable energy level 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 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 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 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. (c) Tissue and blood damage: If the device is not designed properly, ultrasonic energy can be released into the body at levels that can damage tissue and blood.

PROPOSED CLASSIFICATION

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. 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 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.

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 § 870.2100 as follows:

§ 870.2100 Cardiovascular blood flowmeter.

(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).

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. 79-6142 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1446]

MEDICAL DEVICES

Classification of Extravascular Blood Flow 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 extravascular blood flow probes into class II (performance standards). The FDA is also publishing the recommendation 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. Rabmoeller, Bureau of Medical Device (HFK-450), Food and Drug Administration, Depart-

ment 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 regarding classification of extravascular blood flow probes:

1. Identification: An extravascular blood flow probe is an extravascular ultrasonic or electromagentic probe used in conjunction with a blood flowmeter to measure blood flow in a chamber or vessel.

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 extravascular blood flow probes be classifed 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 blood flow measurement, the resulting misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body through the skin or the exterior surface of the blood vessels 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 blood flow measurement, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. 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 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) 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 catherterization or surgical procedure, and this may lead to iatrogenic complications. (b) Tissue and blood damage: If the device is not properly designed, excessive energy can be released into the body at levels that can damage tissue and blood. (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.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panels' recommendations and is proposing that the extravascular blood flow 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. 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 extravascular blood flow probes 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 § 870.2120 as follows:

§ 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. 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. 79-6143 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1447]

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.

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, the General Hospital and Personal Use Device Classification Panel, and the Anesthesiology 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 for this device be a high priority.

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 even when properly used. Failure of the device to accurately measure heart rate can 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 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, 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. 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 § 870.2300 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. 4-65, 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. 79-6144 Filed 3-8-79; 8:45 am]

[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 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:

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 significant negative 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 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 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 visusl 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, 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. 79-6145 Filed 3-8-79; 8:45 am]

[4110-03-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. 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 backgound 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 place, 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 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 distrub 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 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 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 § 870.2320 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6146 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1450]

MEDICAL DEVICES

Classification of Echocardiographs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying echocardiographs 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.

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 recommendation 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 inadequate for accurate and precise imaging of cardiovascular structures, resulting 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 emission of unsafe 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, need to meet certain 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.

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 designed properly, 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, 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 § 870.2330 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, 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. 79-6147 Filed 3-8-79; 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.

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, the Anesthesiology Device Classification Panel, and the General and Plastic Surgery Device Classifica-

tion Panel, FDA advisory committees, made the following recommendations with respect to the classification of electrocardiographs (ECG's):

1. Identification: An electrocardiograph is 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.

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 electrocardiograph 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 electrical activity of the heart, 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, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of the electrical activity of the heart, 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 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. In addition, the Cardiovascular Device Classification Panel referred to the American Heart Association recommendations for performance characteristics of electrocardiographs. (*Circulation*, 35:583-602, 1967.)

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 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, 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 § 870.2340 as follows:

§ 870.2340 Electrocardiograph.

(a) *Identification.* An electrocardiograph is 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.

(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. 79-6148 Filed 3-8-79;8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1452]

MEDICAL DEVICES

Classification of Electrocardiograph Lead Switching Adaptors

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 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. 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 back-

ground 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 (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. 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 ECG lead switching adaptors 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 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 harzard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to 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 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, 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 § 870.2350 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 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. 79-6149 Filed 3-8-79; 8:45 am]

[4110-03-M]

[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. 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 electrocardiograph electrodes:

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 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.

(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. 79-6150 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1454]

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 clasifying electrocardiograph (ECG) surface elecrode 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 classsifying the device. These actions are being taken under the Medical Device Admendments 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 recommendation regarding classification of ECG surface elecrode testers:

1. Identification: An electrocardiograph surface electrode tester is a device used to test the function and application of ECG electrodes.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the 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 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.

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, 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 § 870.2370 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 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. 79-6151 Filed 3-8-79; 8:45 am]

[4110-03-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 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 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 trasmit 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 priorty.

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 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 transmit the electrical signal and the devices's 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 lead to 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 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 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, 90 Stat. 540-546 (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 § 870.2380 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.

Dated: February 26, 1979.

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]

[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 (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 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 even when properly used. If the 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

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 Panel's recommendation and is proposing that the phonocardiograph 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 phonocardiographs 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 § 870.2390 as follows:

§ 870.2390 Phonocardiograph.

(a) *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.

(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. 79-6153 Filed 3-8-79; 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 classsifying 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 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 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.

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 vectorcardiographs 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 electrical activity of the heart, 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 enviroment 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 electrical activity of the heart, 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 onset of car-

diac arrhythmias. (b) Misdiagnosis: If the zero or calibration of the device is inaccurate or unstable, or if the frequency response 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 Panel's recommendation and is proposing that the vectorcardiograph be classifed 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. 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 § 870.2400 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 (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. 79-6154 Filed 3-8-79; 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 (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 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 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 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 provided 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, or the frequency response is indequate, 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 offen incorporates special display features unique to a specific biological signal.

Classification. Class II (performance standards).

Intrested 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. 79-6155 Filed 3-8-79; 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 classsifying the device. These actions are being taken under the Medical Device Admendments 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 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:

1. 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 transducer 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 demestic 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, need to meet cerain requirements. Performance formance characteristics, including electrical isolation, of electrical function, and any limitations on the device's signal isolation 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 along 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: 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 peformance 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 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. 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 § 870.2600 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, 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 p.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6156 Filed 3-8-79; 8:45 am]

[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, 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 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.

3. 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 even 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 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 electrical shock: Failure to accurately monitor the electrical leakage current or failure of the device to keep the power supply isolated can lead to excess 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-

sioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. Although line isolation monitors 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 § 870.2620 as follows:

§ 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 (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. 79-6157 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1461]

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.

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 Fisher 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 portable leakage current alarms:

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 establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panels recommends that portable leakage current alarms be classified into class II because the 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 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 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: 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 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 § 870.2640 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 (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. 79-6158 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. 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 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 priorty.

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 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 assoicated 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 classifed 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 5.1), 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 20856, 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. 79-6159 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR 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. 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 recommendation with respect to the classification of oximeters:

1. 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.

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 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 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 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. 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) Tissue damage and blood damage: Devices which emit energy into the body can emit such energy at levels which may 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 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 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 (sec. 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 § 870.2700 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 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. 79-6160 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1464]

MEDICAL DEVICES

Classification of Ear 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 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.

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 recommendation with respect to the classification of ear oximeters:

1. Identification: An ear oximeter is an extravascular device used to transmit light at known wavelengths 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, and 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 § 870.2710 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 idenitifed with the Hearing Clerk docket number found 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: Februrary 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6161 Filed 3-8-79; 8:45 am]

[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 clasifying 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 classsifying the device. These actions are being taken under the Medical Device Admendments 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 recommendation with respect to the classification of impedance phlebographs:

1. Identification: A 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 clasification: 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 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 enviroment where excessive leakage current can be a serious hazard. Thus the electrical characteristics of this device, e.g., electrical leakage current, need to meet cerain 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 recommendationon 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 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 (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 § 870.2750 as follows:

§ 870.2750 Impedance phlebograph.

(a) *Identification.* A 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. 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. 79-6162 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 Admendments 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 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 Panels recommend 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 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 blood flow, 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 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 (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 preformance 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 measurement of blood flow is an indicator of cardiovalcular 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 71-6163 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1457]

MEDICAL DEVICES

Classification of Hydraulic, Pneumatic, and Photoelectric 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 hydraulic, pneumatic, and

photoelectric plethysmographs 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:

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. 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 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 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, 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. (c) Tissue ischemia: Excessive or prolonged pressure in the cuff of a plethysomograph, which uses vessel occlusion techniques for estimation of blood flow, can cause tissue ischemia (deficiency of blood supply to a portion of the body).

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.

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 § 870.2780 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 measurement techniques.

(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. 79-6164 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1468]

MEDICAL DEVICES

Classification of Medical Magnetic Tape Recorders

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 magnetic tape recorders 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:

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 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 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 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, 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 § 870.2800 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).

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. 79-6165 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1469]

Medical Devices

Classification of Paper Chart Recorders

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying paper chart recorders into class II (performance standards). The FDA is also publishing the recommendations of the Cardiovascular Device Classification Panel and the Ophthalmic 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 perform-

ance 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 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 signal 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 becasue 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, should be maintained at a generally accepted satisfactory level and should be made know 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 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, 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, 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 § 870.2810 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 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. 79-6186 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-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:

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 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 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, 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. 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.

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, 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 § 870.2840 as follows:

§ 870.2840 Apex cardiographic transducer.

(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,

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6167 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-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-

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, 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 and the Anesthesiology Device Classification Panel, FDA advisory committees, made the following recommendation with respect to the classification of extravascular blood pressure transducers:

1. Identification: An extravascular blood pressure transducer is a device used to measure blood pressure by changes in 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.

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 extravascular blood pressure transducers be classified into class II because this electrically operated 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 misdiagnosis could have a significant negative effect on the patient's health. This device is attached to the body by in-line contact with the blood in a catheter system 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'a ability to sense 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 Panel members based their recommendations on the potential hazards associated with the inherent properties of the device and on thier 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 claibration 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 recommendations of the Panels and is proposing that the extravascular blood 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 extravascular blood pressure transducers 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 § 870.2850 as follows:

§ 870.2850 Extravascular blood pressure transducer.

(a) *Identification.* An extravascular blood pressure tranducer 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6168 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1472]

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:

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 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 properly used. If the device is inadequate for accurate and precise detection 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 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 sounds 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 date 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.

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. 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 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 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.

(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 submits 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. 79-6169 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-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 classsifying 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, and 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 realtaion to changes in blood pressure. These changes are transmitted to accessory equipment for processing.

2. Recommended clasification: 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 misdiagnosis 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 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 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 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 electrophsiology 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) Thromboembolism: 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 cardiovalcular 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. 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 § 870.2870 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, 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6170 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1474]

MEDICAL DEVICES

Classification of Ultrasonic 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

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 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 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 § 870.2880 as follows:

§ 870.2880 Ultrasonic transducer.

(a) *Identification.* A 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.

Dated: February 26, 1979.

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.

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 FEDRAL 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 for accurate and precise detection of a partially occluded vessel, the resulting misdiagnosis could have a significant negative effect on the patient's health. 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. In the case of ultrasonic devices of this category, malfunction of the device may result in exposure of the body to an unsafe amount of ultrasonic energy. 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. (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 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. Although vessel occlusion 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 § 870.2890 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6172 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1476]

MEDICAL DEVICES

Classification of Patient Transducer and Electrode Cables (Including Connector)

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 transducer and electrode cables (including connector) 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 effec-

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, 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 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 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) 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. 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, 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. 79-6173 Filed 3-8-79; 8:45 am]

[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, FDA will issue a final regulation classsifying the device. These actions are being taken under the Medical Device Admendments 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 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 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 clasification: 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 enviroment 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 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 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. 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 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 becasue 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 § 870.2910 as follows:

§ 870.2190 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 (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. 79-6174 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.

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 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 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.

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. 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 § 870.2920 as follows:

§ 870.2920 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 20857, written comments regardng 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. 79-6175 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1479]

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-

tions 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 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, the 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 occulsion 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: Slippage may result from 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.

1. Fox, J. L., "Vascular Clips for the Microsurgical Treatment of Stroke," *Stroke*, 7(5):489-500, 1976.

2. Sugita, K. et al. "Comparative Study of the Pressure of Various Aneurysm Clips," *Journal of Neurosurgery*, 44(6):723-727, 1976.

3. Parris, E. B., "The Use of Hemostatic Clips in General Surgery," *American Journal of Proctology*, 23(6):484-488, 1972.

4. Samuels, P. B. and J. J. Cincotti, "The Use of Hemostatic Clips in Vascular Surgery," *Journal of Cardiovascuar Surgery* (Torino), 9(2):150-153, 1968.

5. Drake, C. G. and T. J. Allcock, "Postoperative Angiography and the 'Slipped' Clip," *Journal of Neurosurgery*, 39:683-689, 1973.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend part 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 (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. 79-6176 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1480]

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 (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 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-supporting nor life-sustaining, but is potentialy 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 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 device. In addition, the Panel found further support for their recommendation in the medical literature. This review included a comparison of the four commonly used methods of vena cava interruption: ligation (complete occlusion), plication (narrowing by suture techniques), intracaval filtering, the 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). Also, large pressures produced in the cava during coughing or sneezing tend to dislodge 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 because of poor mechanical design of the device or tissue incompatibility of the materials used in the device. (b) Recurrent thromboemboli: Relaxation of the device due to material creep can lead to recurrent pulmonary thromboemboli, which can be debilitating or fatal.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the vena cava 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.

1. Taber, R. I., et al., "Prevention of Pulmonary Emboli with a Vena Caval Clip," *Journal of the American Medical Association*, 195(11):889-894, 1966.

2. Moretz, W. H., et al., "Partial Occlusion of the Inferior Vena Cava with a Smooth Teflon Clip: Analysis of Long-Term Results," *Surgery*, 71(5):710-719, 1972.

3. Mullick, S. C. and H. B. Wheeler, "Recurrent Pulmonary Emboli After Inferior Vena Caval Clipping," *American Journal of Surgery*, 119:746-748, 1970.

4. Neeley, R. and J. R. Allenberg, "Acute Cardiovascular Effects of Vena Cava Interruption: Ligation Versus Clip Compartmentation with Cardiac Output and Flow Measurements," *Surgery*, 66(4):762-764, 1969.

5. Mandel, S. R., G. Johnson, and J. H. Capps, "Angiographic, Hemodynamic, and Clinical Evaluation of Partial Occlusion of the Inferior Vena Cava," *Southern Medical Journal*, 64(6):647-652, 1971.

6. Miles, R. M., et al., "Long-Term Results with the Serrated Teflon Vena Caval Clip in the Prevention of Pulmonary Embolism," *Annals of Surgery*, 169(6):881-891, 1961

7. Bryant, M. F., "Prophylactic Clipping of the Inferior Vena Cava," *Journal of the Medical Association of Georgia*, 62:105-107, 1973.

8. Miles, R. M. and P. W. Elsea, "Clinical Evaluation of the Serrated Vena Caval Clip, "Surgery, Gynecology and Obstetrics, 132(4):581-587, 1971.

9. Miles, R. M., "Prevention of Pulmonary Embolism by the Use of a Plastic Vena Caval Clip," *Annals of Surgery, 163(2):192-198, 1966.*

10. Silver, D. and D. C. Sabiston, "The Role of Vena Caval Interruption in the Management of Pulmonary Embolism," *Surgery*, 77(1):1-10, 1975.

11. Pollak, E. W., F. C. Sparks, and W. F. Barker, "Inferior Vena Cava Interruption: Indications and Results with Caval Ligation, Clips and Intracaval Devices in 110 Cases," *Journal of Cardiovascular Surgery*, 15:629-635, 1974.

12. Gardner, A. M. N., "Partial Inferior Vena Caval Occlusion Clip," *Proceedings Royal Society Medicine*, 67(1), 1974.

13. Miyauchi, Y. and B. C. Paton, "Teflon Serrated Clips for Prevention of Pulmonary

Embolis," *American Surgery*, 32(9):609-614, 1966.

14. Hendricks, G. L. and W. T. Barnes, "Experiences with the Clip: 100 Cases," *American Surgeon*, 37(9):558-562, 1971.

Therefore under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 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 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. 79-6177 Filed 3-8-79; 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 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.

SUPPLEMENTRAY 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 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 can lead to potentially debilitating or fatal thromboemboli. (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 may result. (d) 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). (e) 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 purported 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-

formance 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 § 870.3300 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, hepatoma) 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6178 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1482]

MEDICAL DEVICES

Classification of Cardiovascular Intravascular 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 cardiovascular intravascular filters 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, 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 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 thromboemboli (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 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. 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 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 thromboemboli. (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 blood flow 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 thromboemboli) 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 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 § 870.3375 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 thromboemboli (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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6179 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1483]

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 into class III (premarket approval). 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 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, 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 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 less than 6 mm diameter:

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 into class III because the device is implanted and is life-sustaining. The Panels believe that artificial grafts of less thn 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 recommendtions 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); hemolysis (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. 2, 4, 9, and 19). Because of loss of tensile strength, use of nylon materials was abandoned (Refs. 5 and 10). Blood compatibility of the materials has always been a problem, because no truly blood-compatible artificial material has been discovered. Thrombogenicity of the materials should be reduced to a minimum. However, there is no present agreement on the most effective means to achieve this. For example, Guidoin (Ref. 20) cited conflicting reports on the thrombogenicity of Dacron used in vascular graft prosthesis. Szilagyi et al. (Ref. 2) reported late patency of 15 percent for artificial grafts in the femoralpopliteal position, while endarterectomy and autogenous vein grafts had late patencies of 90 percent and 80 percent, respectively. 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 polytetrafluoroethylene (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.

5. 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 stitch can cause ripping of the graft when punctured with a surgical needle. (c) Dilatation: Dilatation can result from insufficient physical strength of the material or from improper design of the weave or knit pattern of the graft. (d) Blood seepage or leakage: Inadequate preclotting of the graft can cause seepage or leakage of blood through the graft wall.

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 a use (artery replacement) 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 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. Because it 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.

1. Hansen, O. K., O. Kraft, C. Mouritzen, "Biologic and Semibiologic Vascular Grafts," *Surgery, Gynecology, and Obstetrics*, 138:940-944, 1974.

2. Szilagyi, D. E., R. F. Smith, J. P. Elliot, and H. M. Allen, "Long-Term Behavior of a Dacron Arterial Substitute," *Annals of Surgery*, 162(3):453-477, 1965.

3. Berger, S. and E. W. Salzman, "Thromboembolic Complications of Prosthetic Devices," *Progress in Hemostasis and Thrombosis*, 2:273-309, 1974.

4. Hallin, R. W., "Complications with the Mandril-Grown (Sparks) Dacron Arterial Graft," *American Surgeon*, 41(9):550-554, 1975.

5. Szilagyi, D. E., J. R. Pfeifer, and F. J. DeRusso, "Long-Term Evaluation of Plastic Arterial Substitutes: An Experimental Study," *Surgery*, 55(1):165-183, 1964.

6. Sauvage, L. R., "The Future of Porous-Fabric Arterial Prostheses," *Annals of Thoracic Surgery*, 19:333-335, 1975.

7. Miller, B. G., K. A. Dyer, B. C. Taylor, J. I. Wright, and W. V. Sharp, "Electrical Conductivity: Effect on Intravascular Performance of Foams, Velour, Flock and Fabric," *Transactions of the American Society for Artificial Internal Organs*, 20:91-100, 1974.

8. Weinstein, G., A. J. Franzone, S. H. Stertzer, and W. Walsh, "Subvalvular Stenosis of Aortic Prostheses," *Journal of Thoracic and Cardiovascular Surgery*, 68:17-20, 1974

9. Ottinger, L. W., R. C. Darling, R. S. Wuithlin, and R. R. Linton, "Failure of Ultralightweight Knitted Dacron Grafts in Arterial Reconstruction," *Archives of Surgery*, 111:146-149, 1976.

10. Lindenauer, S. M., T. R. Weber, T. A. Miller, S. R. Ramsbaugh, C. A. Salles, S. P. Kahn, and R. W. Wojtalik, "The Use of Velour as a Vascular Prosthesis," *Biomedical Engineering*, 11(9):301-306, 1976.

11. Deterling, R. A., "Editorial: Failure of Dacron Arterial Prostheses," *Archives of Surgery*, 108:113, 1974.

12. Cooke, P. A., P. A. Nobis, and R. J. Stoney, "Dacron Aortic Graft Failure," *Archives of Surgery*, 108:101-103, 1974.

13. Hayward, R. H. and F. L. Korompai, "Degeneration of Knitted Dacron Grafts," *Surgery*, 79(5):581-583, 1976.

14. Singh, A., E. A. Letsky, and J. Stark, "Hemolysis Following Correction of Double-Outlet Right Ventricle," *Journal of Thoracis and Cardiovascular Surgery*, 71(2):226-229, 1976.

15. O'Connell, T. X., H. J. Fee, and A. Golding, "Sarcoma Associated with Dacron Prosthetic Material," *Journal of Thoracic and Cardiovascular Surgery*, 72(1):94-96, 1976.

16. Thompson, J., T. Dirksen, M. Nube, and A. G. Brom, "Prosthesis Endocarditis," *Journal of Thoracic and Cardiovascular Surgery*, 72(1):28-32, 1976.

17. Florian, A., L. H. Cohn, G. J. Dammin, and J. J. Collins, "Small Vessel Replacement with Gore-tex (Expanded Polytetrafluoroethylene)," *Archives of Surgery*, 111:267-270, 1976.

18. Campbell, C. D., D. Goldfarba, D. D. Detton, R. Roe, K. Goldsmith, and E. B Diethrich, "Expanded Polytetrafluoroethylene as a Small Artery Substitute," *Transactions of the American Society for Artifical Internal Organs*, 20:86-90, 1974.

19. Read, R. C., "Uninfected Anastomotic False Aneurysms Following Arterial Reconstructuring with Prosthetic Grafts," *Journal of Cardiovascular Surgery*, 16:558-561, 1975.

20. Guidoin, R. G., J. A. Awad, C. Gosselin, C. Rouleau, and G. H. Haggis, "Preclotting and Thrombosis of a Dacron Prosthesis: A Scanning Electron Microscope Study," *Biomaterials, Medical Devices, and Artificial Organs*, 3(3):365-382, 1975.

21. Leininger, R. I., J. P. Crowley, R. D. Falb, and G. A. Grode, "Three Years' Experience in vivo and in vitro with Surfaces and Devices Treated by the Heparin Complex Method," *Transactions of the American Society for Artificial Internal Organs*, 18:312-315, 1972.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 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 (permarket 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6180 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1484]

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 classifyng 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.

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 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 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.

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: Although the device is implanted and life sustaining, the Panels recommend that vascular graft prostheses of 6 mm and greater diameter be classified into class II. Vascular grafts of 6 mm and greater in diameter perform as well as the alternatives of endarterctomy or autogenous vein grafts. Because of the tissue and blood interfaces involved in the use of these devices, the materials need to be controlled by standards. In addition, the device has characteristics, such as porosity and tensile strength, that should be maintained at a generally accepted satisfactory level. 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 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 graft 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); aneurysms and dilation of the prostheses or "false aneurysm" (Refs. 2, 4, 9, and 19). Material and mechanical failures include kinking (Refs. 4 and 5) and dilation (Refs. 2, 4, 9, and 19). Loss of tensile strength occurred with nylon materials and caused them to be abandoned (Refs. 5 and 10). Blood compatibility of the materials has always been a problem, because no truly blood-compatible artificial material has been discovered. Yet, thrombogenicity of the materials used should be reduced to a minimum. However, there is no present agreement on the most effective means to achieve this. For example, Guidoin (Ref. 20) cited conflicting reports on the thrombogenicity of Dacron used in vascular graft prostheses. for materials now used, it appears that artificial grafts of 6 mm and greater in diameter compare favorably with alternative forms of vascular replacement. In 1965, Szilagyi (Ref. 2) reported late patency of 85 percent for artificial grafts in the aortoiliac position, while endarterectomy and autogenous vein grafts had late patencies of 90 percent and 80 percent, respectively.

5. 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 stitch can cause ripping of the graft when punctured with a surgical needle. (c) Dilatation: dilatation can result from insufficient physical strength of the material or from improper design of the weave or knit pattern of the graft. (d) Blood seepage or leakage: Inadequate preclotting of the graft can cause seepage or leakage of blood through the graft wall.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panels' recommendations and is proposing that the vascular graft prosthesis of 6 mm and greater diameter 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. 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.

1. Hansen, O. K., O. Kraft, and C. Mouritzen, "Biologic and Semibiologic Vascular Grafts," *Surgery, Gynecology, and Obstetrics*, 138:940-944, 1974.

2. Szilagyi, D. E., R. F. Smith, J. P. Elliot, and H. M. Allen, "Long-Term Behavior of a Dacron Arterial Substitute," *Annals of Surgery*, 162(3):453-477, 1965.

3. Berger, S. and E. W. Salzman, "Thromboembolic Complications of Prosthetic Devices," *Progress in Hemostasis and Thrombosis*, 2:273-309, 1974.

4. Hallin, R. W., "Complications with the Mandril-Grown (Sparks) Dacron Arterial Graft," *American Surgeon*, 41(9):550-554, 1975.

5. Szilagyi, D. E., J. R. Pfeifer, and F. J. DeRusso, "Long-Term Evaluation of Plastic Arterial Substitutes: An experimental Study," *Surgery*, 55(1):165-183, 1964.

6. Sauvage, L. R., "The Future of Porous-Fabric Arterial Prostheses," *Annals of Thoracic Surgery*, 19:333-335, 1975.

7. Miller, B. G., K. A. Dyer, B. C. Taylor, J. I. Wright, and W. V. Sharp, "Electrical Conductivity: Effect on Intravascular Performance of Foams, Velour, Flock and Fabric," *Transactions of the American Society for Artificial Internal Organs*, 20:91-100, 1974.

8. Weinstein, G., A. J. Franzone, S. H. Stertzer, and E. Wallsh, "Subvalvular Stenosis of Aortic Prostheses," *Journal of Thoracic and Cardiovascular Surgery*, 68:17-20, 1974.

9. Ottinger, L. W., R. C. Darling, R. S. Wuithlin, and R. R. Linton, "Failure of Ultralightweight Knitted Dacron Grafts in Arterial Reconstruction," *Archives of Surgery*, 111:146-149, 1976.

10. Lindenauer, S. M., T. R. Weber, T. A. Miller, S. R. Ramsbaugh, C. A. Salles, S. P. Kahn, R. S. Wojtalik, "The Use of Velour as a Vascular Prosthesis," *Biomedical Engineering*, 11(9):301-306, 1976.

11. Deterling, R. A., "Editorial: Failure of Dacron Arterial Prostheses," *Archives of Surgery*, 108:113, 1974.

12. Cooke, P. A., P. A. Nobis, and R. J. Stoney, "Dacron Aortic Graft Failure," *Archives of Surgery*, 108:101-103, 1974.

13. Hayward, R. H. and F. L. Korompai, "Degeneration of Knitted Dacron Grafts," *Surgery*, 79(5):581-583, 1976.

14. Singh, A., E. A. Letsky, and J. Stark, "Hemolysis Following Correction of Double-Outlet Right Ventricle," *Journal of Thoracic and Cardiovascular Surgery*, 71(2):226-229, 1976.

15. O'Connell, T. X., H. J. Fee, and J. Golding, "Sarcoma Associated with Dacron Prosthetic Material," *Journal of Thoracic and Cardiovascular Surgery*, 72(1):94-96, 1976.

16. Thompson, J., T. Kirksen, M. Nube, and A. G. Brom, "Prosthesis Endocarditis," *Journal of Thoracic and Cardiovascular Surgery*, 72(1):28-32, 1976.

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19. Read, R. C., "Uninfected Anastomotic False Aneurysms Following Arterial Reconstruction with Prosthetic Grafts," *Journal of Cardiovascular Surgery*, 16:558-561, 1975.

20. Guidoin, R. G., J. A. Awad, C. Gosselin, C. Rouleau, and G. H. Haggis, "Preclotting and Thrombosis of a Dacron Prosthesis: A Scanning Electron Microscope Study," *Biomaterials, Medical Devices, and Artificial Organs*, 3(3):365-382, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner 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).

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. 79-6181 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1485]

MEDICAL DEVICES

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 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 Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of intracardiac patches and pledgets made of polypropylene, Teflon, and Dacron:

1. Identification: An intracardiac patch or pledget made of polypropylene, Teflon, or Dacron is a fabric device placed in the heart that is used to repair septal defects, to patch grafting, to repair tissue, and to buttress sutures.

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 the device is implanted, the Panel recommends that intracardiac patches and pledgets made of polypropylene, Teflon, or Dacron be classified into class II. 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 properties such as porosity and tensile strength, should be maintianed 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 implanted 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, the device. In addition, the Panel found further support for their recommendation in the medical literature. The following complications associated with this device are cited in the literature reviewed by the Panel: thromboembolism (Refs. 1 through 6); material or mechanical failure (Refs. 4, 5, and 7 through 11); hemolysis (Ref. 12); sarcoma (Ref. 13); and late infection (Ref. 14). Improper healing, including insufficient or excessive tissue ingrowth, is cited as a cause of patch or pledget rejection (Refs. 2, 4, and 6). Tissue reactions, such as inflammation, are common. However, patch or pledget rejection is rare (Ref. 15). Because nylon patches and pledgets caused loss of tensile strength, the use of nylon was abandoned (Refs. 5, 8, and 15). Thrombogenicity of the materials should be reduced to a minimum. However, all artificial materials are associated with some degree of blood incompatibility, and there is no agreement on the most effective means of reducing thrombogenicity. Guidoin (Ref. 16), for example, cites conflicting reports on the thrombogenicity of the Dacron used in different graft pros-

theses. For the materials now in use, it appears that artificial patches and pledgets perform as well as the alternative of autogenous tissue grafts.

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) Tissue and blood damage: If the materials, surface finish, or cleanliness of this 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 intracardiac patches and pledgets 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.

1. Hansen, C. K., O. Kraft, and C. Mouritzen, "Biologic and Semibiologic Vascular Grafts," *Surgery, Gynecology, and Obstetrics*, 138:940-944, 1974.

2. Szilagyi, D. E., R. F. Smith, J. P. Elliot, and H. M. Allen, "Long-Term Behavior of a Dacron Arterial Substitute," *Annals of Surgery*, 162(3):453-477, 1965.

3. Berger, S. and E. W. Salzman, "Thromboembolic Complications of Prosthetic Devices," *Progress in Hemostasis and Thrombosis*, 2:273-309, 1974.

4. Hallin, R. W., "Complications with the Mandril-Grown (Sparks) Dacron Arterial Graft," *American Surgeon*, 41(9):550-554, 1975.

5. Szilagyi, D. E., J. R. Pfeifer, and F. J. DeRusso, "Long-Term Evaluation of Plastic Arterial Substitutes: An Experimental Study," *Surgery*, 55(1):165-183, 1964.

6. Sauvage, L. R., "The Future of Porous-Fabric Arterial Prostheses," *Annals of Thoracic Surgery*, 19:333-335, 1975.

7. Ottinger, L. W., R. C. Darling, R. S. Wuithlin, and R. R. Linton, "Failure of Ultralightweight Knitted Dacron Grafts in Arterial Reconstruction," *Archives of Surgery*, 111:146-149, 1976.

8. Lindenauer, S. M., T. R. Weber, T. A. Miller, S. R. Ramsbaugh, C. A. Salles, S. P. Kahn, and R. S. Wojtalik, "The Use of Velour as a Vascular Prosthesis," *Biomedical Engineering*, 11(9):301-306, 1976.

9. Deterling, R. A., "Editorial: Failure of Dacron Arterial Prostheses," *Archives of Surgery*, 108:13, 1974.

10. Cooke, P. A., P. A. Nobis, and R. J. Stoney, "Dacron Aortic Graft Failure," *Archives of Surgery*, 108:101-103, 1974.

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12. Singh, A., E. A. Letsky, and J. Stark, "Hemolysis Following Correction of Double-Outlet Right Ventricle," *Journal of Thoracic and Cardiovascular Surgery*, 71(2):226-229, 1976.

13. O'Connell, T. X., H. J. Fee, and A. Golding, "Sarcoma Associated with Dacron Prosthetic Material," *Journal of Thoracic and Cardiovascular Surgery*, 72(1):94-96, 1976.

14. Thompson, J., T. Dirksen, M. Nube, and A. G. Brom, "Prosthesis Endocarditis," *Journal of Thoracic and Cardiovascular Surgery*, 72(1):28-32, 1976.

15. Transcript of Proceedings—Food and Drug Administration, Cardiovascular Device Panel Meeting, Washington, DC, Oct. 18, 1976, p. 166.

16. Guidoin, R. G., J. A. Awad, C. Gosselin, C. Rouleau, and G. H. Haggis, "Preclotting and Thrombosis of a Dacron Prosthesis: A Scanning Electron Microscope Study," *Biomaterials, Medical Devices, and Artificial Organs*, 3(3):365-382, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3470 as follows:

§870.3470 Intracardiac patch and pledget made of polypropylene, Teflon, or Dacron.

(a) *Identification.* An intracardiac patch or pledget made of polypropylene, Teflon, or Dacron is a fabric device placed in the heart that is used to repair septal defects, to patch grafting, to repair tissue, and to buttress sutures.

(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. 79-6182 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1487]

MEDICAL DEVICES

Classification of Intra-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, 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, 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 use 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 cleanlinesss can lead to potentially debilitating or fatal thromboemboli. (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) Gas embolism: Balloon rupture or a leak in the balloon can cause potentially debilitating or fatal gas emboli 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 CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the intra-aortic balloon and control system be classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use (maintaining blood circulation during certain types of heart failure) 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 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 § 807.3535 as follows:

§ 870.3535 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, 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. 79-6183 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1488]

MEDICAL DEVICES

Classifaction of Ventricular Bypass (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 (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, 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 electical 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 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, 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 thromboemboli. (b) Excessive hemolysis: Poor design of the hemodynamic charactristics of the device can lead to excess hemolysis. (c) Inability 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 purported or represented to be for a 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 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 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, 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 § 870.3545 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 (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. 79-6184 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1489]

MEDICAL DEVICES

Classification of External 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 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 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. 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 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.

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 external pacemaker pulse generators be classified into class III because the device provides temporary life-support. The Panel believes that premarket approval is necessary to assure its safety and effectiveness. The device is in contact with the patient's heart through a pacemaker electrode catheter. Certain kinds of failure could cause this device to emit inappropriate electrical signals, which could cause cardiac irregularities and death. Failure of the power source, usually a battery, could lead to cardiac standstill or other pacing irregularities. Although the device may be in contact with the patient's skin, the materials that touch the patient are generally acceptable and require no additional controls. Performance characteristics, including accuracy, reproducibility, and any limitations on the rate and level of the output stimuli and the input sensitivity of the device, 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, 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 its life-supporting function.

5. Risks to health: (a) Failure to pace: A failure of the electronic circuitry can cause failure to pace the patient's heart. (b) Improper pacing: Electromagnetic interference with the pacemaker electronics or improper sensing by the pacemaker can lead to improper pacing. (c) Cardiac arrythmias: Pacing during vulnerable periods of the cardiac cycle due to a sensing failure of the pacemaker can induce cardiac arrythmias. (d) Improper pacing rate: An electronic circuit failure or an inaccurate rate controller in the circuit can cause improper pacing rates.

PROPOSED CLASSIFICATION

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 purported or 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 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 § 870.3600 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 stength, 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

single copies of comments, and shall be indentified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

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-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 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, 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 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. It is surgically implanted in patients with heart pacing or conduction defects. The patients may be totally dependent upon this device for their continued survival. The Panel states that, although a proposed standard has been written, it does not cover all the performance characteristics of the device. The Panel noted further that the proposed standard is not widely accepted. The Panel believes that general controls alone would not provide sufficient control over the performance characteristics of the device. In addition, the Panel believes that sufficient scientific and medical data do not exist to establish a complete standard to assure the safety and effectiveness of particular aspects 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, their personal knowledge of and experience with the device, and the life-supporting function of the device.

5. Risks to health: (a) Failure to pace: A failure of the electronic circuitry or early battery depletion can cause failure to pace the patient's heart. (b) Improper pacing cycle: Electromagnetic interference with pacemaker electronics or improper sensing by the pacemaker can lead to improper pacing. (c) Arrhythmias: A sensing failure of the pacemaker during vulnerable periods of the cardiac cycle can induce cardiac arrhythmias. (d) Improper pacing rate: An electronic circuit failure or an inaccurate rate controller in the circuit can cause improper pacing rates. (e) Tissue damage: If the materials, surface finish, or cleanliness of this device are inadequate, damage to the local tissue may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the implantable pacemaker pulse generator 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 § 870.3610 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 continous 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, 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. 79-6186 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1491]

MEDICAL DEVICES

Classification of Pacemaker Lead Adaptors

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 lead adaptors 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, 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, 301-427-7559.

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 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 clasified 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 assembled, used, and maintained. The Panel believes that there are insufficient medical, engineering, and scientific data to establish a 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 mehancial 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 performace 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 (21U.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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs

[FR. Doc. 79-6187 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1492]

MEDICAL DEVICES

Classification of 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 pacemaker generator 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. 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 recommendation with respect to the classification of pacemaker generator function analyzers:

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 arrythias. 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 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 5.1), 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-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. 79-6188 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1493]

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. 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, 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 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 arrythmias. 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 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, which can lead to onset of cardiac arrhythmias. (b) Misdiagnosis: 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), 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 § 870.3640 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 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. 79-6189 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1494]

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.

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 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 that 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 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. In addition, the Panel reviewed the following information from the medical literature. The fabric mesh bag used with a cardiac pacemaker 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 no specific attention in the medical literature. However, both Wesolowski (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 either vascular graft prostheses or artificial heart valves. Lindenauer 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, tracheal tube grafts, artificial tendons, percutaneous A-V shunt seals, and artificial breasts among many other applications. Some other concerns expressed by Skelton (Ref. 5) included specification of polymeric composition and 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), intraocular 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 time, pore size, and percent porosity of the implant was studies and reported by Hulbert et al. (Ref. 8). Brais and Braunwald (Ref. 10) reported on a method for accelerating and controlling and rate of 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 material and the ingrown tissue. Electron microscopic 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 the ingrowth of tissue 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.

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13. Weiss, J. P., F. V. Lorenzo, C. D. Campbell, R. L. Myerowitz, and M. W. Webster, "The Behavior of Infected Arterial Prostheses of Expanded Polytetrafluoroethylene (Gore-Tex)," *Journal of Thoracic and Cardiovascular Surgery*, 73(4):630-636, 1977.

14. Sawatani, S., C. Mandell, I. Kiso, and A. Kantrowitz, "Antologous Arterial Grafts Grown on Polyester Molds: Observations of Graft Growth and Patency in Experimental Animals," *Journal of Cardiovascular Surgery (Torino)*, 18(1):63-70, 1977.

Therefore, under the Federal Food, Drug and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3650 as follows:

§ 870.3650 Pacemaker polymeric mesh bag.

(a) *Identification.* A pacemaker polymeric mesh bag is a device used to hold a pacemaker pulse generator that is designed to create a stable implant environment for the pulse generator.

(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. Recieved 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. 79-6190 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1496]

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 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 Avenue, 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 regarding classification of pacemaker chargers:

1. Identification: A pacemaker charger is a device used transcutaneously to recharge the batteries of a rechargeable pacemaker.

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 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 slowly stops functioning: Failure of the device to recharge the battery or a misindication 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 by the device. (d) Failure of the pacemaker: Overcharging by 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 Commis-

sioner also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectivenes 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, 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. 79-6191 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.

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, Dureau 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 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, including requirements for 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 configuration designed to reduce the current drain per pulse and to avoid electrode 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 corkscrew-mesh and suture types, which are secured by sutures or a combination of electrode screw-in 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 electrodes—platium-iridium and cobalt-nickel (Elgiloy); generator anode—stainless steel titanium; lead wires—stainless steel and 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, 11, and 16), which is sometimes broken 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 the optimum design has not 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. 2) 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 for a lead of more recent 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. 2 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 current output. This condition is caused by the natural development of a nonexcitable, fibrous tissue sheath around the electrode tip. Threshold rise occurs after all electrode implantations and usually levels off after approximately 2 weeks (Ref. 1). 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 6 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 14). 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 8), thrombosis (Refs. 2 and 6), and subepicardial infarction (Ref. 13). Small surface area electrodes used in demand pacing have been found to fail to sense properly and thus cause loss of pacing (Ref. 12). Although these problems are less common, they can cause serious complications. For example, thromboitic developments can easily become emboli 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 endocardial leads used in that study. It has been shown that small surface area electrodes reduce the threshold current, thus reducing current drain and increasing pacer life. However, Hughes, et al. (Ref. 12), have reported that these 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 Panel concluded from the literature that clinical and preclinical studies to establish the safety and effectiveness of electrode lead designs are necessary.

5. Risks to health: (a) Loss of pacing: Poor mechanical and material properties can cause lead breakage. Improper electrical impedance of the lead can cause inadequate sensing or pulse delivery. Either of these conditions leads to loss of pacing of the patient's heart. (b) Thromboembolism: Inadequate blood compatibility of the materials used in this device and inadequate surface finish and cleanliness can lead to potentially debilitating or fatal thromboemboli. (c) Improper pacing: Tissue reactions at the electrode tissue interface can cause a rise in pacing threshold and lead to loss of or improper pacing function by causing "exit block."

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the permanent and temporary pacemaker electrode 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 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 (HFA-305), Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Roy, O. Z. "The Current Status of Cardiac Pacing," *CRC Citical Reviews in Bioengineering*, 2(3):259-327, 1975.

2. Grogler, F. M., G. Frank, G. Greven, D. Dragojevic, H. Oelert, K. Leitz, H. Dalichau, U. Brinke, D. Lohlein, D. Rogge, R. Hetzer, G. Hennersdorf, H. G. Borst, "Complication of Permanent Transvenous Cardiac Pacing," *Journal of Thoracic and Cardiovasular Surgery*, 69(6): 395-404, 1975.

3. Green, G. D., "Hazards of Cardiac Pacing," *Biomedical Engineering*, 10(11):410-13, 1975.

4. Tegtmeyer, C. J., "Complications of Cardiac Pacemakers," *American Family Physician*, 14(1):66-75, 1976.

5. Furman, S., J. Garvey, P. Hurzeler, "Pulse Duration Variation and Electrode Size of Factors in Pacemaker Longevity," *Journal of Thoracic and Cardiovascular Surgery*, 69(3): 382-389, 1975.

6. Chung, E. K., "Artificial Cardiac Pacing," *Postgraduate Medicine*, 60(7):63-67, 1976.

7. Green, G. D., "Pacemaker Leads," *Impulse*, Cardiac Pacemakers, Inc., pp. 1-6 and 13-14, June 1976.

8. Sidd, J. J., L. I. Sellar, P. F. Gryska, A. E. O'Dea, "Thrombus Formation on a Tranvenous Pacemaker Electrode," *New England Journal of Medicine*, 280(16):877-878, 1969.

9. Di Luzio, V., G. Curzi, G. Capestro, A. Boccanelli, R. Renzi, "Electrolytic Phenomena and Massive Gas Generation Around Pacemaker Electrodes," *European Journal of Cardiology*, 3(4):297-305, 1975.

10. Yarnoz, M. D., L. A. Attai, S. Furman, "Infection of Pacemaker Electrode and Removal with Cardiopulmonary Bypass," *Journal of Thoracic and Cardiovascular Surgery*, 69(1):43-46, 1974.

11. Green, G. D., "The Reliability of Pacemaker Electrode-Leads," *Journal of Electrocardiology*, 8(2):195-200, 1975.

12. Huges, H. C., R. R. Brownlee, G. F. O. Tyers, "Failure of Demand Pacing with Small Surface Area Electrodes," *Ciculation*, 54(1):128-132, 1976.

13. Steinke, W. E., F. T. Thomas, Z. Hassan, R. A. Mandeza, A. S. Grea, "Subepicardial Infarction, Myocardial Impression, and Ventricular Penetration by Sutureless Electrode and Leads," *Chest*, 70(1):80-81, 1976.

14. Magilligan, D. J., J. Hakimi, J. C. Davila, "The Sutureless Electrode: Comparison with Transvenous and Sutured Epicardial Electrode Placement for Permanent Pacing," *Annals of Thoracic Surgery*, 22(1):80-86, 1976.

15. Shammash, J. B., Letter: "The Sutureless Electrode," *Annals of Thoraic Surgery*, 22(1):104-105, 1976.

16. Implantable Pacemaker Literature Summaries, Association for the Advancement of Medical Instrumentation, Arlington, Va., FDA Contract No 223-74-5083, January 1975.

17. Pacemaker Standard, Association for the Advancement of Medical Instrumentation, Arlington, Va., FDA Contract No. 223-74-5083, August 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3680 as follows:

§ 870.3680 Permanent and temporary pacemaker electrode.

(a) *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 stimulas from the pulse generator to the heart and/or to transmit the electrical signal of the heart to the 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 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. 79-6192 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 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:

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 test magnets:

1. Identification: A pacemaker test magnet is a device used to test an inhibited or triggered type of pacemaker pulse generator and cause an inhibited or triggered generator to revert to asynchronous operation.

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 the device is life-sustaining under certain circumstances, the Panel recommends that the pacemaker test magnet be classified into class II. During an operation in which a patient's triggered or inhibited pacemaker might receive stray electrical signals from electrosurgical devices, for example, the reversion magnet assumes a life-sustaining role by preventing interference from disrupting the steady output of the pacemaker. The magnetic strength must be adequate to switch reliably an implanted triggered or inhibited pacemaker to asynchronous operation. This is usually done by closing a reed switch within the pacemaker. 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 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 revert to a fixed rate (Refs. 1 and 2) and inducement of ventricular fibrillation (Ref. 3). The latter was probably caused by faulty pacemaker design. The former is of greater concern here because, although it is possible that failure to revert may be due to an insensitive pacemaker, it may be directly attributable to the properties of the magnet itself.

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

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 (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Driller, J., S. S. Barold, and V. Parsonnet, "Normal and Abnormal Function of the Pacemaker Magnetic Reed Switch," *Journal of Electrocardiology*, 9(3):283-292, 1976.

2. Barold, S. S., "Current Problems with Demand Pacemakers," *European Journal of Cardiology*, 1(4):339-345, 1974.

3. Seipel, L., E. Bub, and S. Driwas, "Ventricular Fibrillation During Testing of a Demand Pacemaker," *Deutsch Medizinische Wochenschrift*, 100(47):2437-2442, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart D by adding new § 870.3690 as follows:

§ 870.3690 Pacemaker test magnet.

(a) *Identification.* A pacemaker test magnet is a device used to test an inhibited or triggered type of pacemaker pulse generator and cause 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 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. 79-6193 Filed 3-8-79; 8:45 am]

[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 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. 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 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-

posing 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 which is of 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. 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 § 870.3700 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6194 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1500]

MEDICAL DEVICES

Classification of Pacemaker Repair and Replacement Materials

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 repair and replacement materials 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, 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 pacemaker repair and replacement materials:

1. 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.

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 pacemaker repair and replacement materials be classified into Class III because these materials are implanted in the human body and serve to connect or aid in the connection of the vital link between a pacemaker pulse generator and a pacemaker lead. The connection function of the device is life-supporting because it maintains the conduction of the pacing pulse. 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. 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 inherent properties of the device, the life-supporting function of this implanted device, and their personal knowledge of, and experience with, the device.

5. Risks to health: (a) Tissue damage: If the biocompatibility of the materials used in this device is inadequate, damage to the surrounding tissue may result. (b) Loss of pacing function: Failure to seal the lead properly could allow the intrusion of fluid into the pacemaker connection. This could in turn lead to a loss of pacing function through electrical leakage at the connector or through an interruption of the electrical path from the pulse generator to the lead.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the pacemaker repair and replacement materials 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 § 870.3710 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 29857, 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. 79-6195 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-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 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:

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, 301-427-7559.

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 committe, 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 use. 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 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) 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: 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, can result in 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-

ard 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 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-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. 79-6196 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 regulation 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 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 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). The Panel recommends that there be no exemption.

3. Summary of reasons for recommendation: The Panel recommends that pacemaker service tools be classified into class I because the device is composed of a variety of mechanical tools that are neither life-sustaining nor life-supporting and present no potential hazard to health when properly used. The materials used in the device are generally acceptable and need no special control requirements. The Panel believes that general controls are sufficient to assure the safety and effectiveness of the device.

4. Summary of data on which recommendation is based: the Panel based its recommendation upon the lack of potential hazards associated with the device and on their personal knowledge of, and experience with, the device.

5. Risks to health: None identified.

PROPOSED CLASSIFICATION

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 § 870.3730 as follows:

§ 870.3730 Pacemaker service tools.

(a) *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.

(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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6197 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1503]

MEDICAL DEVICES

Classification of Annuloplasty Rings

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying annuloplasty rings 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, 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 Wefare, 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 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 annuloplasty 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, it 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 this 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) Dilation of the heart eventually leading to intractable heart failure: If 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 CLASSIFICATION

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 § 870.3800 as follows:

§ 870.3800 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 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. 79-6198 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1504]

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 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 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 stimulator typically consists of an implanted stimulator with electrodes 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 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, damage to the blood and tissue may result. (b) Inability to control blood pressure: Failure of the device to stimulate 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 or represented 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 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), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Stephenson, H. E., "Cardiac Arrest and Resuscitation," C. V. Mosley Co., St. Louis, pp. 413-414, 1974.

2. Levy, M. N. and Ziesks, "Factorial Analysis of the Cardiovascular Response to Carotid Sinus Nerve Stimulation," *Annals of Biomedical Engineering*, 4:111-127, 1976.

3. Schwartz, S. I., L. S. C. Griffith, A. Neistadt, and N. Hagfors, "Chronic Carotid Sinus Nerve Stimulation in the Treatment of Essential Hypertension," *American Journal of Surgery*, 114:5-15, 1967.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and 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-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. 79-6199 Filed 3-8-79; 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-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 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 of, 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 surfact finish and cleaniness 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 purported 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 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. Chun, P. K. C. and W. P. Nelson, "Common Cardiac Prosthetic Valves," *Journal of the American Medical Association*, 238(5):401-403, 1977.

2. Cuddihy, E. F., et al., "In Vivo Degradation of Silicone Rubber Poppets in Prosthetic Heart Valves," *Journal of Biomedical Materials Research*, 10:471-481, 1976.

3. Elster, S. K., et al., "Hemophilus Aphrophilus Endocarditis: Review of 23 Cases," *American Journal of Cardiology*, 35:72-79, 1975.

4. Bristion, J. D. and E. L. Kremkaw, "Hemodynamic Changes after Value Replacement with Starr-Edwards Prosthesis," *American Journal of Cardiology*, 35:716-724, 1975.

5. Lee, S. J. K., et al., "Long-Term Survival After Aortic Value Replacement Using Smeloff-Cutter Prosthesis," *Circulation*, 52:1132-1137, 1975.

6. Kloster, F. E., "Diagnosis and Management of Complications of Prosthetic Heart Valves," *American Journal of Cardiology*, 35:875-885, 1975.

7. Roberts, W. C., M. G. Fishbein, and A. Golden, "Cardiac Pathology After Valve Replacement by Disc Prosthesis," *American Journal of Cardiology*, 35:740-760, 1975.

8. Ionescu, M. I., et al., "Long-Term Evaluation of Tissue Valves," *Journal of Thoracic and Cardiovascular Surgery*, 68(3):361-379, 1974.

9. Suwansirikul, S., et al., "Late Thrombosis of Starr-Edwards Tricuspial Ball Valve Prosthesis," *American Journal of Cardiology*, 34:737-740, 1974.

10. Bjork, V. O., A. Henze, and A. Holmgren, "Five Year's Experience with the Bjork-Shiley Tilting Disc Valve in Isolated Aortic Valvular Disease," *Journal of Thoracic and Cardiovascular Surgery*, 68(3):393-404, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 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).

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. 79-6200 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1506]

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 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 Wefare, 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 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.

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. 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: 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 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 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6201 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1507]

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.

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, and FDA advisory committee, made the following recommendation with respect to the classification of prosthetic heart valve sizers:

1. 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.

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 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) Implantation of an inappropriate size valve: The valve sizer should reflect the total diameter of the valve, including the sewing collar and the diameter of the valve orifice, with sufficient dimensional accuracy and tolerance to protect against implantation of an improperly sized valve.

PROPOSED CLASSIFICATION

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, 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 § 870.3945 as follows:

§ 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 Land, 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. 79-6202 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1508]

MEDICAL DEVICES

Classification of Endomyocardial Biopsy 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 endomyocardial biopsy devices 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:

PANEL RECOMMENDATION

A proposal elsewhere is 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 endomyocardial biopsy devices:

1. Identification: An endomyocardial biopsy device is a device used to

remove samples of tissue from the inner wall 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 recommendaton: 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. Performance characteristics, including any limitations on the device's ability to safely obtain a biopsy specimen, 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. 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 Konno 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 bioptome (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 biopsy device does not appear to be questioned (Refs. 1 through 10). The most serious hazards associated with the use of this biopsy device are perforation into 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 user-related and occur most frequently when the bioptome is advanced to the endomyocardial wall with its jaws closed. This configuration apparently renders the shape of the bioptome "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 bioptome with its jaws open. Other hazards associated with the use of this device are embolization and transient chest pain (Refs. 4, 5, and 7). The incidence of embolization is apparently lower in patients who are receiving anticoagulant drugs (Refs. 5 and 7). Patients can experience chest pain either during or after endomyocardial biopsy (Ref. 7). The most frequently occurring hazard reported in the literature is ectopy (a heartbeat originating from a location in the heart other than the normal originating location) (Refs. 1 through 8). Preventricular contractions (PVC's) occur when the forceps engage the myocardial wall. The PVC's are usually isolated, but runs of PVC's and even sustained ventricular tachycardias (extremely rapid heart rates) requiring cardioversion (electrical shock used to return the heart to its normal rhythm) have been reported (Refs. 7 and 8). Temporary right bundle branch block of 5 minutes duration has been reported in dogs (Ref. 8). It appears that biopsy of the right ventricle is associated with more complications and a higher failure rate than is biopsy of the left ventricle (Ref. 7). Although hazards associated with use of this device are numerous and can be serious or even fatal, they do not appear to be frequent. One study of 164 patients (more than 1,000 biopsy procedures) revealed a low 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 thromboemboli. (b) Embolism: Improper mechanical design can cause premature release of a biopsy specimen that then 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 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.

1. Sakakibara, S. and S. Konno, "Endomyocardial Biopsy," *Japanese Heart Journal* 3(6):537-543, November 1962.

2. Ali, N., "Transvenous Endomyocardial Biopsy Using the Gastrointestinal Biopsy (Olympus GFB) Catheter," *American Heart Journal* 87(3):194-197, March 1974.

3. Caves, P. K. and W. P. Schulz, et al., "New Instrument For Transvenous Cardiac Biopsy," *American Journal of Cardiology*, 33:264-267, February 1974.

4. Richarson, P. J., "King's Endomyocardial Bioptome," *Lancet*, 660-661, April 1974.

5. Dawai, C. and Y. Kitaura, "New Endomyocardial Biopsy Catheter for the Left Ventricle," *American Journal of Cardiology*, 40:63-65, July 1977.

6. Blaufuss, A. and D. Garner, et al., "Technique for Serial Right and Left Ventricular Endomyocardial Biopsy in Dogs" *Journal of Applied Physiology*, 40(5):832-835, May 1976.

7. Brooksy, I. A. and B. S. Jenkins, et al., "Left Ventricular Endomyocardial Biopsy. I: Description and Evaluation of the Technique," *Catheterization and Cardiovascular Diagnosis* 3(2):115-121, 1977.

8. Hirota, Y. L., F. Khaja, and W. H. Abelmann, "Effectiveness and Hazard of Endomyocardial Biopsy in Dogs: Comparison of Two Methods," *American Heart Journal*, (92)6:767-772, Dec. 1976.

9. Copeland, J. G. and E. B. Stinson, et al., "Cardiac Transplantation at Stanford," *Acta Chirurgica Belgium* 76(3):387-392, May-June 1977.

10. Mackay, E. H., D. Pickering, and W. A. Littler, "Cardiac Biopsy in Childhood," *Archives of Disease in Children*, 52(10):785-789, October 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513,

701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 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 to the Hearing Clerk (HFC-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. 79-6249 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 Admendments 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 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 bypas 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-supporting 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 characteristcs 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, 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 § 870.4200 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 (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. 79-6250 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1378]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Bubble Detectors

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 bubble detectors 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.

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 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 inadequate for accurate and precise detection of gaseous 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 ultrasound 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 of, 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 can 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6248 Filed 3-8-79; 8:45 am]

[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). The FDA is also publishing the recommendation of the Cardiovascular Device Classification Panel that the devices be classified 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, 1977. 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 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 are potentially hazardous to life or 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 tissue and blood compatibility, including requirements for adequate surface finish and cleanliness, which may affect the degree of compatibility. The devices should be mechanically designed to minimize blood trauma and to prevent leakage. 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 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 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. 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 § 870.4210 as follows:

§ 870.4210 Cardiopulmonary bypass vascular catheters, cannulas, and tubing.

(a) *Identification.* Cardiopulmonary bypass 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, 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. 79-6251 Filed 3-8-79; 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-

fied 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 20587.

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 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 this 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 reasonable assurance of the safety and effectiveness of the device and that there is sufficient informaton 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 distrub 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 interface 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 6252 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1512]

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 classsifying the device. These actions are being taken under the Medical Device Admendments 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 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 defoamers:

1. Identification: A cardiopulmonary bypass defoamer is a device used in conjunction with an oxygenator during cardivascular bypass surgery to remove gas bubbles from the blood.

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 cardiopulmonary bypass defoamer be classified into class III because, although this device is neither life-supporting nor life-sustaining, it presents a potential unreasonable risk of illness or injury. Failure of the device to adequately remove gas bubbles from the blood in the extracorporal circuit can lead to substantial hazards to the patient's life or 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. The materials used in the device should demonstrate minimal tendency to embolize and adequate ability to remove bubbles. 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 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 of, and experience with, 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) 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 classified into class III (premarket approval). The Commissioner believes the device is purported or represented to be for a use in removing gas bubbles from the blood in the cardiopulmanary 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. 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 § 870.4230 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.

Dated: February 26, 1979.

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. 78N-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:

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 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 heat exchanger 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 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, e.g., electrical 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 blood. 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 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 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 or surgical procedure, and this may lead to iatrogenic 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 thromboemboli. (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 properities 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. 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 § 870.4240 as follows:

§ 870.4240 Cardiopulmonary bypass heat exchanger.

(a) *Identification.* A cardiopulmonary bypass heat exchanger in 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. 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. 79-6254 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1514]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Temperature Controllers

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 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. 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 de-

velopment 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 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) Blood damage or thermal complications: Inaccuracy or instability of temperature control can lead to blood damage or thermal complications.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass temperature controller 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 § 870.4250 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 (performamce 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. 79-6255 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1515]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Arterial Line Blood 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 bypass arterial line blood filters 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: Comment 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 arterial line blood filters:

1. 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 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 premarket approval for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass arterial line blood filter be classified into 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. 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 there is insufficient medical and scientific data on which to base a performance standard for this device. The Panel also believes that the test methodology for establishing satisfactory performance levels is not available. In addition, it has not been clearly established that adverse physiological effects follow when this device is absent from the circuit. Because insufficient information exists to establish a performance standard to provide reasonable assurance of the device's safety and effectiveness, the Panel believes that this device requires 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 inderent properties of the device and on their personal knowledge of, and experience with, the device. In addition, the Panel reviewed the relevant medical literature. References were supplied to the Panel by Panel member Dr. Richard E. Clark, FDA, and Pall Biomedical Products Corp. The summaries from FDA and Pall Biomedical are attached as addenda to the April 4, 1977, minutes of the Cardiovascular Device Classification Panel meeting. Dr. Clark's memorandum is an addendum to the May 2, 1977, minutes of the Cardiovascular Device Classification Panel meeting. Dr. Clark's report (Ref. 1) states that arterial line filters require more complex testing and safety considerations than other blood filters because of their use in a perfusion line which is life-supporting.

Three general problems arise with the use of arterial line filters: excessive pressure gradient or inadequate flow, thromboembolic complications, and embolic complications. Excessive pressure gradients or inadequate flow are caused by blockage of the filter during use. This problem has been handled clinically in two ways: (1) two parallel filters operate simultaneously, alternately, or alternately only when transfilter pressure differences become large; (2) one filter is used with a bypass line. It is important that the capacity of arterial line filters be sufficient to provide adequate blood flow throughout the course of cardiopulmonary bypass surgery. Depth filters may start to channel after 30 to 40 percent of the void spaces are filled, thus lowering efficiency and providing a possible escape for larger micro particles (Ref. 1).

Thromboembolic complications are not well documented in the literature. Blood filters cause a reduction in platelet count, but investigations have shown that the platelets retained by a filter are usually nonfunctioning (Ref. 2). Because of this fact, the impairment of platelet function is not nearly as great as the decrease in the number of platelets would appear to suggest.

The third problem with arterial line filters is embolic complications. Small microemboli have been confirmed 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 gaseous microemboli. Although oxygen and carbon dioxide are the two gases used during extracorporeal circulation, the untoward effects of small (less than 20 to 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 nonprotein 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 (Ref. 8). 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 that 4 hours) on dogs weighing 20 to 30 kilograms (Ref. 9). However, Heimbecker's studies (Ref. 8) indicate that line filters experiencing blood flows of 3 to 5 liters per minute that are not designed for such flows may actually generate fibrin 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 and inadequate surface finish and cleanliness may lead to potentially debilitating or fatal 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 embolic complications. (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 for 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.

2. Lindsay, R., C. Forbes, C. Thompson, and C. Prentice, "The Effect of Blood Filtration on Platelets," *British Journal of Haematology*, 28(1):146, 1974.

3. Barrett, J., E. Miller, and M. Litwin, "Filtration Characteristics of Polyester Mesh (Pall) Micropore Blood Transfusion Filter," *Surgery*, 111(1):56-59, 1976.

4. Barrett, J., H. Dhurandhar, E. Miller, and M. Litwin, "Comparison in Vivo of Dacron Woll (Seank) and Polyester Mesh (Pall) Micropore Blood Transfusion Filters in the Prevention of Pulmonary Microembolism Associated with Massive Transfusion," *Annals of Surgery*, 182(6):690-695, 1975.

5. Connell, R. and M. Webb, "Filtration Characteristics of Three New In-Line Blood Transfusion Filters," *Annals of Surgery*, 181(3):273-278, 1975.

6. Cullen, D. and L. Ferrara, "Comparative Evaluation of Blood Filters: A Study in Vitro," *Anesthesiology*, 41:568, 1974.

7. Mason, K., L. Hall, R. Lamoy, and C. Wright, "Evaluation of Blood Filters: Dynamics of Platelets and Platelet Aggregates," *Surgery*, 77(2):235-240, 1975.

8. Heimbecker, R., C. Robert, and F. McKenzie, "The Extracorporeal Pump Filter—Saint or Sinner?", *Annals of Thoracic Surgery*, 21:55, 1976.

9. Guidoin, R., Y. Laperche, J. Awad, and J. Winchester, "Disposable Filters for Microaggregate Removal from Extracorporeal Circulation," *Journal of Thoracic and Cardiovascular Surgery*, 71:502, 1976.

10. Carlson, R. G., "Lande-Edwards Membrane Oxygenator For Heart Surgery and Prolonged Lung or Heart Support," *New York State Journal of Medicine*, 2353, 1973.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4260 as follows:

§ 870.4260 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 circulation by blocking a vessel) out of the blood. It is used in the arterial return line.

(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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6256 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1516]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Cardiotomy Suction Line Blood 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 bypass cardiotomy suction in line blood 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 classsifying 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 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 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 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 foreign 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

device. In addition, the Panel found further evidence for their recommendation in the medical literature. Literature was supplied to the Panel by Panel member Dr. Richard E. Clark, FDA, and Pall Biomedical Products Corp. The statements submitted by FDA and Pall Biomedical are attached as addenda to the April 4, 1977 minutes of the Cardiovascular Device Classification Panel meeting. Dr. Clark's review is provided as an addendum to the May 2, 1977 minutes of the Cardiovascular Device Classification Panel meeting. The literature on cardiotomy line filters indicates that 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 pressure gradients, 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 emobli (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), convulsive episodes (Ref. 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 an 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 inadequate surface finish and cleanliness can lead to potentially debilitating or fatal thromboemboli. (b) Particle embolism: Inability of the device of filter properly particles from the blood can lead to potentially debilitating or fatal emboli.

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 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.

1. Clark, R. E., and H. W. Margraf, "Fat and Solid Filtration in Clinical Perfusions," *Surgery*, 77:216-224, 1975.

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.

3. Oman-McDanal, J. T., G. T. Smith, G. T. Suehiro, S. Sims, and J. J. McNamara, "Oxygen Consumption Changes with Stored Blood Infusions," *Annals of Surgery*, 182:104, 1975.

4. Guidoin, R., Y. Laperche, L. Martin, and J. Awad, "Disposable Filters for Microaggregate Removal From Extracorporeal Circulation," *Journal of Thoracic and Cardiovascular Surgery*, 71:504, 1976.

5. Cullen, D. J., and L. Ferrara, "Comparative Evaluation of Blood Filters: A Study In Vitro," *Anesthosiology*, 41:568, 1974.

6. Reul, G. J., S. D. Greenberg, E. A. Lefrak, W. B. McCollum, A. C. Beall, and G. L. Jordon, "Prevention of Post-Traumatic Insufficiency Fine Screen Filtration of Blood," *Archives of Surgery*, 106:386, 1973.

7. Williams, I. M., N. C. R. Merrillees, and P. M. Robinson, "Microembolism and the Visual System. Part II: The Consequence of Emboli in the Microcirculation of Nervous Tissue, Especially That Comprosing the Visual System," *Proceedings of the Australian Association of Neurologists*, 12:179, 1975.

8. Kilman, J. W., T. E. Williams, G. S. Kakos, J. Graenen, and D. M. Hosier, "Surgical Correction of the Transposition Complex in Infancy," *Journal of Thoracic and Cardiovascular Surgery*, 66:387, 1973.

9. Aberg, T., "Effect of Open Heart Surgery on Intellectual Function," *Scandinavian Journal and Cardiovascular Surgery*, Supp. 15, 1974.

10. Barrett, J., E. Miller, and M. Litwin, "Filtration Characteristics of Polyester Mesh (Pall) Micropore Blood Transfusion Filter," *Archives of Surgery*, 111(1):56-59, 1976.

11. Barrett, J., H. Dhurandhar, E. Miller, and M. Litwin, "Comparision in Vivo of Dacron Wool (Swank) and Polyester Mesh (Pall) Micropore Blood Transfusion Filters in the Prevention of Pulmonary Microembolism Associated with Massive Transfusion," *Annals of Surgery*, 182(6):690-695, 1975.

12. Connell, R., and M. Webb, "Filtration Characteristics of Three New In-Line Blood Transfusion Filters," *Annals of Surgery*, 181(3):273-278, 1975.

13. Gervin, A., K. Mason, and C. Wright, "The Filtration Limitations of Ultrapore Filters," *Surgery*, 7(92):186-193, 1975.

14. "Blood Transfusion Micro-filter Standard,"Association for the Advancement of Medical Instrumentation, Arlington, Va., 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4270 as follows:

§ 870.4270 Cardiopulmonary bypass cardiotomy 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).

Intersted 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. 79-6257 Filed 3-8-79; 8:45 am]

[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 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 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, reproducibility, 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 by 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 § 870.4280 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6258 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1518]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Adaptors, Stopcocks, manifolds, and fittings

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 adaptors, stopcocks, manifolds, and fittings 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.

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 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 life or 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 thromboemboli. (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 CLASSIFICATION

The commissioner agrees with the Panel's recommendation and is proposing 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. 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 § 870.4290 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, 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. 79-6259 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.

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 recommendation with respect to the classification

of cardiopulmonary bypass gas control units:

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 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: 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 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 § 870.4300 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. 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. 79-6260 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1520]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Coronary Pressure Gauges

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 coronary pressure gauges 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:

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 coronary pressure gauges:

1. 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.

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 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 perfusion line, should be maintained at a generally accepted satisfactory level and should be made known to the user through special labeling. This device is attached to the body through the extracorporeal blood 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. 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) 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 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 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 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.

Dated: February 26, 1979.

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-1521]

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 proposed 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.

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 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 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

with the inherent properties of the device and on their personal knowledge of, and experience with, the device. The Panel 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 physican during a catheterization or surgical procedure, and this may lead to iatrogenic complications. (b) Blood damage: If the materials, surface finish, cleanliness, or mechancial 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 improper mechanical design may lead to potentially debilitating or fatal thromboemboli. (d) Gas embolism: Rupture of the pumping bladder or a leak in the pumping chamber 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 pulsatile flow generator be classified into class III (premarket approval). After reviewing the literature, FDA has found that pulsatile flow in oxygenator circuits is a major topic of debate. The hazards of pulseless flow of a rate less than 100 milliliters per kilogram per minute have been listed as metabolic acidosis, weight gain, edema, visceral pooling, capillary stasis, opening of the arterial 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 renin 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, pulsatile 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 a use in establishment of pulsatile 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.

1. Nose, Y., "The Oxygenator," *in* "Manual and Artificial Organs," Vol. 2., C. V. Mosby, St Louis, pp. 167-175, 1973.

2. Bartlett, R. H. and B. E. Harken, "Instrumentation for Cardiopulmonary Bypass: Present and Future," *Medical Instrumentation*, 10(2):119-124, 1976.

3. Many, M. et al., "Effects of Depulsation of Renal Blood Flow Upon Renal Function and Renin Secretion," *Surgery*, 66(1):242-249, 1969.

4. Kusserow, D.,K., R. W. Laro, and J. E. Nickels, "Decreased Reticuloendothelial Phagocytic Function Following Prolonged IN VIVO Blood Pumping—Preliminary Observations," *in* "Transactions of the American Society for Artificial Internal Organs," 21:388-393, 1975.

5. Bartlett, R. H., "Mechancial Cardiopulmonary Substitution During Open-Heart Surgery," *Cardiovascular Clinics*, 3(3):134-152, 1971.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat, 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposed to amend Part 870 in Subpart E by adding new § 870.4320 as follows:

§ 870.4320 Cardiopulmonary bypass pulsatile flow generator.

(a) *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.

(b) *Classification.* Class III (premerket 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 bracket 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. 79-6263 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-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 for 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 classsifying the device. These actions are being taken under the Medical Device Admendments 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 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 clasification: 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, need to meet certain requirements. Performance characteristics, including accuracy, reproducibility, and any limitations on the device's measurement of blood gas levels, 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) 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 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, 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 § 870.4330 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, 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. 79-6264 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 regulation classifying cardiopulmonary bypass level sensing monitors 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 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, 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

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 to the cardiopulmonary bypass circuit through a transducer and is used in a clinical environmemt 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 resevoir 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6265 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. 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 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 premarket 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 believe that general controls alone

would not provide sufficient control over the performance characteristics of this device. The Panel members also believes 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 thromboemboli. (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 the device is purported or represented to be for a use (providing oxygen and carbon dioxide transfer for the blood during cardiopulmonary bypass operations) 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.

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 § 870.4350 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, 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
Regulatory Affairs.

[FR Doc. 79-6266 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1525]

MEDICAL DEVICES

Classification of Nonroller-Type Cardiopulmonary Bypass Blood Pumps

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nonroller-type cardiopulmonary bypass blood pumps 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 classsifying 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 recommendation 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 cardiopulmonary bypass blood pump be classified into class III because this device is life supporting and life 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 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.

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 categories: pulsatile flow 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 a 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, splanchnic 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 renin production has also been shown to occur with pulseless flow (Refs. 2 and 5), and Kusserow 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 cannula, 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 nonroller-type cardiopulmonary bypass blood 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. Electric 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, or cleanliness of this device 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 characteristics of the device 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 purported 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 effectivness 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.

1. Nosé, Y., "The Oxygenator," *in* "Manual on Artificial Organs," Vol. 2, C. V. Mosby Co., St. Louis, pp. 167-175, 1973.

2. Bartlett, R. H. and D. E. Harken, "Instrumentation for Cardiopulmonary Bypass—Past, Present and Future," *Medical Instrumentation*, 10(2):119-124, 1976.

3. Bartlett, R. H., "Mechanical Cardiopulmonary Substitution During Open Heart Surger," *Cardiovascular Clinics*, 3(3):134-152, 1971.

4. Bernstein, E. F. and L. R. Gleason, "Factors Influencing Hemolysis with Roller Pumps," *Surgery*, 61(1):432-442, 1967.

5. Many, M., F. Giron, W. C. Birtwell, R. A. Deterling, and H. S. Saroff, "Effects of Depulsation of Renal Blood Flow Upon Renal Function and Renin Secretion," *Surgery*, 6(1)A242-249, 1969.

6. Kusserow, B. K., R. W. Larrow, and J. E. Nichols, "Decreased Reticuloendothelial Phagocytic Function Following Prolonged IN VIVO Blood Pumping—Preliminary Observations," *Transactions of the American Society for Artificial Internal Organs*, 21:388-393, 1975.

7. Jacobs, L. A., W. Seamone, and V. L. Gott, "Improved Organ Function During Cardiac Bypass with a Roller Pump Modified to Deliver Pulsatile Flow," *Journal of Thoracic and Cardiovascular Surgery*, 58(5):704-712, 1969.

8. Dalton, M. L., R. T. McCarty, K. E. Woodward, and T. G. Barila, "The Army Artificial Heart Pump. II. Comparison of Pulsatile and Nonpulsatile Flow," *Surgery*, 58(5):840-845, 1965.

9. Trinkle, J. K., N. E. Helton, R. E. Wood, and L. R. Bryant, "Metabolic Comparison of a New Pulsatile Pump and a Roller Pump for Cardiopulmonary Bypass," *Journal of Thoracic and Cardiovascular Surgery, 58(4):562-569, 1969.*

10. Sallam, I. A., A. Shaw, and W. H. Bain, "Experience in the Development of Low Haemolysis Pumps," *Physics in Medicine and Biology*, 21(2):272-279, 1976.

11. Sanderson, J. M., P. G. Morton, T. S. Tolloczki, T. Vennart, and G. Wright, "The Morton-Keele Pump—A Hydraulically Activated Pulsatile Pump for Use in Extracorporeal Circulation," *Medical and Biological Engineering*, 11(2):182-190, 1973.

12. Balakrishnan, S. and D. Sridhar, "Development of a Pulsatile Blood Pump," *Biomaterials, Medical Devices, Artificial Organs*, 4(3-4):323-332, 1976.

13. Ashmore, P. G., V. Svitek, and P. Ambrose, "The Incidence and Effects of Particulate Aggregation and Microembolism in Pump-Oxygenator Systems," *Journal of Thoracic and Cardiovascular Surgery*, 55(5):691-697, 1968.

14. Kessler, J. and R. H. Patterson, "The Production of Microemboli by Various Blood Oxygenators," *Annals of Thoracic Surgery*, 9(3):221-228, 1970.

15. Patterson, R. H. and J. Kessler, "Microemboli during Cardiopulmonary Bypass Detected by Ultrasound," *Surgery, Gynecology and Obstetrics*, 129:505-510, 1969.

16. Simmons, E., E. Litchi, S. Dwyer, B. Rowley, R. Young, J. Mackenzie, and C. H. Almond, "Detection of Microparticles During Cardiopulmonary Bypass by Use of Electronic Devices," *in* "Mechanical Devices for Cardiopulmonary Assistance," *Advances in Cardiology*, 6:94-110, 1971.

17. "Safety and Efficacy of Blood Oxygenators," FDA contract No. 223-74-5253, Utah Biomedical Test Laboratory, Final report, May 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 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

blood through the cardiopulmonary bypass circuit during bypass surgery.

(b) *Classification.* Class III (premarket approval).

Interested pesons may, on or before May 3, 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. 79-6267 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1526]

MEDICAL DEVICES

Classification of Roller-Type Cardiopulmonary Bypass Blood Pumps

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying roller-type cardiopulmonary bypass blood pumps 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-350), 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, 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 and on their personal 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 types of blood pumps available. These can be divided into two categories, namely, pulsatile flow pumps and nonpulsatile flow pumps. The roller pump is an example of a nonpulsatile type of pump. It is the most commonly used pump for 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 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 particulates, including 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 pulseless flow can be controlled and that, because of pulsatile flow through narrow cannula, blood velocity increases causing increased hemolysis and a greater chance of rupture of leaks. Therefore, Bartlett believes a roller pump to be the preferable 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 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 hemolysis 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 60-centimeter column 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 safety and 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 roller 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-

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) Blood damage or damage to bypass circuit tubing resulting in embolic complications: Inadequate mechanical design of the pump can cause excessive compression of the tubing and blood, leading to the formation of blood clots and the splintering of particles from the tubing, thus forming potentially debilitating of fatal emboli. (c) Variability in stroke volume: Inadequate mechanical design of the pump head and torque developed in the pump head are characteristics of the device that can cause a variability in stroke volume, thereby reducing the physican's control over the flow rate in the bypass circuit.

Proposed Classification

The Commissioner agrees with the Panel's recommendation and is proposing that the roller-type cardiopulmonary bypass blood pump 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.

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. Nosé, Y., "The Oxygenator," *in* "Manual on Artificial Organs," Vol. 2, C. V. Mosby Co., St. Louis, pp. 167-175, 1973.

2. Bartlett, R. H. and D. E. Harken, "Instrumentation for Cardiopulmonary Bypass—Past, Present, and Future," *Medical Instrumentation*, 10(2):119-124, 1976.

3. Bartlett, R. H., "Mechanical Cardiopulmonary Substitution During Open Heart Surgery," *Cardiovascular Clinics*, 3(3):134-152, 1971.

4. Bernstein, E. F. and L. R. Gleason, "Factors Influencing Hemolysis with Roller Pumps," *Surgery*, 61(3):432-442, 1967.

5. Many, M., F. Giron, W. C. Birtwell, R. A. Deterling, and H. S. Saroff, "Effects of Depulsation of Renal Blood Flow Upon Renal Function and Renin Secretion," *Surgery*, 66(1):242-249, 1969.

6. Kusserow, B. K., R. W. Larrow, and J. E. Nichols, "Decreased Reticuloendothelial Phagocytic Function Following Prolonged IN VIVO Blood Pumping—Preliminary Observations," *Transactions of the American Society for Artificial Internal Organs*, 21:388-193, 1975.

7. Jacobs, L. A., W. Seamone, and V. L. Gott, "Improved Organ Function During Cardiac Bypass with a Roller Pump Modified to Deliver Pulsatile Flow," *Journal of Thoracic and Cardiovascular Surgery*, 58(5):704-712, 1969.

8. Dalton, M. L., R. T. McCarty, K. E. Woodward, and T. G. Barila, "The Army Artificial Heart Pump. II. Comparison of Pulsatile and Nonpulsatile Flow," *Surgery*, 58(5):840-845, 1965.

9. Trinkle, J. K., N. E. Helton, R. E. Wood, and L. R. Bryant, "Metabolic Comparison of a New Pulsatile Pump and a Roller Pump for Cardiopulmonary Bypass," *Journal of Thoracic and Cardiovascular Surgery*, 58(4):562-569, 1969.

10. Sallam, I. A., A. Shaw, and W. H. Bain, "Experience in the Development of Low Haemolysis Pumps," *Physicis in Medicine and Biology*, 21(2):272-279, 1976.

11. Sanderson, J. M., P. G. Morton, T. S. Tolloczki, T. Vennart, and G. Wright, "The Morton-Keele Pump—A Hydraulically Activated Pulsatile Pump for Use in Extracorporeal Circulation," *Medical and Biological Engineering*, 11(2):182-190, 1973.

12. Balakrishnan, S. and D. Sridhar, "Development of a Pulsatile Blood Pump," *Biomaterials, Medical Devices, Artificial Organs*, 4(3):323-332, 1976.

13. Ashmore, P. G., V. Svitek, and P. Ambrose, "The Incidence and Effects of Particulate Aggregation and Microembolism in Pump-Oxygenator Systems," *Journal of Thoracic and Cardiovascular Surgery*, 55(5):691-697, 1968.

14. Kessler, J. and R. H. Patterson, "The Production of Microemboli by Various Blood Oxygenators," *Annals of Thoracic Surgery*, 9(3):221-228, 1970.

15. Patterson, R. H. and J. Kessler, "Microemboli During Cardiopulmonary Bypass Detected by Ultrasound," *Surgery, Gynecology and Obstetrics*, 129:505-510, 1969.

16. Simmons, E., E. Litchi, S. Dwyer, B. Rowley, R. Young, J. Mackenzie, and C. H. Almond, "Detection of Microparticles During Cardiopulmonary Bypass by Use of Electronic Devices, *in:* Mechnical Devices for Cardiopulmonary Assistance," *Advances in Cardiology*, 6:94-110, 1971.

17. "Safety and Efficacy of Blood Oxygenators," FDA contract No. 223-74-5253, Utah Biomedical Test Laboratory, Final Report, May 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 870 in Subpart E by adding new § 870.4370 as follows:

§ 870.4370 Roller-type cardiopulmonary bypass blood pump.

(a) *Identification.* A roller-type cadiopulmonary bypass blood pump is a device that 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-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 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6268 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1527]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Pump Speed 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 pump speed 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 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, and FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary bypass pump speed controls:

1. Identification: A cardiopulmonary pump speed control is a device that incorporates 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 performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the cardiopulmonary bypass pump speed control by 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 cardiopulmonary 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 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) Inadequate or excessive flow: Inaccuracy or instability of the control system can lead to improper flow rates.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the cardiopulmonary bypass pump speed 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 § 870.4380 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 cardiopulmonary bypass surgery.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before May 8, 1978 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6269 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1528]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Pump 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 pump tubing 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 proposed become effective 30 days after the date of its publication in the FEDERAL REGISTER.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

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 pump tubing:

1. 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.

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 electicity 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 form potentially debilitating or fatal emboli.

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, 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 § 870.4390 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6270 Filed 3-8-79; 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, 301-427-7559.

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 blood reservoirs:

1. 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 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 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 defoamer or filter, it is classified into the same category as the defoamer 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6271 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1530]

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 sensors 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:

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 to minimize 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 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 sense gas levels, 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) Misdiagnosis: 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, 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 § 870.4410 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).

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. 79-6272 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1531]

MEDICAL DEVICES

Classification of Cardiopulmonary Bypass Cardiotomy 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 cardiotomy 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:

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 cardiotomy return suckers:

1. 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.

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 cardiotomy 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 cardiotomy 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, 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 § 870.4420 as follows:

§ 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 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. 79-6273 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.

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 COMMENT 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 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 be a serious hazard. Thus the electrical characteristics of the 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 the amount of vacuum 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 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) Blood and tissue damage: If the device produces excessive or unstable vacuum pressure, damage to the blood and tissue may result. (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 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 E 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

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. 79-6274 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1533]

MEDICAL DEVICES

Classification of Vascular Clamps

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying vascular clamps 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 Springs, 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 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 recommends 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6275 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1534]

MEDICAL DEVICES

Classification of Surgical Vessel Dilators

AGENCY: Food and Drug Administration

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying surgical vessel dilators 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:

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 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, 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 § 870.4475 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 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. 79-6276 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.

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 surgical instruments:

1. 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.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that cardiovascular surgical instruments be classified into class II because the devices are neither life-supporting nor life-sustaining but are potentially hazardous to life and health even when properly used. Because these devices are used in cardiovascular surgery and are in direct contact with body tissues, the 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 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: Tissue damage: If the materials, surface finish, or cleanliness of these devices are inadequate, damage to body tissues may result.

PROPOSED CLASSIFICATION

The Commissioner agrees with the Panel 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 devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 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 (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. 79-6278 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 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 Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of intraluminal artery strippers:

1. Identification: An intraluminal artery stripper is a device used to perform an endarterectomy (removal of plaque deposits from arterosclerotic arteries).

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 intraluminal artery 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. 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 the intraluminal artery 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 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 § 870.4875 as follows:

§ 870.4875 Intraluminal artery stripper.

(a) *Identification.* An intraluminal artery stripper is a device used to per-

form an endarterectomy (removal of plaque deposits from arterosclerotic 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.

Dated: February 26, 1979.

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 (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 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. 540-546 (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 § 870.4885 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 (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. 79-6279 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 (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 Cardiovaseular Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of patient care suction appratus:

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. 360c, 371(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 (performamce 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. 79-6280 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: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation 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, and FDA advisory committee, made the following recommendation with respect to the classification of embolectomy catheters:

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 tree 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 even 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, which may affect 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 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 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 (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 § 870.5150 as follows:

§ 870.5150 Embolectomy catheter.

(a) *Identification.* An embolectomy catheter is a ballon-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, 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. 79-6281 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 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 classsifying 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 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 blood stream 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 compatability 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.

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 stand 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 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regualtory Affairs.

[FR Doc. 79-6282 Filed 3-8-79; 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 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, 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, 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 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. This device has the advantage of efficiency and consistency (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 operator to perform 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 cardiopulmonary resuscitation (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 (Ref. 4). Several other hazards are associated with the use of the device. The device can cause fractures of the ribs and sternum (Refs. 5, 6, and 8), and heart (Refs. 5 through 8); damage to the liver (Refs. 5, 6, 8, and 9), lungs (Refs. 5 and 8); and possible bone marrow emboli (Ref. 8). However, these injures 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 purported 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 (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "External Cardiac Compressors," *Health Devices*, 2(6):136-150, 1973.

2. Boaz, R. R., and J. C. Findeiss, "Heart-Lung Resuscitators" *in* "Emergency Management of the Critical Patient," Edited by J. C. Findeiss, Stratton, New York, pp. 267-268, 1975.

3. Little, K., J. M. Auchincloss, and C. S. Reaves, "A Mechanical Cardiopulmonary Lifesupport System," *Resuscitation*, 3:63-68, 1974.

4. Allen, J. R., "The Use of the Life Aid Cardiopulmonary Resuscitator—Preliminary Report," *British Journal of Clinical Practice*, 28(8):286-288, 1974.

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6. Nachlas, M. M. and M. P. Siedband, "Clinical Experiences with Mechanized Cardiac Massage," *American Journal of Cardiology*, 15(3):310-319, 1965.

7. Murtomaa, M. and K. Korttila, "Experience of Cardiopulmonary Resuscitation Outside Hospital by a Mobile Intensive Care Unit," *Resuscitation*, 3:211-214, 1974.

8. Tambascia, J. J., "Mechanical External Cardiopulmonary Resuscitation," *Journal of the Medical Society of New Jersey*, 62(11):507-509, 1965.

9. Nachlas, M. M., D. I. Miller, and M. P. Siedband, "Determination of Cardiorespiratory Variables in Experimental Cardiac Resuscitation Using a Mechanized Pump for External Cardiac Massage," *Annals of Surgery*, 158(2):295-307, 1963.

10. Pearson, J. W., R. N. Navarro, and J. S. Redding, "Evaluation of Mechanical Devices of Closed-Chest Cardiac Massage," *Anesthesia and Analgesia*, 45(5):590-598, 1966.

11. Jude, J. R., "Current Standards in Cardiopulmonary Resuscitation," *in* "Emergency Management of the Critical Patient," Edited by J. C. Findeiss, Stratton, New York, pp. 19-25, 1975.

12. Nachlas, M. M. and M. P. Siedband, "A Simple Portable Pneumatic Pump for External Cardiac Massage," *American Journal of Cardiology*, 10(1):107-109, 1962.

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 § 870.5200 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6283 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1542]

MEDICAL DEVICES

Classification of External Counter-Pulsating 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 external counter-pulsating 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 (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 external counter-pulsating devices:

1. 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, reproduciblity, and any limitations on the device's cardiac synchronization 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 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 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 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: 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.

PROPOSED CLASSIFICATION

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 the device is purported or represented to be for a use (assisting a weak heart in pumping blood) 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. 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 § 870.5225 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.

(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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6285 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1543]

MEDICAL DEVICES

Classification of DC-Defibrillators (Including Paddles)

AGENCY: Food and Drug Administration.

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, 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 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 ventricals 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 or death may result.

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 defibrillators using damped sinusoidal wave forms 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. The debate about the classification of defibrillators continued and, after reviewing significant additional data, the Panel, on April 7, 1978, voted 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. At the April 7, 1978 Panel meeting three classification motions for defibrillators were entertained. The vote on each motion was split, and after this meeting one Panel member indicated that he wished to change his vote on a motion to place the device into class III based upon the discussion which took place on a later motion to divide the device into a class II and class III category.

A summary of the safety and efficacy data for defibrillators was prepared and provided to each Panel member in November 1978. At that time, because of what had occurred at the April 7, 1978 meeting, each Panel member was asked to review the summary, to indicate if he or she believed the summary to be accurate, and then to vote to either: (1) Classify all defibrillators into class II; (2) classify all defibrillators into class III; (3) classify defibrillators with a maximum delivered energy equal to or less than 360 joules into class II and classify all others into class III; or (4) classify defibrillators with a maximum delivered energy equal to or less than 400 joules into class II and classify all others into class III. The result of that vote was that three members voted to classify all defibrillators into class III, and two members voted to classify some defibrillators into class II and others into class III.

The Panel's final recommendation is based on this last vote. During the discussions about classifying defibrillators, significant contradictory data were presented to the Panel. It became apparent that dividing the classification of the device between class II and class III subgroups could be unnecessarily detrimental to the development of those devices placed into class III.

Because of the controversy over delivered energy, wave form, duration, current, and other defibrillation parameters, the Panel believes that premarket approval is necessary for this device. The Panel also believes that general controls alone would not provide sufficient control over the performance characteristics of the device, and that sufficient data do not exist to establish a performance standard to assure the safety and effectiveness of the device. Because of the controversy surrounding the classification of defibrillators, the Panel has requested FDA to schedule a Panel meeting at which interested parties may present data on the safety and efficacy of defibrillators before a final regulation classifying the device is published in the FEDERAL REGISTER.

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 of, and experience with, the device. In addition, the Panel sought information from the medical and scientific community, the industry, and the medical literature.

Representatives of industry, concerned private medical practitioners, and individual panel members presented their views to the Panel. The Panel discussed the classification of this device at the following Panel meetings: March 15, 1976; July 30, 1976; October 18, 1976; January 14, 1977; April 4, 1977; July 29, 1977; October 7, 1977; January 13, 1978; April 7, 1978; and June 30, 1978.

The summary minutes (Refs. 1 through 10) of these meetings contain the data and discussions on which the Panel made 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, hypoxic and acidotic conditions, and endogenously liberated substances such as adrenalin. Much of the dabate about classification of defibrillators focused upon the amount of energy required to defibrillate a patient, espe-

cially a patient weighing over 100 kilograms.

There are two theories regarding the energy required for defibrillation. The first theory is a dose concept for defibrillation energy—as bodyweight increases the amount of energy required for defibrillation increases. Data in support of the first theory were presented by Geddes (Refs. 1 and 4), Grayzel (Ref. 9), Gordon (Ref. 9), Levin (Ref. 9), Gallagher (Ref. 9), Babbs (Ref. 9), and the Health Industries Manufacturers Association (Ref. 6) represented by Gallagher and Larsen.

A paper by Tacker, et al. (Ref. 11), which retrospectively studied defibrillation 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 defibrillation places the patient at a greater risk of heart damage without increasing the probability of successful defibrillation. Lown (Ref. 8) presented his data on human cardioversion from ventricular tachycardia and atrial fibrillation indicating that weight had no bearing upon the energy required to accomplish cardioverson.

Pantridge (Ref. 8) reviewed a study he had performed, where 100-percent successful defibrillation occured at a stored energy of 400 joules. Crampton (Ref. 8) reported a prospective study in which he achieved 98-percent successful 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 253 episodes involving patients of all weights. In conjunction 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 permanently stop the heart and that damage occurs at 15 times the defibrillation therehold.

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-kilogram 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 referring to a study by Ewy (Ref. 16), indicated 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 juoles when applied to 23-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 percent damage is expected from shocks with 90-percent effectiveness and that 10-percent damage is expected from shocks with 99-percent effectiveness. Dr. Babbs defined damage as any detectable degree of myocardial necrosis by either gross or pathological examination. Another subject of debate in the classification of defibrillators was the electrical wavefrom used to defibrillate. There are now two types of waveform used for defibillation: the damped sinusoidal and the truncated exponential (trapezoidal). Geddes (Ref. 1) noted that defibrillation is possible with many waveforms provided the current and duration parameters are chosed properly.

Schuder (Ref. 1) indicated that successful defibrillation cannot be expected from an untruncated exponential waveform and that a long, low-amplitude tail may actually cause the heart to refibrillate after the initial portion of the waveform has defibrillated the heart. Larsen (Ref. 3) gave a presentation demonstrating that the waveform can be controlled and described in engineering 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 required for defibrillation increases, such that when the tilt reaches 95 percent the energy required with a trapezoidal waveform is approximately equal to that required with a damped sinusoidal waveform.

Geddes and Tacker (Ref. 3) presented references showing the effectiveness of various specific marketed defibrillator waveforms. Other issues involving defibrillator design discussed in much less detail by the Panel were peak and average current, duration, paddle size and position, current density, and charge. As regards peak current, 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 percentage of arrhythmias that occur following successful defibrillation increases rapidly as the current amplitude 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 damaging than other waveform characteristics. With respect to duration, Geddes (Ref. 6) indicated that currently marketed defibrillators have a duration of 4 to 12 milliseconds. Schuder (Ref. 1) stated that duration of greater than 8 milliseconds can successfully defibillate but that more consideration must then be placed upon waveform and energy.

Tacker (Ref. 1) indicated that the relative importance of duration, voltages, and currents for different waveforms 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 difference in defibrillation success between transchest or chest-to-back paddle positions so long as the left chest paddle was placed over the apex of the heart. Geddes (Ref. 6) stated that paddle position data were collected 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 properties are intimately related to paddle size and waveform, among other properties.

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 Laboratories (Ref. 26).

5. Risks to Health: (a) Electrical shock to operator: Improper electrical design of the device can lead to a serious electrical shock to the operator. (b) Inability to defibrillate or persistence of the arrhythmia: Inability to defibrillate or persistence of the arrhythmia may occur because of excessive energy, excessive current, insufficient 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 defibrillate due to paddle design: Inability to defibrillate may result from inappropriate paddle size or inappropriate 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 function) 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 to provide this assurance. At the Panel's request, the Commissioner is also announcing his intention to schedule a Panel meeting prior to the final classification of difibrillators 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.

1. Summary Minutes of the Panel on Review of Cardiovascular Devises Ad Hoc Subcommittee on Defibrillators Meeting, March 15, 1976.

2. Summary Minutes of the Panel on Review of Cardiovascular Devises, Joint Meeting of the Implants and Monitors Subcommittees, July 30, 1976.

3. Summary Minutes of the Panel on Review of Cardiovascular Devises Meeting, October 18, 1976.

4. Summary Minutes of the Cardiovascular Devises Classification Panel Meeting, January 14, 1977.

5. Summary Minutes of the Cardiovascular Devises Classification Panel Meeting, April 4, 1977.

6. Summary Minutes of the Cardiovascular Devises Classification Panel Meeting, July 29, 1977.

7. Summary Minutes of the Cardiovascular Device Classification Panel Meeting, October 7, 1977.

8. Summary Minutes of the Cardiovascular Device Classification Panel Meeting, January 13, 1978.

9. Summary Minutes of the Cardiovascular Device Classification Panel Meeting, April 7, 1978.

10. Summary Minutes of the Circulatory System Devices Panel Meeting, June, 30, 1978.

11. Tacker, W. A., Jr., F. M. Galioto, Jr., E. Giuliani, L. A. Geddes, D. C. McNamara, "Energy Dosage for Human trans-Chest Electrical Ventricular Defibrillation," *New England Journal of Medicine*, 290:214-215, 1974.

12. Geddes, L. A., W. A. Tacker, Jr., J. P. Rosborough, et al., "Electrical Dose for Ventricular Defibrillation of Large and Small Animals Using Precordial Electrodes," *Journal of Clinical Investigations*, 53:310-319, 1974.

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14. Gold, J. H., J. C. Schuder, H. Stoeckle, T. A. Granberg, S. Z. Hamdani, J. M. Rychlewski, "Transthoracic Ventricular Defibrillation in the 100 kg Calf with Unidirectional Rectangular Pulses," *Circulation*, 56(5):745-750, 1977.

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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 § 870.5300 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 (restorating normal heart rhythm) the atria or ventricals 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 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,
Assoicated Commissioner for Regulatory Affairs.

[FR Doc. 79-6285 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[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, Rm. 4-65, 5600 Fisher 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 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 establishing a performance standard for this device be a 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 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: Inadequate design with regard to indication of defibrillator output can lead to generation of inaccurate defibrillator output data. If 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, 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 § 870.5325 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6286 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1545]

MEDICAL DEVICES

Classification of External Transcutaneous Cardiac Pacemakers (Noninvasive)

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 transcutaneous cardiac pacemakers (noninvasive) 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, 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-

fare, 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 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. Summary 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 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. 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 § 870.5550 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 (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. 79-6287 Filed 3-8-79; 8:45 am]

[4110-03-M]

[21 CFR Part 870]

[Docket No. 78N-1546]

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, 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 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 establishing a performance standard for this device be a low priority.

3. Summary of reason for recommendation: The Panel recommends that the 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 even when primarily used. The device fits around 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 Panel believes that the pressure limits should be controlled by performance standards. Materials used in the device should meet a generally accepted satisfactory level of tissue 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: (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 CLASSIFICATION

The Commissioner agrees with the Panel's recommendation and is proposing that the compressible limb sleeve 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 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.

Dated: February 26, 1979.

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.

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, 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 temperture 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 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: (a) Cardiac arrhythmias: Excessive electrical leakage current can disturb the normal electrophysiology of the heart, leading to the onset of cardiac arrhythmias. (b) Thermal tissue damage: Inaccuracy of temperature control can lead to burns or tissue damage related to hypotermia. (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. 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 § 870.5900 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 doucment. 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. 79-6289 Filed 3-8-79; 8:45 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 (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 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 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 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 labelng. 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 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 recommnedation 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.

Dated: February 26, 1979.

JOSEPH P. HILE,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-6290 Filed 3-8-79; 8:45 am]

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